THERAPEUTIC ADVANCES in
Ophthalmology

Case Series

Teleguided photocoagulation treatments across continents with a remotely programmed laser for retinal diseases

Ther Adv Ophthalmol

2025, Vol. 17: 1–6

DOI: 10.1177/25158414241311078

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***Abstract*:** Diabetic retinopathy and retinal vein occlusion represent two prevalent vision-threatening retinal diseases. Retinal laser therapy still plays an important role in treating these conditions, but its successful administration often requires referral to specialized centers and retina experts. It is, therefore, essential to develop a new treatment methodology that enables patients to benefit from the expertise of specialists from reference centers. For this purpose, we investigated the feasibility of teleguided photocoagulation conducted across continents to determine if different ophthalmologists can consensually devise and safely execute treatment plans remotely. Two patients from Italy (Europe) with diabetic retinopathy and one from Arizona (USA) with central retinal vein occlusion underwent retinal photocoagulation using Navilas® 577s with remote teleguidance from the corresponding continental counterpart. The process included remote planning and execution, supported by an audio connection for real-time communication. Teletreatment success criteria included treatment plan completion, patient tolerance, remote connection stability, and technical quality. All treatments have been successfully performed with accurate spot application and no technical issues. Follow-ups at three weeks confirmed positive outcomes for each patient. Remote teleguided retinal photocoagulation appears feasible, offering a promising tool for global collaborations in retina care and potential benefits to regions with limited access to expert supervision.

Plain language summary

Remote-planned laser treatment for retinal diseases, connecting patients and eye-specialists worldwide

- Diabetic retinopathy and retinal vein occlusion are two of the most common vision-threatening eye diseases, affecting over 190 million people globally. Retinal laser photocoagulation is a well-established treatment, but referral Centres and retina specialists are often necessary. For this reason, a new treatment methodology was needed to reach patients even in the most remote places, offering them the possibility of having the best possible treatment. In this study, ophthalmologists from Europe and the USA successfully used a remotely programmed laser to treat retinal diseases across continents. The work involved planning and executing the retinal laser treatment through remote guidance and real-time communication. Each treatment was conducted successfully with precise laser spot application and without any technical issues. Subsequent examinations at three weeks confirmed positive outcomes for every patient. Remotely programmed laser treatment appeared feasible and successful, offering potential benefits for global collaboration in retina care, especially in areas with limited access to expert supervision.

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Keywords: diabetic retinopathy, navigated retinal laser, retinal vein occlusion, telemedicine, teleophthalmology, teletreatment

Received: 7 July 2024; revised manuscript accepted: 12 December 2024.

Introduction

In recent years, the development of telemedicine in ophthalmology has provided great benefits for diagnosing and treating retinal diseases.[1,2] Several studies have evaluated the feasibility and effectiveness of teleconsultation for both screening and diagnosis, particularly for diabetic retinopathy (DR).[3] However, therapeutic telemedicine is still in the development stage for treating retinal diseases.

Retinal laser therapy still plays an important role in treating retinal vascular diseases, such as DR and retinal vein occlusions.[4,5] However, events such as the COVID-19 pandemic have shown that it's not always feasible to have an expert onsite to observe retinal laser treatments. This challenge is amplified in areas where expertise is limited, requiring specialists to travel significant distances to be present. Furthermore, several studies indicated differences between therapeutic approaches in laser photocoagulation and even more so in subthreshold laser procedures.[6–8]

The navigated retina laser separates treatment planning from treatment execution and allows simultaneous remote observation of the laser device screen.

To date, only two studies have utilized this type of laser device for conducting therapeutic telemedicine. A recent work describes a planned and remotely conducted laser treatment for diabetic macular edema.[9] However, this study provided a delay between the planning and treatment phases, which may represent a difficult situation for local people who require long-distance travel to receive treatment. Therefore, approaches are needed that reduce the delay between sending the images to an expert and waiting—an indefinite time—for the plan to be realized. Another study evaluated the feasibility of a real-time retinal laser treatment in which an expert from the reference center remotely treated patients suffering from DR in a rural area of the same country.[10] This work required an excellent connection with the 5G network and could pose legal problems of treatment responsibility, especially if carried out between different countries with their own medicolegal regulations.

This feasibility study aims to evaluate a teleguided retinal photocoagulation treatment across continents to support collaboration and education between ophthalmologists. The study investigated if proper understanding and agreement on treatment approaches between remote experts can be achieved and if safe and effective treatment can be technically implemented.

Materials and methods

This feasibility case series included three male patients (age 55–73 years) with high-risk proliferative DR (two patients in Rome, Italy, Europe) and ischemic central retinal vein occlusion (CRVO) complicated by neovascularization (1 patient in Scottsdale, AZ, USA).

Written informed consent was obtained from all patients after carefully explaining all potential risks and benefits of remote planning and treatments. Specifically, the consent form explained that there would be a co-planned treatment with an additional expert opinion. Patients were informed that treatment itself would be the same as usual but with additional quality review as another ophthalmologist would work on the treatment plan together with the local treating physician. The study was conducted in accordance with the Declaration of Helsinki as revised in 2013.

All patients had a medical indication to undergo retinal laser photocoagulation. Before laser treatment, all participants underwent a complete ophthalmological examination, including best corrected visual acuity (BCVA) assessment, intraocular pressure measurement, slit-lamp biomicroscopy of the anterior and posterior segment after pharmacological mydriasis, color fundus photography, optical coherence tomography (OCT), OCT-angiography (OCTA), and fluorescein angiography.

Ophthalmologists communicated via a separate live audio connection during both planning and treatment. Treatment plans and execution were performed using a navigated retinal laser (Navilas® 577 nm; OD-OS GmbH, Teltow, Germany). If applicable, external diagnostic images were uploaded in advance and then registered to the fundus image captured with the laser device. Specifically, images were exported in high-resolution JPEG format from the local clinic's imaging devices. They were imported directly from a shared folder into the laser software on the treatment device. This software features an import option that automatically adjusts magnification and overlays the imported images onto the navigated laser's fundus image. Additionally, the alignment of both images can be adjusted manually based on the vessel structures.

To enable remote planning, the remote expert accessed the local laser system remotely and created the treatment plan on the fundus image or overlaid diagnostic image using the planning software via remote access with the permission of the local user. The separate audio connection allowed the discussion between ophthalmologists on the treatment scheme and parameters. The treatment plan, which included initial parameters such as spot size, power, and exposure, was developed collaboratively by both parties before starting the procedure. Throughout the treatment, the ophthalmologists can communicate and, if necessary, make adjustments (i.e., optimal retinal blanching). Ultimately, the final decision rested with the local physician administering the treatment.

When both experts agreed on the proposed treatment plan, the operator in front of the laser device performed the treatment without possible direct interference, but with the other expert monitoring and commenting if necessary (see remote planning and treatment of Patient 1 in the Supplemental File).

This work aimed to determine the feasibility of shared planning and treatment between two continents with optimal patient safety and outcomes. The success of the treatment was defined by the completion of the treatment plan, the acceptance and collaboration of the patients involved, the stability of the remote connection, and the clinical outcome of the treatments conducted. Patient feedback was collected in a guided interview after the treatments. Questions asked were: "*How did you feel afterward? Did you experience any pain? How did you feel about being treated collaboratively?*" The evaluation of the Internet connection was conducted through visual observation. However, any interruption in the connection would not have interfered with the effective execution of the treatment. Follow-up of patients after 3 weeks was included in the outcome evaluation.

Results

Patients 1 and 2 in Rome suffered from high-risk proliferative DR in the right eye and required panretinal laser photocoagulation (Figure 1(a) and (b)). The BCVA of the treated eye was 20/200 and 20/20, respectively. Patient 1 treated eye had cortical and nuclear cataracts, while Patient 2 was pseudophakic. Both patients were regularly treated with injections of VEGF inhibitors for diabetic macular edema. Patient 3 in Scottsdale suffered from ischemic CRVO complicated by neovascularization in an eye with a history of rhegmatogenous retinal detachment

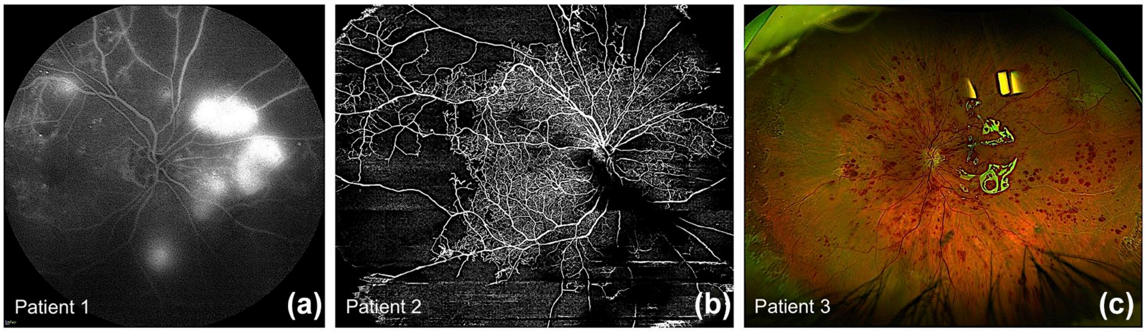

Figure 1. Patients' retinal conditions at presentation. (a) fluorescein angiography showing retinal neovascularization in proliferative high-risk diabetic retinopathy of Patient 1. (b) optical coherence tomography angiography showing extensive retinal ischemia in proliferative high-risk diabetic retinopathy of Patient 2. (c) retinography showing hemorrhages and ischemia in central retinal vein occlusion complicated by neovascularization of Patient 3.

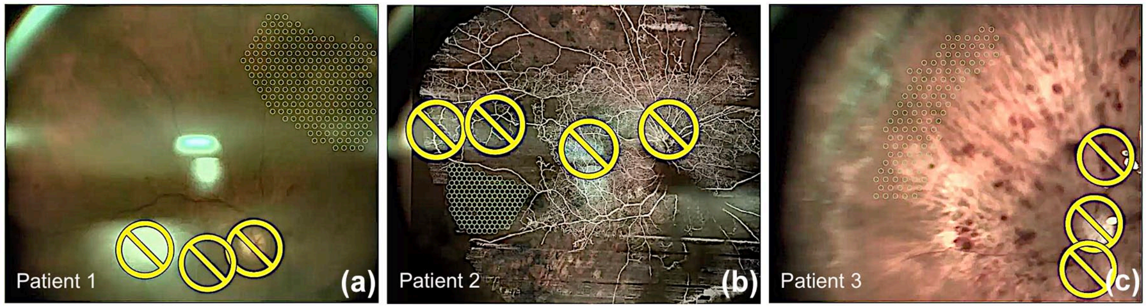

Figure 2. Remote planned treatment plans. (a) treatment plan of Patient 1 in Rome (Italy) designed by the ophthalmologist in Scottsdale (Arizona). (b) treatment plan of Patient 2 in Rome (Italy) designed by the ophthalmologist in Scottsdale (Arizona). (c) treatment plan of Patient 3 in Scottsdale (Arizona) designed by the ophthalmologist in Rome (Italy).

(Figure 1(c)). The BCVA of the treated eye was 20/125. The eye was pseudophakic and was treated with dexamethasone implants for macular edema.

For Patient 1 in Rome, the ophthalmologist in the United States planned 209 spots (spacing x1) on the fundus image in the superior nasal periphery (Figure 2(a)), and for Patient 2, 179 confluent spots in an OCTA temporal ischemic area (Figure 2(b)). For Patient 3 in Scottsdale, the ophthalmologist in Rome planned 122 spots (spacing ×1) on the fundus image in the superior nasal far peripheral retina of the left eye (Figure 2(c)). Patients 1 and 2 were treated without contact lenses using a noncontact wide-field lens, while Patient 3 was treated with a standard contact lens due to pupillary miosis and the presence of silicone oil in the vitreous chamber. The energy was titrated with a few spots and then adjusted if necessary. Laser treatments were performed with a spot size of 330 µm, a pulse duration of 20 ms, and a laser power ranging from 260 to 550 mW. The average duration of the treatments was 3.5 min. In the first two treatments, 100% of the expected spots were successfully applied, while in the third treatment, 98.4% of the spots were performed; only two scheduled spots were skipped due to a joint decision of both experts. Under no circumstances were operators required to use the emergency stop. No inadvertent spot placement occurred during the laser treatments, and no Internet or power line issues occurred.

The patients' questionnaires showed that they tolerated the treatments well. They did not report any specific discomfort during the procedures but were enthusiastic about the collaboration of more than one retinal expert to treat their ocular condition.

The expected quality and outcome of the treatment were achieved in the patients' follow-up after 3 weeks in terms of optimal retinal scarring in the treated areas, stability of visual acuity, and absence of complications. The patients successively completed the laser treatments in later sessions in their respective Centers.

Discussion

The role of telemedicine in the management of retinal vascular diseases continues to be consolidated and expanding, particularly concerning diagnostics, but few studies to date have verified the feasibility of telemedicine treatment. There is a growing disparity between the number of health personnel and patients requiring care, especially in low-income countries.[11] Therefore, interventions are needed to address the need for treatments with an ever-decreasing number of experts worldwide. To improve this situation, continuous training is necessary. With the growing capabilities of online education and communication, it is essential to develop new educational and therapeutic paradigms to provide high-quality care. Remotely guided activities are now well established and can support education in countries with expert shortages.[11] Similarly to telediagnosis and screening, teletreatment may be a potential solution to address this need, where available experts from developed countries can support treatments in poor regions where there is a lack of ophthalmologists.

This work aimed to develop a remotely guided treatment process across continents to support appropriate education and collaboration between ophthalmologists. We performed remote photocoagulation treatments between Europe and North America for DR and CRVO. When evaluating the feasibility of this approach, several parameters were considered. Safe and effective treatments were achieved with proper understanding and agreement on treatment protocols among remote experts. The success of the treatment resulted in the completion of the programmed plan, with the acceptance and collaboration of the patients involved. A stable remote connection supported the quality of the treatments conducted. To our knowledge, this is the first time that a real-time remote-guided treatment was applied between two different continents to treat retinal diseases.

Unlike previous teletreatment works,[9,10] which used a specific study configuration that modified the technical assembly of the original medical product, our study uses a new technological configuration for teleguidance that is fully integrated with the latest version of the Navilas 577s navigated laser system. This configuration is approved for use in standard clinical environments, making it easier to implement without requiring technical modifications. Kozak, in a letter to the editor, also emphasized this concept.[12]

We believe that the development of this procedure could bring benefits to both patients and ophthalmologists. The advantages for the patient are the possibility of being treated according to the opinion of the expert of the reference center or the result of collaboration between different experts. The remote expert has the opportunity to disseminate and share his knowledge with colleagues worldwide as well as being able to offer his experience to patients whom he would otherwise not be able to reach. The local ophthalmologist who has the medical responsibility for the treatment has the advantage of carrying it out with the plan proposal and the collaboration of an expert in the sector, increasing the chances of providing the best possible treatment to his patient. Another important advantage to highlight of this methodology is the applicability without breaking any local regulations and without legal responsibility for the remote expert who proposes the treatment plan. However, it is necessary to emphasize that the responsibility for performing the treatment and the training required for the individual performing it must always comply with the applicable laws of the place of treatment. The person applying the laser, who physically presses the pedal of the device, is responsible for the treatment. This is further reinforced by the technical configuration since the remote ophthalmologist does not have the ability to activate the laser application.

One of the limits to the development of this method in poor regions is the necessary presence of a navigated laser with an eye-tracking system which is the only way to allow photocoagulation faithful to the proposed treatment. Another limitation may be the availability of diagnostic instruments to define the need for treatment. However, although very useful, it is not strictly necessary to define most of the indications for laser treatment, such as panretinal photocoagulation. A poor Internet connection may cause communication issues between ophthalmologists or cause a delay in treatment planning. However, this may not directly affect treatment outcomes. The ophthalmologist who performs the laser treatment remains responsible for its execution, and there is no possibility of remote interference with the device during treatment, whatever the status of the connection.

Limitations of the present study included the involvement of only developed countries with stable connection and electricity supply and the limited number of patients involved. Further studies involving more patients with the same or different indications will be necessary, even in countries with less stable Internet connections.

Conclusion

The results of this feasibility study suggested that teleguided retinal photocoagulation treatment using a remotely programmed retinal laser appeared to be a safe and effective option for proper education and collaboration between ophthalmologists across continents. In this work, we aimed to highlight the potential benefits of telemedicine in ophthalmology as a therapeutic tool. Telemedicine allows patients to access specialists' expertise worldwide, reducing costs and increasing patient safety by eliminating the need for dedicated sanitary travel. Our method also opens the possibility of creating mobile stations capable of reaching remote locations and making therapeutic telemedicine practically feasible without requiring highly specialized ophthalmologists. Furthermore, it does not violate any local regulations (medical license) since the local specialist accepts and performs the treatment himself. It opens the opportunity for remote local training, and we believe it can be a tool for social unity by overcoming geographical, ethnic, cultural, and religious barriers. This approach could benefit especially countries that do not have specialized expert resources in retinal laser therapy. Further work will be necessary to help evaluate a comprehensive training program, especially in locations with less stable Internet connections.

Declarations

Ethics approval and consent to participate

The Institutional Review Board waived the requirement for approval since it was a case series involving three patients. Written informed consent was obtained from all patients after carefully explaining all potential risks and benefits of remote planning and treatments.

Consent for publication

Written informed consent for publication was provided by the participants.

Author contributions

Andrea Cusumano: Conceptualization; Methodology; Supervision.

Robin Ross: Investigation; Supervision.

Benedetto Falsini: Visualization; Writing – original draft.

Marco Lombardo: Investigation; Validation; Writing – original draft.

Acknowledgements

We express our gratitude to OD-OS company for providing information and support about remote planning and remote observation tools on the navigated retinal laser.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

The data generated during the current study are available from the corresponding author upon reasonable request.

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Supplemental material

Supplemental material for this article is available online.

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