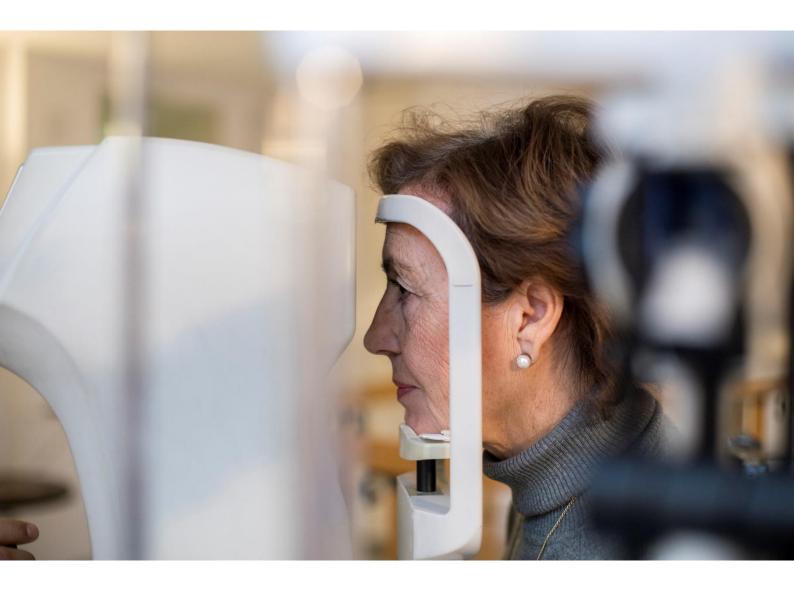




fielmann



Ocumeda whitepaper on teleophthalmologic eye screening for optician customers

Ocumeda is a leading company in the field of accessible eye screening. The company was founded in 2019 by two ophthalmologists. In their everyday clinical work, both were repeatedly confronted with patients in whom eye diseases could only be diagnosed at a very advanced stage, when the loss or noticeable impairment of vision was already advanced and irreversible. This observation was the impetus for the founding of ocumeda, with the aim of making eye screening accessible to the population in a cost-effective, accessible and, above all, timely manner.

Further information at: www.ocumeda.com

Fielmann is the market leader in opticians in Central Europe and is one of the largest companies in the optical industry worldwide. Fielmann has shaped and revolutionized the optician industry. The company was born out of the simple idea of putting the customer first when Günther Fielmann opened his first store in Cuxhaven in 1972. Within a few decades, Fielmann democratized eyewear fashion, pioneering selection, guarantees and service in optic stores.

Further information at: www.fielmann.de

ACTO e.V. works as an institution between the university and the value-oriented economy. This special position favors the development processes in basic and specialized areas, serves intensive interlocking and moderates optimally, especially where academic administration is not yet conducive to developments in terms of economic profit thinking due to its public mandate. This includes, in particular, new development processes based on clinical problems and the transfer of results from basic research into clinically applicable concepts.

Further information at www acto de





Authors

Prof. Dr. Norbert Schrage Chief Physician, Merheim Eye Clinic, Clinics of the City of Cologne, Germany Chairman, ACTO e. V., Aachen, Germany Honorary doctorate, Pirogov University, Moscow, Russia

Prof. Dr. Hans-Jürgen Grein Department of Medical Optics, Lübeck University of Technology, Germany Head of Science, Fielmann Academy Plön Castle, Germany

Prof. Dr. Frank Tost Senior Consultant and Deputy Clinic Director, Clinic and Polyclinic for Ophthalmology, University Medicine Greifswald, Germany

PD. Dr. Catharina Busch Chief medical officer, ocumeda GmbH, Munich, Germany Consultant, Department of Ophthalmology, Leipzig University Hospital, Germany

Prof. Dr. Marcel N. Menke Chief Scientific Advisor, ocumeda AG, Riedt bei Erlen, Switzerland Chief Physician and Clinic Director, Eye Clinic, Cantonal Hospital Aarau, Switzerland Titular professorship, Inselspital Eye Clinic, Bern University Hospital, Bern, Switzerland







Table of contents

Ke	y message at a glance	
1.	The demographic problem	3
2.	Visual impairment and blindness: a cost analysis	5
3.	The ocumeda eye screening concept	6
4.	The benefits of preventive eye examinations are scientifically proven	8
5.	The use of telemedicine in ophthalmology: experiences from other countries	1C
6.	The ocumeda prevention program: initial facts and figures	12
7.	Outlook	14
Re	ferences	16

For better readability, the masculine form is used for personal names and personal nouns on this report. Corresponding terms apply in principle to all genders in the sense of equal treatment. The abbreviated form of language is for editorial reasons only and does not imply any valuation.





Key message

Due to demographic change, in particular diseases affecting the ocular fundus will increase significantly in the coming years. Ophthalmological capacity is expected to decrease while demand grows significantly. The traditional eye care system in many countries, including Germany, will therefore be overloaded and increasingly overwhelmed by the increase in treatment of diseases. As of now, there is already insufficient capacity available to provide the population with urgently needed accessible preventive eye care.

The benefits of specific screening offered for various eye diseases have already been scientifically proven. In countries such as Scandinavia, the UK and Spain, a teleophthalmological screening is already established as part of government programs. Therapies that are initiated earlier through screenings can delay and often even prevent vision loss. This not only reduces individual suffering but can also be economically advantageous in socio-economic terms, as severe visual impairment and blindness are associated with very high direct and indirect costs.

Ocumeda has developed an accessible screening service to improve the availability of preventive eye care and make it quickly and easily accessible to the public. Fielmann recognized the value of the service at an early stage and supported ocumeda in piloting and optimizing the service. The screening is now offered to the public in over 50 locations in Germany and Switzerland. ACTO e.V. has provided scientific support for this development.

The screening service involves specially trained opticians and teleophthalmologists working together to carry out an ophthalmologic risk assessment. In the opticians' stores, general health data, eye pressure, best-corrected visual acuity, refraction and a fundus image of the central ocular fundus are collected. The data generated is encrypted and shared via the ocumeda platform with specially trained ophthalmologists for evaluation. The ophthalmologists evaluate the data as part of a risk analysis and categorize the data collected into green, yellow or red according to the traffic light logic. The customer receives a precautionary report with a classification of the evaluation.

Currently, several thousand people have already been screened and 20.42% of the results showed abnormalities. Approximately 1.97% of the screened persons even showed serious deviations from normal values and were referred to emergency ophthalmological care. Continuous, strict quality control of the teleophthalmological evaluation will be important





for the future medical acceptance of such screening offers. Ocumeda has developed numerous automated and manual measures for this purpose to be able to offer teleophthalmological evaluations in a standardized and reproducible high quality.

Innovative approaches, such as ocumeda's teleophthalmologic screening concept, have the potential to make an important contribution to eye care for the population in the future.



Figure: Ocumeda teleophthalmology platform





Technical article

A teleophthalmologically supported ophthalmological screening of optician customers who are not under ophthalmological care

Prof. Dr. Norbert Schrage¹, Prof. Dr. Hans-Jürgen Grein², Prof. Dr. Frank Tost³, PD. Dr. Catharina Busch^{4,5}, Prof. Dr. Marcel N. Menke^{4,6,7}

- 1. Merheim Eye Clinic, Clinics of the City of Cologne; ACTO e. V., RWTH Aachen, Aachen, Germany.
- 2. Lübeck University of Applied Sciences, Lübeck, Germany.
- 3. Clinic and Polyclinic for Ophthalmology, University Medicine Greifswald, Germany.
- 4. Ocumeda AG, Riedt bei Erlen, Switzerland.
- 5. Department of Ophthalmology, Leipzig University Hospital, Germany.
- 6. Cantonal Hospital Aarau Eye Clinic, Aarau, Switzerland.
- 7. Inselspital Eye Clinic, Bern University Hospital, Bern, Switzerland.

1. The demographic problem

In ageing societies with a consecutive increase in age-related eye diseases, there is a steadily growing number of people with moderate or severe vision loss. For this reason, the *World Health Organization (WHO)* and the *International Agency for the Prevention of Blindness* launched the "Vision 2020" initiative in 1999 with the aim of reducing avoidable blindness. A paper published in the journal *The Lancet Global Health* in 2021 showed that the prevalence of avoidable blindness and moderate to severe vision loss has not been significantly reduced as hoped but has actually continued to rise due to population growth and demographic ageing. Worldwide, the main causes of blindness in people over 50 are still cataracts and uncorrected refractive anomalies. Glaucoma, diabetic retinopathy and age-related macular degeneration (AMD) are also responsible for more than 19 million cases of moderate or severe vision loss in the +50 population, making them an important target for screening and early treatment.¹

The need for eye screening is not widely known among the population and is nowhere near as well established as breast cancer screening, prostate screening or bowel cancer prevention. This is despite the fact that the fear of blindness is significantly more pronounced compared to many other diseases and is classified as the "worst" disease in psychometric studies.² However, unlike the preventive services mentioned above, eye screening is not yet covered by health insurance, which also increases the barrier for eye screening.





According to the *Association of German Ophthalmologists* (BVA) $^{\beta}$, only 24.61% of the population visited an ophthalmologist in 2019. This apparent discrepancy is surprising and may be due to a lack of education about eye conditions on the one hand, but also to the difficult access to ophthalmological care for capacity reasons on the other. In many regions, it is already difficult to get an appointment for an ophthalmologist's examination. This problem has now become so great that politicians in Germany have reacted. Associations of statutory health insurance physicians have had to set up appointment service centers in order to guarantee appointments for a wide range of medical specialties for patients with general health insurance within a reasonable period of time.⁴

In many regions, preventive ophthalmological capacity is already barely sufficient and, due to the foreseeable huge need for treatment of dry age-related macular degeneration (AMD) with high-frequency surgical care for large groups of older patients in the context of demographic change, will certainly not be able to adequately address the needs of the population in the future.⁵ The *German Ophthalmological Society (DOG)* has recognized the problem and published a whitepaper on the situation of ophthalmological care back in 2012.⁶

The authors already write in the introduction:

More than other medical specialties, ophthalmology is affected by the demographic changes in our society as well as by structural changes in outpatient and inpatient care. It will not be possible to ensure comprehensive, up-to-date and high-quality care in the future if the necessary resources are not increased at an early stage in response to the growing demand for care."

The authors continue:

"The demand for ophthalmology services is already very high today and will continue to grow significantly in the future. The high demand is offset by an ophthalmological supply that can hardly meet the increasing future demand. There have been fundamental structural changes in both the outpatient and inpatient sectors in recent years, which have led to a restructuring and reduction rather than a necessary increase in resources."

Although it has been obvious at least since 2012 that ophthalmological care capacity urgently needs to be increased, this has not happened since then. For example, ophthalmological care capacity only increased by 1% between 2000 and 2019.⁷ In the same period, however, age-related eye diseases such as AMD and glaucoma increased by 22-34%.⁷

The *Association of German Ophthalmologists* also provides information about the ophthalmological care situation in Germany on its website www.augeninfo.de. Among other things, the Barmer 2022 physician report is cited there.⁸

"Compared to other specialties, contacts to ophthalmologists are of considerable importance, which is significantly higher than the ratio of ophthalmologists to other doctors (ophthalmologists account for 4.1% of all contract doctors). The demand for ophthalmological services, especially in the basic care of older people, has already increased in recent years and will continue to rise. This is also reflected in the statistics of





the health insurers. Around a quarter of the total population (24.61%) in Germany visited at least one ophthalmologist in 2019."8

The Federal Association of German Ophthalmologists website goes on to quote:

"In ophthalmology, there were 5,014 treatment cases for every ophthalmologist in 2019 - that is over 50% more than the average for all specialist areas, which was 3,293 treatment cases."9

From these figures from the Association of German Ophthalmologists and the assessment of the DOG, it quickly becomes clear that in future, local ophthalmologists will need to concentrate on the treatment of diseases and, in addition, alternatives for the detection of eye diseases. An increase in the number of ophthalmologists would certainly be necessary; however, this goal could not be achieved in the past. Technical developments in the field of screening using telemedicine or developments in the field of artificial intelligence offer opportunities to relieve the burden on ophthalmologists and ensure the provision of care. In our view, teleophthalmological eye screening is a sensible and correct way of specifically detecting and preventing eye diseases. Through such screening, people with anomalies/ findings can be referred to ophthalmologists for further consultation and treatment. This pre-selection combined with professional allocation processes, including the provision of already collected and available data, conserves the limited resources of ophthalmologists and reserves waiting room places for people who will benefit from rapid diagnosis and therapy. The problems of conflicts of interest, professional group-centric approaches and prioritization prevent a patient-centric view of screening services.¹⁰ It is a truism that early identification and initiation of therapy for common eye conditions such as AMD, diabetes, glaucoma and cataracts can delay or even prevent severe visual impairment or blindness. This not only reduces the personal suffering of those affected, but also makes good use of ophthalmologists' working time. Ultimately, such an approach also saves enormous social costs.

2. Visual impairments and blindness: a cost analysis

Visual impairment and blindness (VI&B) have increased globally by 47% in the last 20 years. VI&B not only affects those directly affected, but also their families. In countries such as Australia, for example, the cost of VI&B to the healthcare system is even higher than that of coronary heart disease, depression, stroke and diabetes mellitus. In addition to the direct suffering of those affected, VI&B also has an enormous economic impact due to direct costs (medication and treatment costs), indirect costs (loss of productivity, loss of income for patients and relatives, state support services, loss of work due to illness, etc.) and intangible effects (loss of quality of life, emotional stress, depression, social isolation, risks of falls and accidents due to S&B). The mortality rate due to VI&B increases from 4.5% (normal vision) to 22.2% (blindness).¹¹

According to data published by the *German Association for the Blind and Visually Impaired (DBSV)*, 1.2 million people are affected by VI&B in Germany alone.¹² This causes annual costs of 49.6 billion euros in Germany, which is 1.2% of the gross domestic product of 3,869 billion euros.¹¹ Due to demographic change, the number of patients with VI&B will increase between 9-17% over the next 10 years, while ophthalmologic care capacity only increased by 1% between 2002 and 2017 and is





expected to stagnate over the next 15 years due to the retirement of baby boomers.¹³ Most of the increase in blindness will be due to AMD, diabetic retinopathy and glaucoma. The publication cited was the result of a collaboration between self-help organizations, ophthalmological associations (German Ophthalmological Society and Association of Ophthalmologists Germany e.V.) and international aid organizations to raise awareness in an annual nationwide information campaign "Week of Sight". The authors write in the brochure:¹²

"In view of this situation, it is unacceptable that people should continue to suffer vision loss unnecessarily, that medical progress in eye care does not reach those affected and that the majority of people with irreversible vision loss receive no or only inadequate rehabilitation measures."

Six specific demands are also made to the German healthcare policy. The first demand is as follows:

"Early detection and care must be available and secured for everyone. This includes a sustainable strategy for the care of patients in rural areas and for particularly vulnerable patient groups such as those in need of care (especially in care facilities) and people with multiple disabilities. This includes their funding and the securing of a sufficient number of specialists."¹²

Based on the available data, we conclude that prevention should be given greater priority due to the immense costs of VI&B and the predicted sharp increase due to demographic trends. Many cases of VI&B can be prevented or at least significantly delayed through good prevention and good patient care. Due to the high level of comorbidities (falls, depression, problems due to reduced medication compliance, etc.) in VI&B, massive long-term cost savings are possible. This is why a new, patient-oriented prevention model in terms of medicine and screening is urgently needed. In "traditional" ophthalmological care, there is currently too little capacity for a comprehensive screening concept that can address socio-economic needs and withstand demographic developments in the long term.

3. The ocumeda eye screening concept

In cooperation with Fielmann AG, Ocumeda has been offering telemedicine-supported preventive eye examinations in opticians' stores since 2021, in which, in addition to general health data (questionnaire), eye pressure is measured using non-contact tonometry (CT-1P tonometer/pachymeter, Topcon), best-corrected visual acuity, refraction and a fundus image of the central fundus using a non-mydriatic camera (iCare DRSplus).

Every customer is informed in detail about the limitations of a teleophthalmological assessment before the screening and it is emphasized that the assessment cannot replace a comprehensive ophthalmological examination on site. In addition, the screening offer is aimed exclusively at customers who do not have acute eye complaints and are not already regularly seen by an ophthalmologist. The screening offer is aimed primarily at people aged 40 and over, in line with the screening recommendations of the Association of German Ophthalmologists.¹⁴





In addition, all customers over the age of 18 can take part in this eye screening. The following conditions apply as exclusion criteria for an eye screening: 1. the customer is already (or has been in the last 5 years) undergoing ophthalmological treatment; 2. the customer is currently suffering from eye complaints/symptoms; 3. the customer already has knowledge of an ophthalmological disease of the fundus. In the event of an exclusion criterion, the customer will be referred directly to their local ophthalmologist for ophthalmological treatment.

This preventive service is currently a self-pay service that the customer pays for in the store.

The fundus camera used is a true color, confocal imaging system that offers various imaging options (true color fundus photo, red-free, infrared, images of the outer eye, stereo images). The confocal system allows high-quality fundus images down to a minimum pupil diameter of 2.5 mm and can also generate panoramic retinal images from various individual photos thanks to a mosaic function. For the ocumeda preventive service, individual images are taken from the posterior pole with a 45-degree exposure. When selecting the device, specific care was taken to choose an intuitive, user-friendly system that can produce high-quality fundus images independently of the examiner. Thanks to software and modern robotics, the DRSplus camera automatically aligns itself to the respective eye (auto-alignment), automatically focuses the fundus image (autofocus), automatically calculates the optimum exposure (auto-exposure) and automatically triggers the image capture (auto-capture). This means that the entire examination process is triggered at the touch of a button and is hardly influenced by the operator.

The non-contact tonometer used (CT-1P Tonometer/Pachymeter, Topcon) is also fully automated and has a fully automated adjustment and measurement system with the option of automatic and manual adjustment of the eye pressure values to the corneal thickness. In addition, the device produces a reliability statement for each measurement so that measurements can be repeated in case of doubt.

All generated data is encrypted and shared via the ocumeda telemedicine platform with specially trained ophthalmologists for evaluation. The ophthalmologists evaluate the data in the sense of a risk analysis and categorize the collected data according to the traffic light logic in the categories green, yellow or red. No teleophthalmological diagnosis or therapy recommendation is made in this context. These medical risk assessments are communicated to the customer two to three days after the measurements have been taken. The customer receives a precautionary report with a classification (traffic light) and a recommendation for action.

- A green report means that no deviations from the norm requiring further clarification were found. A periodic routine check is suggested.
- In the case of yellow reports, changes from normal values have been detected that indicate the need for further ophthalmological consultation on site at practicing ophthalmologists or eye clinics. The urgency is determined by the teleophthalmologist and ranges from one to six months.





In the case of a red report, the deviations are so serious that an immediate consultation with a registered ophthalmologist is recommended.

Currently, ocumeda relies solely on the ophthalmologists' expertise to carry out a teleophthalmologic risk assessment. In our opinion, the artificial intelligence (AI) solutions currently available on the market are not sufficiently developed to be used independently in preventive screening. The main limitation is the very limited number of eye diseases that can be automatically diagnosed by AI. Numerous other changes in the fundus are not yet detected by software solutions (such as vascular diseases, nevi, various types of maculopathies, etc.), which could potentially lead to many false negative results in a screening context and lull patients into a false sense of security. The ocumeda screening concept is constantly being developed and improved by ophthalmologists for ophthalmologists to ensure a smooth process from screening to any necessary referral of the patient to an ophthalmologist in private practice, particularly in terms of optimal patient care. The aim is to assign the patient in need of treatment to the treating doctor without wasting time and without duplicating diagnostics. The selected diagnostic systems are evaluated by ophthalmologists for their suitability and quality before being used in opticians' branches and correspond to the technical standard used in many ophthalmologists' practices and clinics.

The quality of the teleophthalmological medical evaluations is continuously monitored. Ocumeda has developed screening guidelines based on the recommendations of international teleophthalmology guidelines and uses a constantly growing collection of sample cases to better classify green, yellow and red reports. All doctors undergo a standardized onboarding process with training by experienced teleophthalmologists. 20% of the evaluations are randomly assigned to a second review in a peer review process. In the event of discrepancies, there is an evaluation by a third expert with extensive experience in teleophthalmology. All doctors are subject to continuous quality monitoring. For example, the evaluation times are recorded, comparative statistics are tracked between the doctors (proportion of green, yellow and red reports) and test cases are sporadically submitted for evaluation. Follow-up training is provided in the event of anomalies/ findings in the evaluation quality. In addition, ocumeda holds regular case discussions for professional exchange. The digital platform also includes the option for doctors to directly request a 2nd opinion if there are any uncertainties regarding the classification between green, yellow and red. The minimum requirement for doctors working in teleophthalmology is a specialist diploma in ophthalmology recognized in the respective country (of the customer). These measures ensure high quality and will hopefully increase the acceptance of teleophthalmologic evaluation in the medical community.

4. The benefits of preventive eye examinations are scientifically proven

Ophthalmologic screening examinations are diverse, and the health effect of systematic screening examinations has been scientifically proven for many eye conditions. Even in children, vision screening at the age of three to five can reduce the risk of permanent amblyopia. The *US Preventive*





Services Task Force has produced a review of existing publications on this subject. Early initiation of amblyopia therapy can effectively prevent severe visual impairment. The Task Force therefore recommends that all children between the ages of three and five undergo at least one amblyopia screening.¹⁵

Although amblyopia screening in children is not the focus of the study, this review shows the general benefit of teleophthalmologic screening examinations. The significant benefits of screening for diabetic retinopathy have also been scientifically proven several times. In a study comparing the effectiveness of non-mydriatic fundus photography vs. an on-site fundus examination by an ophthalmologist for the detection of diabetic retinopathy, a sensitivity of 96% and a specificity of 98% were determined for pure fundus photography. The rate of false negative findings was 8% and the rate of false positive findings was 2%. In a systematic review from 2010, the cost-effectiveness of such examinations was analyzed. The data show that screening is costeffective by increasing the number of years with good visual acuity. The authors conclude that teleophthalmological examinations with digital fundus photography have the potential to be a costeffective, accessible screening concept in remote areas or in populations that are difficult to reach.¹⁸ Aoki et al. published a comparative study of two screening strategies (teleophthalmology vs. non-teleophthalmology (standard ophthalmologic care)) to identify diabetic retinopathy in a prison population. A stochastic (Markov) model based on probabilities and cost data from previously published epidemiologic studies was created for analysis. In the teleophthalmology group, 12.4% went blind vs. 20.5% in the non-teleophthalmology group. The absolute risk reduction was 8.1%. The total cost per patient was USD 16,514 in the teleophthalmology group vs. USD 17,590 in the non-teleophthalmology group. The teleophthalmologic screening approach was therefore not only more effective in preventing blindness, but also more cost-effective.¹⁸

In May 2022, the *Agency for Healthcare Research and Quality* of the *U.S. Department of Health and Human Services* conducted a comprehensive literature review on glaucoma.²⁰ Untreated glaucoma leads to irreversible vision loss and blindness. Early changes in glaucoma are often asymptomatic, and visual field loss is often not noticed by the patients.²¹ At least 50% of patients with open-angle glaucoma are unaware of their glaucoma.^{22, 23, 24} For this reason, several countries recommend glaucoma screening for the general population. In the USA, for example, an eye exam is recommended at the age of 40. In people without risk factors, the eyes should be examined every two to four years for people aged 40-54, every one to three years for people aged 55-64 and every one to two years for people >65.²⁴

For tonometry, data are available from 13 randomized, controlled studies with 32,892 subjects. The sensitivity for glaucoma detection was 0.48, and the specificity was 0.94. For glaucoma detection based on fundus images (optic disc photographs), there is evidence from several controlled studies with 3,133 subjects in which the optic discs were evaluated on fundus photographs. In one of the studies, the sensitivity was 0.64 and the specificity 0.73 for distinguishing patients with suspected glaucoma from patients with manifest glaucoma.²⁵ In another study, the sensitivity was 0.71 and the specificity 0.49 for distinguishing glaucoma from non-glaucoma, based on a disc excavation of 0.65 for average-sized discs and 0.5 for small discs.²⁷

The data on the effectiveness of teleophthalmological screening examinations for AMD is still limited. A review and meta-analysis published in 2022 clearly summarizes the available data.²⁷ To





date, there are three randomized, controlled studies on diagnostic accuracy in the detection of AMD. The average sensitivity across the three studies was 0.71.²⁹

The role of optical coherence tomography (OCT) in traditional ophthalmology for diagnosis and disease monitoring is undisputed. However, the implementation of OCT in teleophthalmological screening programs is still controversial. For example, a direct comparative study of fundus photography alone or combined with OCT showed no advantage of combined diagnostics in terms of sensitivity or specificity in the detection of glaucoma or other retinal diseases.^{29,30,31}

5. The use of telemedicine in ophthalmology: experiences from other countries

The potential of teleophthalmological examinations in ophthalmology can so far best be assessed in diabetic retinopathy, as screening programs for diabetic retinopathy are already being carried out in various countries, some of them state-run, with sufficiently long observation periods. A paper by *PH Scanlon* published in 2021 summarizes the available data well.³²

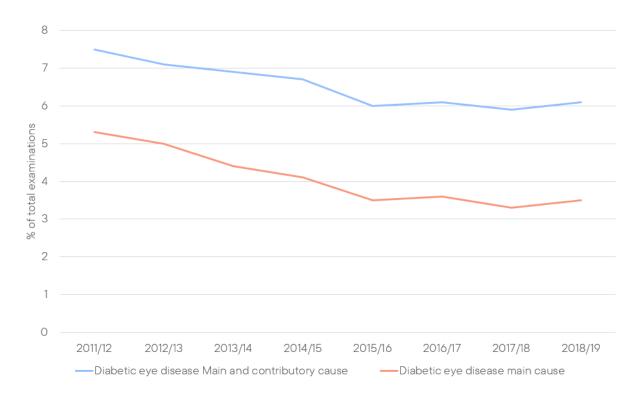


Figure 1: Own figure according to reference 32, Scanlon PH, Acta Diabetol, 2021, (%)

The figure shows a continuous decrease in diabetes-associated, certified severe visual impairment or blindness in the UK (screening examinations started in 2003).





The *NHS Diabetic Eye Screening Program* in England was launched in 2003. From 2008 onwards, it achieved quite good coverage in the diabetic population. The first major success came in 2009-2010 when, for the first time in 50 years, diabetic retinopathy was no longer the main cause of certified blindness as a result of the screening program.³³ Between 2017 and 2018, 2.7 million people with diabetes were offered screening in England and 2.23 million patients were screened (45-degree fundus photographs assessed by trained non-ophthalmologists). There were 8,782 emergency referrals and 54,893 routine referrals to ophthalmologists during the period.

A large-scale screening program for diabetic retinopathy is also being carried out in Andalusia, Spain. Within 15 years, 407,762 diabetics were screened at least once.³⁴ At the end of the observation period, there was a significant reduction in the cumulative incidence of diabetic retinopathy and a significant reduction in cases of certified diabetes-associated VI&B.

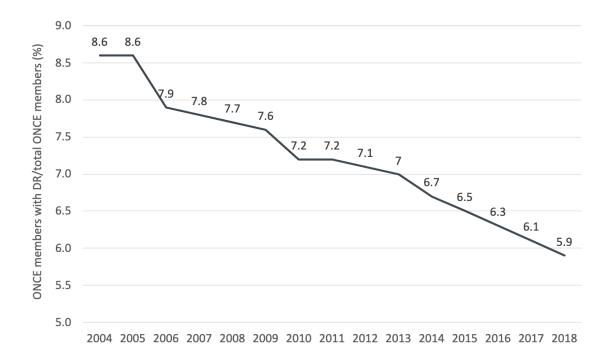


Figure 2: Figure according to reference 34: Rodriguez-Acuña R et al. BMJ Open Diabetes Res Care, 2020, (%). Note: ONCE = Organización Nacional de Ciegos Españoles / Spanish National Association for the Blind

With the introduction of screening, the percentage rate of registered visually impaired and blind people with diabetic retinopathy decreases.

Comprehensive data on the benefits of screening for diabetic retinopathy are also available from Scandinavia.³⁵ In the Scandinavian countries, screening data has been collected and evaluated since the 1990s. The incidence of VI&B in patients with insulin-dependent diabetes is significantly higher in populations without screening programs (annual incidence between 0.4-3.7%) than in populations with screening programs (annual incidence 0.0-0.1%).³⁵





In summary, it can be stated that screening offers for diabetic retinopathy have been very well examined for their benefits and have had a clearly positive effect on the incidence rates of VI&B in many different countries. It can be assumed that the population of diabetics in Germany would also benefit from nationwide screening.

6. The ocumeda prevention program: initial facts and figures

Since the beginning of the cooperation with Fielmann AG, >7,000 screenings have already been carried out in opticians' branches and assessed by ophthalmologists between January 2021 and April 2023. Of all customers, 3,774 have given their consent to the scientific evaluation of their anonymized data. The following statistics therefore relate to this cohort.

Of the 3,774 people, 909 people (24.1%) have been screened in Germany so far, while 2,865 people (75.9%) have taken part in a screening in Switzerland.

56.4% of the people were female, and the average age was 50.9 ± 13.6 years. The age distribution of the cohort is shown in Figure 3.

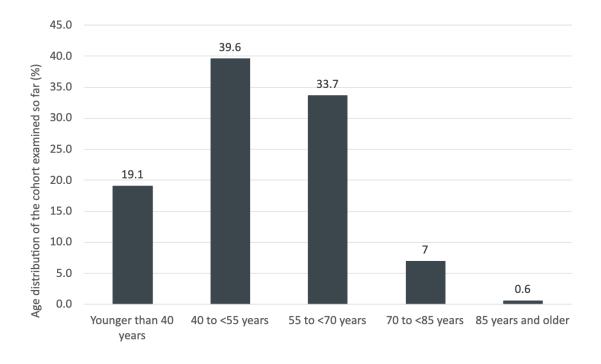


Figure 3: Age distribution of the cohort screened to date (%) (n=3,774). (Persons who did not consent to a scientific evaluation of the data were not included).

Results of the teleophthalmological evaluations

As already mentioned, the available data were evaluated by ophthalmologists and divided into three categories according to traffic light logic (the traffic light system is described in Chapter 4).



In the overall cohort, 79.6% were assessed as green (no need for clarification). Yellow assessments (further consultation recommended promptly) were found in 18.4% of cases and 2.0% of cases were assessed as red (prompt consultation). The gender-specific distribution of the assessments according to green, yellow, and red is shown in Figure 4.

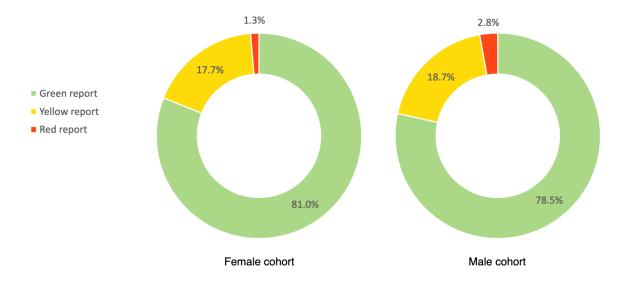


Figure 4: Gender-specific distribution of assessments by green, yellow and red (%)

The average best-corrected visus (logMAR) was 0.04 ± 0.10 (female 0.04 ± 0.10 , male 0.03 ± 0.11). Eye pressure was measured by non-contact tonometry (CT-1P tonometer/pachymeter, Topcon) and averaged 18.2 ± 2.5 mmHg (female: 18.3 ± 2.5 mmHg; male: 18.1 ± 2.6 mmHg). Image quality was rated by the ophthalmologists on a scale of 1-4, where 1 = not usable; 2 = poor image quality, but just sufficient for assessment; 3 = good image quality, 4 = excellent image quality. The average image quality was 3.35 ± 0.07 (N=2,200). For submitted fundus images that could not be assessed due to the image quality (scale = 1), the staff in the opticians' branches were asked to take new images of better quality. Only 0.26% of all images were ultimately unusable and could therefore not be assessed.

The six most common anomalies/ findings sorted by yellow and red evaluations can be found in Table 1.





Frequency of occurrence in

Rank	Anomalies/findings	Total cohort	Yellow cohort	• Red cohort
1	Macular drusen	8.59%	18.92%	21.24%
2	Peripapillary atrophy	2.91%	12.16%	6.79%
3	Retinal hemorrhages	2.53%	28.38%	10.55%
4	Susp. epiret. membranes	2.48%	17.57%	9.83%
5	Increased papillary excavation	2.27%	22.97%	9.39%
6	Suspicion of media turbidity	2.21%	5.41%	8.96%

Table 1: The six most common anomalies/ findings sorted by yellow and red evaluations

7. Outlook

A central component of ocumeda's work will always be a scientific evaluation of the data collected (if the persons screened have given their consent). For example, we are currently carrying out a retrospective evaluation of people with a yellow and red evaluation. The examination results are requested and evaluated by the treating ophthalmologists (with the consent of the patients concerned). The method of evaluation is a direct comparison of the teleophthalmologically collected assessments with the examination findings of the ophthalmologists on site. The aim of this effort is to evaluate the sensitivity and specificity of the recommendations in such a way that the number of false positive classifications is reduced, and the ophthalmologists are presented with a highly accurate and adequate screening report.

In a second prospective, randomized study, a cohort of screening subjects is first assessed online by one doctor and then examined directly on site by a second ophthalmologist for miosis (neutral pupil without drug dilation) and a third ophthalmologist for mydriasis (with drug-induced pupil dilation). All three doctors examine independently of each other and are blinded. With this study







design, we would like to determine both the sensitivity and the specificity for screening with the three different screening methods (teleophthalmologic vs. miosis vs. mydriasis) and thus also identify the rate of false negative as well as false positive cases.

The scientifically collected data will be presented at specialist conferences and published in peer-reviewed journals.





8. References

- GBD 2019 Blindness and Vision Impairment Collaborators; Vision Loss Expert Group of the Global Burden of Disease Study. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study [published correction appears in Lancet Glob Health. 2021 Apr;9(4):e408]. Lancet Glob Health. 2021;9(2):e144-e160. doi:10.1016/S2214-109X(20)30489-7.
- 2 Giridhar P, Dandona R, Prasad MN, Kovai V, Dandona L. Fear of blindness and perceptions about blind people. The Andhra Pradesh Eye Disease Study [published correction appears in Indian J Ophthalmol. 2002 Dec;50(4):299]. Indian J Ophthalmol. 2002;50(3):239-246.
- 3 Berufsverband der Augenärzte Deutschlands e.V. Retrieved 03.06.2023. www.augeninfo.de.
- 4 Website of the National Association of Statutory Health Insurance Physicians. Accessed 19.09.2023. https://www.kbv.de/html/terminvermittlung.php.
- 5 Liao DS, Metlapally R, Joshi P. Pegcetacoplan treatment for geographic atrophy due to age-related macular degeneration: a plain language summary of the FILLY study. Immunotherapy. 2022;14(13):995-1006. doi:10.2217/imt-2022-0078.
- 6 Wolfram C, Pfeiffer N. Weißbuch zur Situation der ophthalmologischen Versorgung in Deutschland. 2012. Accessed 03.06.2023. https://www.dog.org/wp-content/uploads/2013/03/DOG_Weissbuch_2012_fin.pdf.
- 7 Schuster AK, Wolfram C, Pfeiffer N, Finger RP. Ophthalmology 2019 Where do we stand?: An analysis of the treatment situation in Germany [Augenheilkunde 2019 Wo stehen wir?: Eine Betrachtung der Versorgungssituation in Deutschland]. Ophthalmologist. 2019;116(9):829-837. doi:10.1007/s00347-019-0894-2.
- 8 Barmer. Arztreport 2022. Accessed on 03.06.2023. https://www.bifg.de/media/dl/Reporte/Arztreporte/2022/BARMER_Arztreport_2022.pdf.
- 9 Federal Association of Statutory Health Insurance Physicians. Key figures of the billing groups 1st quarter 2019 to 4th quarter 201. Accessed on 03.06.2023. https://gesundheitsdaten.kbv.de/cms/html/17023.php.
- 10 Lee L, Moo E, Angelopoulos T, Dodson S, Yashadhana A. Integrating eye care in low-income and middle-income settings: a scoping review. BMJ Open. 2023;13(5):e068348. Published 2023 May 26. doi:10.1136/bmjopen-2022-068348.
- 11 Köberlein J, Beifus K, Schaffert C, Finger RP. The economic burden of visual impairment and blindness: a systematic review. BMJ Open. 2013;3(11):e003471. Published 2013 Nov 7. doi:10.1136/bmjopen-2013-003471.





- Woche des Sehens. Sehen und Sehverlust in Deutschland. Broschüre. 2020. Accessed on 03.06.2023. https://www.woche-des-sehens.de/broschuere-sehverlust.
- 13 Statistisches Bundesamt. Bruttoinlandsprodukt stagniert im 1. Quartal 2023. 2023. Accessed on 03.06.2023. https://www.destatis.de/DE/Presse/Pressemitteilungen/2023/04/PD23_169_811.html.
- 14 Kassenärztliche Bundesvereinigung. Projektion 2030: Arztzahlentwicklung. 2016. Accessed on 03.06.2023. https://www.kbv.de/media/sp/2016_10_05_Projektion_2030_Arztzahlentwicklung.pdf.
- 15 Berufsverband der Augenärzte Deutschlands e.V. Wann zum Augenarzt. Accessed 03.06.2023. https://www.augeninfo.de/offen/index.php?themenseite=Wann-zum-Augenarzt.
- 16 Donahue SP, Ruben JB; American Academy of Ophthalmology; US Preventive Services Task Force vision screening recommendations. Pediatrics. 2011;127(3):569-570. doi:10.1542/peds.2011-0020.
- Williams R, Nussey S, Humphry R, Thompson G. Assessment of non-mydriatic fundus photography in detection of diabetic retinopathy. Br Med J (Clin Res Ed). 1986;293(6555):1140-1142. doi:10.1136/bmj.293.6555.1140.
- 18 Jones S, Edwards RT. Diabetic retinopathy screening: a systematic review of the economic evidence. Diabet Med. 2010;27(3):249-256. doi:10.1111/j.1464-5491.2009.02870.x.
- 19 Aoki N, Dunn K, Fukui T, Beck JR, Schull WJ, Li HK. Cost-effectiveness analysis of telemedicine to evaluate diabetic retinopathy in a prison population. Diabetes Care. 2004;27(5):1095-1101. doi:10.2337/diacare.27.5.1095.
- 20 Chou R, Selph S, Blazina I, et al. Screening for Glaucoma in Adults: A Systematic Review for the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (US); May 2022.
- 21 Gordon MO, Kass MA. The Ocular Hypertension Treatment Study: design and baseline description of the participants. Arch Ophthalmol. 1999;117(5):573-583. doi:10.1001/archopht.117.5.573.
- 22 Banister K, Boachie C, Bourne R, et al. Can Automated Imaging for Optic Disc and Retinal Nerve Fiber Layer Analysis Aid Glaucoma Detection?. Ophthalmology. 2016;123(5):930-938. doi:10.1016/j.ophtha.2016.01.041.
- 23 Francis BA, Varma R, Vigen C, et al. Population and high-risk group screening for glaucoma: the Los Angeles Latino Eye Study. Invest Ophthalmol Vis Sci. 2011;52(9):6257-6264. published 2011 Aug 5. doi:10.1167/iovs.09-5126.
- 24 Hammond EA, Begley PK. Screening for glaucoma: a comparison of ophthalmoscopy and tonometry. Nurs Res. 1979;28(6):371-372.





- 25 Asrani S, Robin AL, Serle JB, et al. Netarsudil/Latanoprost Fixed-Dose Combination for Elevated Intraocular Pressure: Three-Month Data from a Randomized Phase 3 Trial. Am J Ophthalmol. 2019;207:248-257. doi:10.1016/j.ajo.2019.06.016.
- 26 Blumberg DM, De Moraes CG, Liebmann JM, et al. Technology and the Glaucoma Suspect. Invest Ophthalmol Vis Sci. 2016;57(9):OCT80-OCT85. doi:10.1167/iovs.15-18931.
- 27 Hark LA, Myers JS, Pasquale LR, et al. Philadelphia Telemedicine Glaucoma Detection and Follow-up Study: Intraocular Pressure Measurements Found in a Population at High Risk for Glaucoma. J Glaucoma. 2019;28(4):294-301. doi:10.1097/IJG.0000000000001207
- 28 Mehraban Far P, Tai F, Ogunbameru A, et al. Diagnostic accuracy of teleretinal screening for detection of diabetic retinopathy and age-related macular degeneration: a systematic review and meta-analysis. BMJ Open Ophthalmol. 2022;7(1):e000915. Published 2022 Feb 10. doi:10.1136/bmjophth-2021-000915.
- 29 Maa AY, McCord S, Lu X, et al. The Impact of OCT on Diagnostic Accuracy of the Technology-Based Eye Care Services Protocol: Part II of the Technology-Based Eye Care Services Compare Trial. Ophthalmology. 2020;127(4):544-549. doi:10.1016/j.ophtha.2019.10.025.
- 30 Conlin PR, Asefzadeh B, Pasquale LR, Selvin G, Lamkin R, Cavallerano AA. Accuracy of a technology-assisted eye exam in evaluation of referable diabetic retinopathy and concomitant ocular diseases. Br J Ophthalmol. 2015;99(12):1622-1627. doi:10.1136/bjophthalmol-2014-306536.
- 31 Maa AY, Evans C, DeLaune WR, Patel PS, Lynch MG. A novel tele-eye protocol for ocular disease detection and access to eye care services. Telemed J E Health. 2014;20(4):318-323. doi:10.1089/tmj.2013.0185.
- 32 Scanlon PH. The contribution of the English NHS Diabetic Eye Screening Program to reductions in diabetes-related blindness, comparisons within Europe, and future challenges. Acta Diabetol. 2021;58(4):521-530. doi:10.1007/s00592-021-01687-w.
- 33 Liew G, Michaelides M, Bunce C. A comparison of the causes of blindness certifications in England and Wales in working age adults (16-64 years), 1999-2000 with 2009-2010. BMJ Open. 2014;4(2):e004015. Published 2014 Feb 12. doi:10.1136/bmjopen-2013-004015.
- 34 Rodriguez-Acuña R, Mayoral E, Aguilar-Diosdado M, et al. Andalusian program for early detection of diabetic retinopathy: implementation and 15-year follow-up of a population-based screening program in Andalusia, Southern Spain. BMJ Open Diabetes Res Care. 2020;8(1):e001622. doi:10.1136/bmjdrc-2020-001622.
- 35 Stefánsson E, Bek T, Porta M, Larsen N, Kristinsson JK, Agardh E. Screening and prevention of diabetic blindness. Acta Ophthalmol Scand. 2000;78(4):374-385. doi:10.1034/j.1600-0420.2000.078004374.x.





Contact us

ocumeda

☑ info@ocumeda.com

窗 (GER) +49 89-215 261 26

☎ (CH) +41 31-528 2647

Fielmann

☑ kundenservice@fielmann.com

雹 (GER) +49 800 3435626

雹 (CH) +41 800 805905

ACTO

☑ info@acto.de

8 +49 241 - 9974 180