Preliminary Safety Recommendations in Rhinoplasty Post Covid-19

Rod J. Rohrich, M.D., F.A.C.S.
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## Global Covid

These numbers are heavily dependent on presence of testing!

<table>
<thead>
<tr>
<th>Country, Other</th>
<th>Total Cases</th>
<th>New Cases</th>
<th>Total Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>4,421,460</td>
<td>+84,023</td>
<td>297,534</td>
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<tr>
<td>USA</td>
<td>1,427,739</td>
<td>+19,103</td>
<td>85,041</td>
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<td>Texas</td>
<td>42,984</td>
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<tr>
<td>Dallas</td>
<td>6,602</td>
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</table>

Coronavirus Cases: **4,421,460**

Deaths: **297,534**

Recovered: **1,654,653**

*view by country*
Minimum Standard of Safe Practice at DPSI / DDSC

• All office personnel and patients must wear masks/social distancing

• Develop and follow office policies for screening and testing

• Before any encounter, all patients must be screened for related Covid-19 symptoms or verify prior screening.

• For care involving mucous membrane or respiratory tract (rhinoplasty), minimum PPE should include N95 mask or equivalent, and face shield.
Minimum Standard of Safe Practice at DPSI / DDSC

• UNIFORM STRICT PROTOCOLS TO BE FOLLOWED BY ALL

• NO WAITING ROOMS/ NO REFRESHMENTS

• NO MAGAZINES /NO COFFEE/NO TOUCH MATERIAL

• PATIENTS WAIT in TEXT IN CAR -SLOWER PATIENT PACE

• ALL ROOMS CLEANSED/DISINFECTED AFTER EACH PATIENT

• ALL PUBLIC AREAS/ELEVATORS DISINFECTED EVERY HOUR
Texas Society of Plastic Surgeon
Recommendations

- Screen patients and staff
- Script staff with proper screening questionnaire
- Identify high-risk patients
- Clinic / Operating Room / UNIFORM STRICT Protocols
Screening Patients and Staff

Daily Staff Screening

- Symptoms questionnaire
- Temperature T>99.6
- Febrile, symptomatic → HOME
- Clean all personal phones when entering
- Wash hands upon entering/leaving
Screening Patients and Staff

Daily Patient Screening
- Symptoms questionnaire
- Temperature T>99.6
- Febrile, symptomatic → RESCHEDULE
- Offer **Virtual Consult** if appropriate
- Inform patients of new screening protocol
- Instruct patients to **come alone**
- Instruct patients to **bring mask**
Screening Patients and Staff

Daily Patient Screening
- Symptoms questionnaire
- Temperature T>99.6
- Febrile, symptomatic → RESCHEDULE
- Offer Virtual Consult if appropriate
- Inform patients of new screening protocol
- Instruct patients to come alone
- Instruct patients to bring mask
Identify Patients- Increased Risk- Not Operating on these Patients Currently!

**Medium Risk**
- First Responders EMT, Fire Department, bus driver
- Asymptomatic, prior exposure to COVID-19 patients
- Recent Travel (<3 weeks)
- Recovered recently from respiratory symptoms
- Has someone sick at the house
- Has comorbidities ASA 3

**High Risk**
- Has COVID-19
- Recovered from COVID-19
- Has current symptoms consistent with COVID-19
- Has someone in house with COVID-19
HIGHLY SELECTIVE

- Do not perform surgery on patients with Covid-19 comorbidities associated with increased complications
  - Age >60
  - Arterial HTN
  - DM
  - Lung disease
  - Obesity
  - Smoker

I AM NOT OPERATING ON SLEEP APNEA PATIENTS CURRENTLY
Prior to Surgery

• ALL patients screened over the phone with a series of questions

• Fever (>99.6)
• SOB, cough, or other respiratory symptoms
• Unexplained muscle aches
• GI symptoms
• Loss of taste or smell
• Conjunctivitis
• Chills
• Extreme fatigue
• Age > 70: confused, dizzy, falls, mental status change
• Close proximity to lab proven Covid+ patient for more than 5 minutes without PPE
Separate Informed Consent -ASPS and ASAPS – staff and patients
Perioperative Rhinoplasty Protocol

(1) PREOPERATIVE
- RT-PCR
- Screening

(2) DAY OF SURGERY
- Betadine Spray
- Screening

(3) OPERATIVE
- Anesthesia Protocol
- OR Circulation
- Patient Prep
- Surgeon / Staff PPE
Global

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Likelihood of + Test Varies with Subsite Location

ACE-2 Receptors are most prevalent in the lower airways (basilar lungs), which might explain the increased test sensitivity with BAL

- Bronchoalveolar Lavage – 93%
- Sputum – 72%
- Nasal Swabs – 63%
- Pharyngeal Swabs – 32%
- Bronchoscope brushings – 46%
- Other
  - Feces – 29%
  - Blood – 1%
Testing Options

- Nasopharyngeal swab
- Tissue sample after autopsy
- Stool
- Plasma & Blood
- Fingertip blood

CT Scan
- Ground-glass opacities
- Inter-/intra-lobular septal thickening
- Air space consolidation
- Bronchovascular thickening
- Traction bronchiectasis

RT-PCR analysis
- Nucleic acid amplification for viral DNA
- Measures current infection

ELISA

Rapid detection test

<table>
<thead>
<tr>
<th>Type</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Scan</td>
<td>- Available earlier&lt;br&gt;- Check severity of condition&lt;br&gt;- Check possible infection&lt;br&gt;- Track lung based recovery</td>
</tr>
<tr>
<td>Nucleic acid amplification for viral DNA</td>
<td>- Increased accuracy&lt;br&gt;- Targets different components of viral genome&lt;br&gt;- Individual can be monitored to prevent disease progression&lt;br&gt;- Identify patients with COVID-19</td>
</tr>
<tr>
<td>Measures current infection</td>
<td>- Detection of immune individuals&lt;br&gt;- Identify individuals with antibodies for potential use as therapy&lt;br&gt;- Identify susceptible individuals&lt;br&gt;- Aid in tracing individuals in contact with infected person</td>
</tr>
</tbody>
</table>
Real Time –Polymerase Chain Reaction (PCR)

- RT PCR checks for presence of viral RNA – determines active infection
- Abbott → 5 min
  - Needs their platform
  - High false positive of ~ 15% → UPMC no longer using this test
- Mesa → 30 min
  - Uses palm-sized Acula system
- Cepheid → 45 min
  - Requires their GeneXpert System
  - False negative rate reportedly 1.8%

- DiaSorin Molecular Simplexa
  - Requires LIAISON® MDX instrument
  - False negative 11%

- LabCorp Pixel → 1-2 days
  - Sample at home and send in for results
  - No need to visit medical site and risk exposure
  - $119

- Quest has a home test through QuestDirect
“The currently accepted RT-PCR test for SARS-CoV-2 has varying sensitivity according to which subsite of the aerodigestive tract is sampled. Nasal swab sensitivities appear to be about 70%. ”

False positive with non-malignant coronavirus infection → 20% of common colds caused by coronavirus
### Recommendations to Mitigate Risks from False Negative Test Results

<table>
<thead>
<tr>
<th>Recommendations</th>
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<tbody>
<tr>
<td>1. Strictly adhere to infection control measures, including:</td>
</tr>
<tr>
<td>- Physical distancing</td>
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<tr>
<td>- Hand hygiene</td>
</tr>
<tr>
<td>- Environmental cleaning and disinfection</td>
</tr>
<tr>
<td>- Adequate PPE for healthcare workers</td>
</tr>
<tr>
<td>2. Develop and disseminate accurate diagnostic tests</td>
</tr>
<tr>
<td>- Improved RT-PCR tests</td>
</tr>
<tr>
<td>- Serological assays</td>
</tr>
<tr>
<td>- Report diagnostic test characteristics from methodologically rigorous studies</td>
</tr>
<tr>
<td>3. Assess risk levels before testing</td>
</tr>
<tr>
<td>- For individuals and environments with higher pretest probability of COVID-19 infection, confidence in negative COVID-19 test results should be lower</td>
</tr>
<tr>
<td>4. Establish risk-stratified protocols for management of negative COVID-19 test results</td>
</tr>
<tr>
<td>- For higher-risk individuals (including healthcare workers), delay return to work even in the absence of symptoms</td>
</tr>
</tbody>
</table>
Antibody Tests

- Tests for the presence of antibodies in the blood – indicating an ongoing or previous infection
- They can test for antibodies IgM, IgG or both.
  - IgM appears earlier in the infectious cycle
  - IgG appears later
  - **a patient may be infected and not have IgM antibodies yet, early in the infection
Antibody Tests

- 3 Antibody tests have “Emergency Use Authorization” (EUA) from the FDA
  - NONE are FDA-APPROVED

- Cellex → 15 min turnaround (original)

- Chembio Diagnostic
  - 15 min
  - Uses chembio microreader 1 and 2

- Ortho Clinical Diagnostics
  - (Abbott – pending application for EUA)
Issues & Concerns

● Presence of antibodies DOES NOT equal immunity!
  ● Antibody presence only indicates that the patient was infected at some point

● We do not have a clear sense of false positive / negative rates yet

● We do not know how to interpret these tests yet
<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRE-OP VALUE?</th>
<th>BENEFITS</th>
</tr>
</thead>
</table>
| Imaging (CT scan)             | No            | Checks severity of condition
                               | Tracks recovery             |
| Nucleic Acid Amplification    | Yes           | Measures current infection  |
| Antibody Detection            | Yes??         | Detects past exposure       |
Immune Response

- Pre-symptomatic and Asymptomatic stage
- IgM becomes detectable
- IgG production begins
- Patient begins to recover
- IgM disappears
- Convalescence
<table>
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<tr>
<th>TEST</th>
<th>DETAILS</th>
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<tr>
<td><strong>Abbott</strong> 5 Minutes</td>
<td>Needs their platform; High False Positive 15% → UPMC no longer using this test</td>
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<td><strong>LabCorp Pixel</strong> 1 – 2 days</td>
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<tr>
<td><strong>Quest</strong> 1 – 2 days</td>
<td>Sample at home and send in for results</td>
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qRT-PCR – the current gold standard diagnostic test?

- Nasopharyngeal swab
- Nasal Nares only
- Saliva

The challenge – Lack of good sensitivity/reliability data currently?!
qRT-PCR- NASOPHARYNGEAL SWAB

- qRT-PCR is the gold standard diagnostic test
- False negative cases are possible
- Asymptomatic patients with low viral load
  - Samples taken lower in the respiratory tract are more sensitive
    - 40% sensitivity nasal samples
    - 50% for oropharyngeal samples
    - 80-100% for bronchoalveolar lavage
Sensitivities appear to be about 70%.
Antibody Tests

Cellx → 15 min turnaround (original)

Positive Percent Agreement (PPA) = 120/128 (93.8%), 95% CI: 88.2% to 96.8%
Negative Percent Agreement (NPA) = 240/250 (96.0%), 95% CI: 92.8% to 97.8%

Chembio Diagnostic
15 min
Uses chembio microreader 1 and 2

Ortho Clinical Diagnostics
(Abbott – pending approval but has an EUA)
Immune Response

- Window period
- Onset of symptoms, for those who develop symptoms
- IgM becomes detectable
- IgG production begins
- Patient begins to recover
- IgM disappears
- Convalescence

Days since infection

SARS-CoV-2 RNA and Antigen
- IgM antibody
- IgG antibody
Antibody Tests

Quality of tests:

- Were allowed on the market by FDA under emergency protocols
  - quality and reliability of these tests are unknown!
- Cross-reactivity with other non-COVID-19 coronaviruses
Antibody Tests

Utility of tests:

• Unknown whether protective or still susceptible to COVID-19

• Unknown if all previous COVID-19 + patients will have antibodies and how long they persist

• Current tests do not establish immunity or exclude active infection.
Perioperative Rhinoplasty Protocol

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- Anesthesia Protocol
- OR Circulation
- Patient Prep
- Surgeon / Staff PPE
Upon Arrival

- ALL patients and staff will be screened daily by staff member
- Series of questions and temperature taken
- N95 Mask must be worn by all patients and staff for RHINOPLASTY
- PPE/FACE MASKS/EYE PROTECTION
- No visitors unless minor
- Waiting rooms closed
Preoperative Decolonization

Consideration of povidone-iodine as a public health intervention for COVID-19: Utilization as “Personal Protective Equipment” for frontline providers exposed in high-risk head and neck and skull base oncology care

1. Apply nasal and oral PVP-I every 2–3 h, up to 4×/day in patients that:
   a. Have suspected/confirmed SARS-CoV-2 infection
   b. Are undergoing high-risk procedures (e.g. those involving nasal mucosal, oral, pharyngeal, and pulmonary secretions)
   c. Are from COVID-19 hotspots

PRELIMINARY DATA ONLY

DECREASES THE VIRAL LOAD IN NASAL CAVITY/NASOPHARYNX
ClinicalTrials.gov

Gargling and Nasal Rinses to Reduce Oro- and Nasopharyngeal Viral Load in Patients With COVID-19

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04344236

Recruitment Status: Recruiting
First Posted: April 14, 2020
Last Update Posted: April 14, 2020
See Contacts and Locations
<table>
<thead>
<tr>
<th>Study Design</th>
<th></th>
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<tbody>
<tr>
<td>Study Type</td>
<td>Interventional (Clinical Trial)</td>
</tr>
<tr>
<td>Estimated Enrollment</td>
<td>48 participants</td>
</tr>
<tr>
<td>Allocation</td>
<td>Randomized</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>Parallel Assignment</td>
</tr>
<tr>
<td>Intervention Model Description</td>
<td>Randomized controlled open label trial, parallel design</td>
</tr>
<tr>
<td>Masking</td>
<td>None (Open Label)</td>
</tr>
<tr>
<td>Primary Purpose</td>
<td>Treatment</td>
</tr>
<tr>
<td>Official Title</td>
<td>A Phase II, Randomized, Open-label, Single-institution Study of the Effects of Povidone Iodine Oral Gargles and Nasal Rinses on Viral Load in COVID-19</td>
</tr>
<tr>
<td>Actual Study Start Date</td>
<td>April 9, 2020</td>
</tr>
<tr>
<td>Estimated Primary Completion Date</td>
<td>May 1, 2020</td>
</tr>
<tr>
<td>Estimated Study Completion Date</td>
<td>May 9, 2020</td>
</tr>
</tbody>
</table>
### Study Description

**Brief Summary:**
For this study, 48 patients who have been diagnosed with COVID-19 will be randomly assigned to four study groups: control, saline, chlorhexidine gluconate, and povidone-iodine. Each patient will be asked to gargle with a solution of either saline, chlorhexidine gluconate, or povidone-iodine or nothing (control group) as well as spray the same solution in their nose four times daily. Patients will then be tested for COVID-19 once daily in the evening for 7 days and viral loads will be measured.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
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</table>
| COVID-19             | Drug: Saline oral/nasal rinse  
Drug: 0.5% Povidone/Iodine oral/nasal rinse  
Drug: 0.12% Chlorhexidine oral/nasal rinse | Phase 2 |

**Detailed Description:**
COVID-19 has emerged as a worldwide pandemic and there is a strong need for identification of any measures that can be used to treat this illness or reduce its transmission from person to person. Povidone-iodine has been shown to have virucidal properties against multiple viruses including against the virus that causes SARS which is very similar in makeup to the virus causing COVID-19.

The investigators hypothesize that 4x daily use of oral gargles and nasal rinses using a povidone iodine solution will help to reduce the viral load in the nasopharynx and oropharynx in patients who are COVID-19+. If this hypothesis is shown to be true this could potentially have an impact on time to recovery of clinical symptoms as well as reduce shedding of the virus by infected patients. A time course of 7 days was chosen in order to recognize a trend in the viral load over time for patients receiving each of the interventions. Chlorhexidine gluconate and saline rinses were chosen as additional treatment arms as these are frequently used for oral and nasal hygiene and their role in affecting viral load is currently unknown.
BETADINE IS A BETTER ANTIVIRAL AGENT

Inactivation of human viruses by povidone-iodine in comparison with other antiseptics.


Abstract

Inactivation of a range of viruses, such as adeno-, mumps, rotavirus, poliovirus (types 1, 2, and 3), coxsackievirus, rhinovirus, herpes simplex, rubella, measles, influenza and human immunodeficiency viruses, by povidone-iodine (PVP-I) and other commercially available antiseptics in Japan was studied in accordance with the standardized protocol in vitro. In these experiments, antiseptics such as PVP-I solution, PVP-I gargle, PVP-I cream, chlorhexidine gluconate, alkylaminomethylglycine hydrochloride, benzalkonium chloride (BAC) and benzethonium chloride (BEC) were used. PVP-I was effective against all the virus species tested. PVP-I drug products, which were examined in these experiments, inactivated all the viruses within a short period of time. Rubella, measles, mumps viruses and HIV were sensitive to all of the antiseptics, and rotavirus was inactivated by BAC and BEC, while adeno-, polio- and rhinoviruses did not respond to the other antiseptics. PVP-I had a wider virucidal spectrum, covering both enveloped and nonenveloped viruses, than the other commercially available antiseptics.
Betadine® Solution
(povidone-iodine 10%)

Antiseptic Non-Sterile Solution

A topical aqueous solution of 10% povidone-iodine
POVIDONE-IODINE AND CORONA VIRUS

In Vitro Bactericidal and Virucidal Efficacy of Povidone-Iodine Gargle/Mouthwash Against Respiratory and Oral Tract Pathogens

Maren Eggerts, Torsten Koburger-Janssen, Markus Eckmann, and Juergen Zorn

Abstract

Recent virus epidemics and rising antibiotic resistance highlight the importance of hygiene measures to prevent and control outbreaks. We investigated the in vitro bactericidal and virucidal efficacy of 1% povidone-iodine (PVP-I) gargle/mouthwash at defined dilution against oral and respiratory tract pathogens.
The Science of Stabilizing Hypochlorous acid (HOCl)
“5” Actions of Hypochlorous Acid

- Eradicates microorganisms - bacteria (including MRSA, VRE), viruses, fungus and spores
- Reduces Inflammation - inhibition of mast cell degranulation
- Reduce Itch and pain
- Increases Oxygenation to improve healing
- Break Down Biofilm
HOCl Action: Eradicates Micro-Organisms

HOCl reacts with surface proteins, interfering with function of affected proteins.

Transmembrane proteins transport nutrients; enzyme activity

HOCl reacts with lipids in membrane, destabilizing cellular integrity leading to lysis.

HOCl and reaction products penetrate cell wall and cell membrane, interfering with intracellular processes.
Super-oxidized water prevents allergen- and calcium-induced mast cell degranulation for up to 8 hours after a single exposure.

Medina et. al., 2006

Anti-Inflammatory Properties: Inhibition of Mast Cell Degranulation

Medina-Tamayo, et.al., Nat’l Inst. of Rehab., Mexico City, 2005
Characterization of Virucidal Activities of Chlorous Acid.

Goda H1, Ikada K2, Nishide M3, Nagao T4, Koyama AH5.

Abstract
Virucidal effects of chlorous acid on enveloped and non-enveloped viruses were characterized. The virucidal activity was prominent in enveloped viruses. However, among non-enveloped viruses, viruses such as human rhinovirus and feline calicivirus showed a significant sensitivity to the reagent, whereas others such as poliovirus and coxsackievirus showed a weak sensitivity to the reagent, suggesting the presence of 2 classes of sensitivity to the reagent, among non-enveloped viruses. In addition, characterization of the mode of inactivation by the reagent revealed that virus inactivation is strongly dependent on virus species, contaminated proteins, and solvent system composition. Comparison of the cytotoxic effects of chlorous acid with those of sodium hypochlorite or sodium dodecyl sulfate (SDS) revealed that chlorous acid was similar to SDS and remarkably weaker than sodium hypochlorite. These results indicate the unique nature of chlorous acid as a potent virucidal agent with tolerable tissue damage, and reveal the merits and limitations of chlorous acid as a disinfectant in food hygiene and sanitizer in healthcare.
NO SCIENTIFIC DATA

CHLORHEXIDINE ORAL RINSE (PERIDEX)

ANTIBACTERIAL >> ANTIVIRAL
EVOLVING SCIENTIFIC DATA

TRANEXAMIC ACID SOLUTION/TABLETS

EXCELLENT ANTIVIRAL
PRE OP BETADINE NASAL SPRAY AND GARGLE

- DILUTE 4:1 BETADINE NASAL SPRAY
- BETADINE- 4:1 MOUTH GARGLE
- 15 SECOND SPRAY PER NOSTRIL
- 15 SECOND MOUTH GARGLE
4:1 Betadine /Alcohol Free Mouthwash
Gargle
Intraoperative/Intubation

- Minimize exposure in OR during intubation and extubation

- Full PPE/ N95 with mask/Face shield

- Minimize intraoperative equipment

- High OR air exchange cycles recommended (>25 exchanges/h) > 99% viral clearance- 8 – 20 minutes

- Prep face with betadine to nasopharynx and betadine throat pack
INTRA – OP PREP

- BETADINE FULL FACE PREP - Full Strength
- BETADINE MOUTH PREP - Full Strength
- BETADINE NASAL PACK – Full Strength
- BETADINE NASAL SWABS – Full Strength
SKIN PREP

NASAL MUCOSA/NOSTRILS

THROAT PACK
RHINOPLASTY PREP

- BETADINE SOAKED NASAL PLEDGETTS
- BETADINE SOAKED THROAT PACK
- OCCLUSIVE MOUTH DRAPE
RHINOPLASTY OPERATION

- N 95 COVERED WITH SURGICAL MASK
- FULL PPE
- FULL FACE/EYE PROTECTON
- NO AERESOL PRODUCING PROCEDURES
- LIMIT NASOPHARYNGEAL SUCTION
Intraoperative - How to Properly Don PPE Gear

- Identify and gather PPE
- Put on NIOSH-approved N95 filtering facepiece respirator or higher
- Put on face shield or goggles
- Put on headlight
- Hand hygiene
- Put on gown
Postoperative – How to Properly Remove PPE Gear

- Remove gloves
- Remove gown
- Hand hygiene
- Remove face shield or goggles
- Remove and discard respirator or facemask
- Hand hygiene
Thank you