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Corneal transplantation during the COVID-19 pandemic: An operational guide

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Abstract

Purpose: To provide an operational guide for corneal transplantation during the COVID-19 pandemic aimed to maintain surgery and avoid spreading of SARS-CoV-2.

Methods: Prospective observational case series study in patients requiring corneal graft manage toward separate free and restricted pathways for those COVID-19 negative or positive, respectively.

Results: During the national lockdown, 30 consecutive patients underwent endothelial ($n = 16$), penetrating ($n = 9$), and anterior lamellar keratoplasty ($n = 5$). Two patients followed the COVID-19 restricted pathway, as they were considered positive while waiting for test results. Nine patients were hospitalized one night in the hospital. On admission to the hospital before surgery, at surgery, the day after surgery and at 7 and 30 days all patients and health-care personnel showed no symptoms and resulted negative at risks factors/exposure to the SARS-CoV-2 infection and occurrence of COVID-19. Nucleic acid testing resulted not detectable in all patients and SARS-CoV-2 antibodies quantification showed IgG and IgM below the positive predicted value in 29 patients. One patient showed IgM above the cut-off of significance (1.21 and 1.03 preoperative and 1-month postoperative, respectively) that were considered irrelevant because of the absence of symptoms and exposure risks.

Conclusions: The concept of donor emergency (i.e. short-term availability of transplant tissues), makes corneal transplantation an always-urgent activity because it is related to the availability of the corneal tissue from a donor. Modest adjustments to ophthalmic clinic and eye surgery organization are required to maintain surgery and care of eye patients in a safe environment.

Keywords

Corneal transplantation, COVID-19, SARS-CoV-2, operational guide

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Introduction

The severe coronavirus respiratory disease (COVID-19) associated with the coronavirus-2 (SARS-CoV-2) infection is generating exceptional stresses on health care at local and national level, and urgently raises the need to assess resources, re-examine health care service capacity, and create strategies for increasing critical care for the sickest patients.[1,2]

To contain the widespread virus many countries have implemented strict measures based on the isolation of cases and contacts, the temporary lockdown of schools, leisure and recreational centers, workplaces, shops selling non-essential goods, and personal precautions to be adopted by citizens. To cope with the increasing number of diseased patients, health care delivery has been reorganized as well, to ensure that essential services are maintained

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and mitigate exposure of non-COVID patients and others to SARS-CoV-2.[3]

The drastic interventions also involved ophthalmic services and the care of patients with eye disorders, as local health care authorities and ophthalmology societies warned that any treatment other than urgent or emergent care should be avoided.

Keratoplasty has been included among those elective surgical operations to postpone, since it is a procedure that can be delayed for the majority of cases, and clinical and surgical teams possibly moved to support the hospital organization and the care of COVID-19 patients instead. However, corneal transplantation must always be considered an urgent activity, not as surgery itself but rather how it is connected to the availability of the corneal tissue from a deceased donor, a non-programmable critical condition for the execution of the transplant, which represents an essential level of care and therapy for many patients.

Moreover, while cornea donation during the COVID-19 pandemic is feasible, organizational factors are leading to a slowdown in donations and the resulting shortage of availability of donor corneas could persist in the coming months and the waiting time for the transplant is expected to increase significantly, even in the face of a surge in requests to recover deferred operations.

Finally, the reduction in cornea requests because of surgery suspension could lead to an excess of preserved eye tissues, with the expectation that they cannot be used before their expiry date. To cope with these concerns we have conceived, in agreement with the reference Eye Bank, an approach to maintain the corneal surgical activity in patients with corneal disorders requiring graft, convinced that the goal of ensuring continuity of care can be achieved for all patients, even those who need a cornea transplantation.

We have defined and implemented an operational guide relating to hospital setting, health-care personnel, and patients involved in corneal transplant activity during the nationwide lockdown because of the COVID-19 pandemic.

This study aims to assess the feasibility and effectiveness of continuing corneal transplantation activity, either scheduled or urgent, while providing services that are necessary to maintain the health of the population and contribute to preventing nosocomial transmission of SARS-CoV-2 during COVID-19 pandemic.

Materials and methods

This prospective observational case series study was performed in accordance with the tenets of the Declaration of Helsinki and the study protocol approved by the Institutional Review Board of the Ss Giovanni and Paolo Hospital.

Patients, surgery, and follow-up

Patients scheduled for keratoplasty confirming the willingness to undergo graft, and those with corneal complaints requiring urgent keratoplasty followed the procedures described below.

We performed penetrating and lamellar grafts at the Ophthalmic Unit of the Ss Giovanni and Paolo Hospital in Venice, under local or general anesthesia starting from uncut or pre-cut corneal tissues without the use of laser, microkeratome, or other aerosol-generating procedures in the Operating Room (OR). After surgery, we assessed patients the day after, and at 1 week and 1 month.

Safety of donor corneal tissues against SARS-CoV-2 infection were validated by The Veneto Eye Bank Foundation (FBOV) that distributed corneal tissues retrieved from deceased donors confirmed negative by using a combination of clinical history and real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) assaying on nasopharyngeal swab.

Measures to contain exposure and spreading of SARS-CoV-2

Transmission-based precautions: Instructions for patients and health care personnel. To go inside the hospital, patients and health-care workers have to wear a surgical mask, rub hands with alcohol-based products, and have a body temperature $\leqslant$37.5°C measured by handheld cutaneous non-contact infrared thermography. Reason of access is verified for each patient, and a colored bracelet indicating the daily date is worn on the wrist as a mark of having passed the procedure.

While moving around inside the hospital, people are recommended to respect effective preventive measures, highlighted by information posters in waiting rooms and passageways, that is, (a) maintaining physical distance from other individuals (*minimum 1 m*); (b) performing hand hygiene with an alcohol-based product (*freely available also inside the Ophthalmic Unit*); (c) avoiding touching eyes, nose, and mouth; (d) practicing respiratory hygiene by coughing or sneezing into a bent elbow or tissue and then immediately disposing of the tissue.[4]

Environmental hygienic recommendations in the face of the COVID-19 outbreak and recommended protocols in outpatient clinics while maintaining Eye Department activity, have been implemented as described by Romano et al.[5]

Patients requiring urgent keratoplasty accessed the hospital through the Emergency Room (ER) and followed the restricted COVID-19 pathway (*see below*).

While waiting for rRT-PCR results and in the intervals between hospital admissions, patients were advised to protect themselves by preventing exposure to the virus through: (a) maintaining protective measures (*washing hands frequently*, *physical distancing*, *respiratory hygiene practice*, . . .); (b) refraining from meeting people other than those living in the same house; (c) avoiding close contact inside their own home; (d) covering mouth and nose with a mask when around others; (e) being alert for fever, cough, shortness of breath, or other symptoms of COVID-19; (f)

avoiding unnecessary travel or activities outside the private home (*running non-essential errands*, *going into the office or workplace*, *and in settings where it may be difficult to keep a physical distance of a minimum of 1 m*).

Evaluation of SARS-CoV-2 infection

Risk factors/exposure assessment. We assess previous exposure to the SARS-CoV-2 and occurrence of COVID-19 by using the following triage checklist to determine which patients should still attend clinic. With at least one positive answer, patients are considered at risk: (a) signs and symptoms of respiratory infection in the last 14 days (*fever*, *shortness of breath*, *cough*, *sore throat*, *altered taste*, *impaired smell*), (b) body temperature >37.5°C measured by handheld cutaneous noncontact infrared thermography, (c) history of direct SARS-CoV-2 exposure (*contact with someone who has been identified as a suspected case or diagnosed with COVID-19; being in a country or area at risk*), (d) previously tested positive for or diagnosed with COVID-19.

Scheduled patients were planned to be assessed six times, the first by phone interview when the date of surgery was approved, the second during the preoperative clinic visit 2 days before surgery, the day of surgery, after 1 and 7 days, and finally at 1-month follow-up. In the case of positive risk factors/exposure assessment result before surgery, patients were rescheduled.

In the case of a positive result to this assessment at any further evaluation time after surgery, patients did not enter the hospital and were redirected to their own general practitioner for the health care assistance of patients at risk for SARS-CoV-2 infection or suspected COVID-19.

Urgent patients were assessed on entering the ER and managed through the COVID-19 *restricted* pathway. In the case of a negative result of the test for current infection, they followed the COVID-19 *free* pathway. In the case of a positive result, they continued in the COVID-19 *restricted* pathway as inpatients or outpatients.

Test for current infection. The presence of SARS-CoV-2 was assessed in nasopharyngeal specimens by qualitative detection of nucleic acid from SARS-CoV-2 extracted from flocked swabs snapped off inside Copan UTM-RT medium. Nucleic acid amplification was performed using commercial kit in automated platform, following manufacturer instructions (Abbott sp2000 and RT, RealTime System, Abbott Laboratories, Abbott Park, IL). Samples with a cycle threshold of internal control (IC) ranging between 5.0 and 25 and no amplification of the viral genome targets were classified as SARS-CoV-2 not detectable, while samples with a cycle threshold ranging between 5.0 and 25 of IC and any amplification of the viral genome targets of two distinct regions within the N gene of SARS-CoV-2 were classified as SARS-CoV-2 detectable. Results were available within 24–48 h after sampling.

We tested scheduled patients during the preoperative assessment clinic visit 2 days before surgery and urgent patients on entering the ER. In the case of positive result, non-urgent patients were rescheduled. Health-care personnel were routinely tested every 10–20 days.

Test for past infection. SARS-CoV-2 specific IgM and IgG antibodies quantification in serum samples of patients were measured by chemiluminescent immunoassay (MAGLUMI 800 platform, Snibe, Shenzhen, PRC) showing calculated clinical sensitivities of IgM and IgG were 78.6% and 91.2%, respectively, while specificities of IgM and IgG were 97.5% and 97.3%, respectively. According to the manufacturer, antibodies used in the direct assays were against both CoV-S (spike) and CoV-N (nucleocapside) the main immunogens proteins of this coronavirus. These types of antibodies seem to correlate with neutralizing antibodies responses.[6] Results of IgG assessment were interpreted as follows: (i) reactive if >1.1 AU/mL; (ii) not reactive if <0.9; (iii) borderline if between 0.9 and 1.1 AU/mL. A single cut off limit of 1.0 for IgM was proposed.[7] Results were available within 48 h after sampling.

We tested scheduled patients during the preoperative assessment clinic visit 2 days before surgery, and urgent patients the day of surgery. All patients repeated testing at 1-month visit after keratoplasty.

Arrangement of the eye surgery

Patients had to comply with the assigned appointment time (neither too early nor late) to avoid crowding of people in the waiting rooms. The personnel of the Ophthalmic Unit supplied written instructions to patients.

The COVID-19 free pathway. Patients scheduled for corneal transplantation who accepted the operation after a phone call, verified negative at the evaluation of symptoms and risk factors accessed the hospital for the preoperative clinic assessment visit 2 days before surgery. Surgery was carried out 2 days after, under local or general anesthesia, and patients went home on the same day, though some required an overnight stay.

To enter the OR, patients wore a disposable surgical mask, and 100% polypropylene hydrophobic cap, gown, and overshoes. Supplemental oxygen airflow under the surgical drapes was delivered to patients by nasal cannula.

The OR has a reserved scrub facility, individual access for personnel, and patients were moved in and out of the operating block through a patient transfer unit, lying down on a stretcher. In the case of overnight stay, patients were hosted in a reserved COVID-19 *free* room ("*week surgery*") easily accessible on the same floor as the OR.

Dressing and hygiene of the surgical team were as follows: overshoes, polypropylene hydrophobic cap, surgical mask, surgical hands scrub, disposable long sleeved

waterproof sterile gown, sterile long gloves covering up to the cuff.

The COVID-19 restricted pathway. Patients requiring urgent keratoplasty entered the hospital through the ER and followed the COVID-19 *restricted* pathway especially arranged to cope with the COVID-19 pandemic while maintaining surgical activities for the emergent non-deferrable surgical cases. Such patients were considered in any case positive for SARS-CoV-2 infection and followed the triage evaluation and nasopharyngeal swab sampling on entry to the ER, wore surgical masks and gloves and were moved in a wheelchair through a one-way COVID-19 *restricted* pathway to the Ophthalmic Unit for evaluation, and then to a COVID-19 *restricted* waiting room next to the operating block.

Patients moved to the COVID-19 *restricted* OR, a room properly set up for COVID-19 positive patients and service guaranteed 24 h by an anesthetist and assistant ("the *urgent surgery team*").

Such OR has a reserved scrub facility, individual access for personnel, and patients were moved in and out of the operating block through a patient transfer unit lying down on a stretcher. Equipment was maintained at the minimum required, wrapped with sterile single use sheets to reduce contamination.[8] Traffic and flow of contaminated air were minimized by locking all doors during surgery. Following use, a special disinfection service cleaned the OR and set up again for the next procedure.

We performed surgery under general anesthesia, patients wearing a disposable surgical mask, gloves, 100% polypropylene hydrophobic cap, gown, and overshoes. Supplemental oxygen airflow under the surgical drapes was delivered to patients by nasal cannula.

Dressing and hygiene of the surgical team were as follows: overshoes, polypropylene hydrophobic cap, eye protection (glasses), facepiece respirators (FFP2 standard mask), surgical hand scrub, sterile gloves, disposable long sleeved fluid repellent sterile gown, a second pair of sterile gloves covering up to the cuff. A maximum of three people were allowed in the OR at the same time.

Patient received overnight stay in an appropriate COVID-19 *restricted* area of the hospital suitable to host suspected or confirmed positive patients, on a different level of the same building as the operating block. Asymptomatic patients would eventually move to a different exclusive hospital for SARS-CoV-2 infected subjects ("*COVID hospital*") or to their home, up to negative rRT-PCR result, or in the case of symptoms, to the Infectious Diseases ward or to the Intensive Care Unit until the resolution of the COVID-19.

Follow-up evaluation. Ophthalmic evaluations were performed the day after surgery, at 1 week and 1 month in a setting described by Romano and coworkers for entering and moving in the hospital and maintaining Eye Department activity.[5]

Patients were seen by the ophthalmologist in the ward they were moved and, in the case of discharge home because of corneal graft not requiring daily monitoring, they were checked by telephone call up to the termination of the quarantine/negative rRT-PCR result. In the case of exclusion of accessing the Hospital after surgery due to positive result at risk factors/exposure evaluation, patients were followed-up by telephone call up to the termination of the quarantine/negative rRT-PCR result.

Thereafter, they restarted accessing the Ophthalmic Unit.

Results

During nearly 100 days of lockdown, between March and May 2020, we performed corneal transplantation on 30 consecutive patients (16 females) mean age 59.4 years (median 65; range 17–92). Two urgent patients, a 92-year old male and a 76-year old female, entered the COVID-19 *restricted* surgical pathway because they showed corneal perforation following severe bacterial infection requiring urgent keratoplasty.

The same ophthalmic surgical team was involved in all surgery and clinical assessments.

Endothelial keratoplasty was performed in 16 patients (9 Descemet stripping automated endothelial keratoplasty, DSAEK, and 7 Descemet membrane endothelial keratoplasty, DMEK), penetrating keratoplasty (PK) in 9 (with reconstructive indication in both the urgent patients), and deep anterior lamellar keratoplasty (DALK) in 5. Indication for graft were Fuchs endothelial dystrophy ($N=12$), regraft ($N=5$), keratoconus ($N=5$), post-infective corneal scars ($N=3$), and post-traumatic or post-vitrectomy leukoma ($N=3$), and perforation ($N=2$).

Nine patients stayed one night in the hospital, the two urgent patients who underwent general anesthesia, and seven patients from those with scheduled graft. None of them refused or acknowledged distress in accepting an overnight stay.

Operational guidance for COVID-19 *free* and COVID-19 *restricted* pathways are described in Figure 1.

At admission to the hospital before surgery, at surgery, the day after surgery and at 7 and 30 days all patients and health care personnel of the OR and Ophthalmic Unit showed no symptoms and resulted negative at the evaluation of risks factors for exposure or SARS-CoV-2 infection.

Virus tests by rRT-PCR resulted not detectable in all patients and SARS-CoV-2 antibodies quantification showed IgG <0.9 (range 0.0–0.35) and IgM <1.0 (range 0.0–0.76) at sampling on the day of surgery and IgG <0.9 (range 0.0–0.28) and IgM <1.0 (range 0.0–0.65) at sampling 1-month after keratoplasty in 9 over 10 patients. One patient showed IgG 0.05 and <0.1 and IgM $=1.21$ and 1.03, preoperative and 1-month postoperative, respectively.

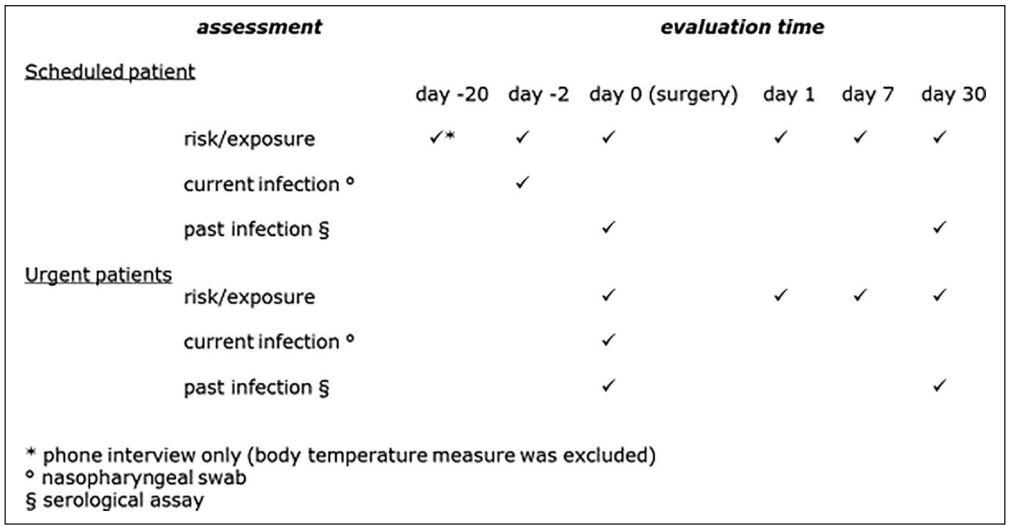

Figure 1. Essential assessment of SARS-COV-2 infection and occurrence of COVID-19 in patient undergoing corneal transplantation.
Scheduled patients were planned to be assessed six times. In the case of positive result at one of the assessments before surgery, patients were re-scheduled. In the case of a positive result at any further risk factors/exposure evaluation after surgery, patients did not enter the hospital and were redirected to their own general practitioner for the health care assistance of patients at risk for SARS-CoV-2 infection.
Urgent patients were assessed on entering the ER and managed through the COVID-19 *restricted* pathway. In the case of a negative result of the test for current infection, they were switched to the COVID-19 *free* pathway. In the case of a positive result, they continued in the COVID-19 *restricted* pathway as inpatients or outpatients.

Despite the quantification of IgM antibodies showing values above the cut-off of significance, results were considered not significant because of the absence of symptoms and risk due to exposure.

Discussion

As expected, the health emergency due to COVID-19 pandemic caused a decline in the retrieval of donor corneas and a more drastic drop in the number of corneal grafts. Similar to what happened for most elective surgeries, corneal transplantation remained operative in the majority of hospitals only for emergent clinical conditions, resulting in a reduction in requests for donor tissues.

Compared to the same period last year, the activity of the FBOV from March to April 2020 showed a 40% reduction in cornea donation and a huge contraction of 90% in the call for transplantation. Because the FBOV includes about 3000 corneal transplantations each year, 50% of all grafts performed annually in Italy,[9] the reduction in surgical activity resulted in almost 250 discarded corneal tissues suitable for transplantation.

In the process of corneal donation and transplantation, withdrawal of transplants challenges not only donation and compromises ethics, due to the expiry of donated tissues, but management and economic issues as well, involving procurement and banking organization at local and national level.[10]

Carrying out corneal transplantation activity as much as possible preventing tissue from being discarded is of utmost importance, in order not to undermine the precious gift of sight that donor cornea represents for persons waiting to be rescued from a lifetime of blindness.

The removal of donor corneas does not constitute in itself a risk factor of exposure to SARS-CoV-2 for the health care providers involved, given the accurate application of personal protective equipment (PPE) during harvesting (medical mask, visor/protective glasses, disposable coat, overshoes, double gloves). The risk of viral transmission to recipients appears to be negligible, in accordance with the criteria already provided for the screening of the eligibility of the corneal donor, as there is no current evidence that corona viruses can be transmitted by blood transfusions or tissue or cell transplants.[11]

Moreover, stopping an ongoing proven network could cause difficulties in the restarting of it, while the slowdown in donations during the COVID-19 pandemic, mainly for organizational reasons, could continue in the coming months, and the waiting time for the transplant could be significantly dilated, even in the face of an increase in requests to recoup deferred operations.

In this study, we set up and implemented a process to ensure health-care continuity for all patients waiting for cornea transplantation. We confirmed that environmental cleaning, dressing and hygiene of patients and health-care operators, adoption of proper behaviors, accurate application of PPE, and procedures allowed the continuation of safe corneal transplantation even at this time of the COVID-19 pandemic.

Results of virus testing obtained within 2 days after sampling are adequate in the programming of the surgery

while a rapid test in the ER, available at the time of the study, can target urgent cases and direct them through the COVID free pathways in case of a negative result.

Testing for current and past SARS-CoV-2 infection corroborated the clinical evaluation of symptoms and risk factors, lacking in all patients throughout the study period, and confirmed that the lack of symptoms is a reliable indicator for the absence of the disease.

We decided to test SARS-CoV-2 specific IgM and IgG antibodies mainly because of the limited knowledge and experience of the antibody production by the immune system at that time. Recent data consistently show serological testing sensibility of about 100%, 14 days after the surge of symptoms, and Centers for Disease Control and Prevention consider COVID-19 assumed diagnosis if it occurs on the basis of clinical data and serology, even with negative swabs.[12]

At the same time, we could test the effectiveness of the procedure regarding the absence of the impact on the spreading of SARS-CoV-2.

The operational guidance we have conceived and experienced relates to all patients, scheduled and urgent, for corneal transplantation under current techniques and donor corneas prepared by the Eye Bank.

Modest adjustment of ophthalmic clinic and eye surgery organization keeps keratoplasty possible and raises awareness of the importance of preserving the capability to realize the gift of sight in our communities updating the traditional definition of *elective procedure* with the concept of *donor emergency*.

Measures to contain the infections should not apply to surgical teams that have to move for tissue retrieval, as an essential health activity, so as not to block the logistics of finding and transporting tissues (and even more so organs) needed for transplants.

Institutions at national and local level must provide the required support to maintain the donation, organs and tissue retrieval, and transplantation activities and include keratoplasty among the emergency activities in the planning and reorganization of surgical teams and hospital logistics, especially in the regions most affected by the COVID-19 pandemic.

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