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Original Article

Inanimate surface contamination of SARS-CoV-2 during midfacial fracture repair in asymptomatic COVID-19 patients

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ABSTRACT

Purposes: To evaluate inanimate surface contamination of SARS-CoV-2 during midfacial fracture repair (MFR) and to identify relevant aggregating factors.
Methods: Using a prospective non-randomised comparative study design, we enrolled a cohort of asymptomatic COVID-19 patients undergoing MFR. The predictor variables were osteofixation system (conventional titanium plates [CTiP] *vs.* ultrasound-assisted resorbable plates [USaRP]). The main outcomes were the presence of SARS-CoV-2 on four different surfaces. Other study variables were categorised into demographic, anatomical, and operative. Descriptive, bi- and multivariate statistics were computed.
Results: The sample consisted of 11 patients (27.3% females, 63.6% right side, 72.7% displaced fractures) with a mean age of 52.7 ± 20.1 years (range, 19–85). Viral spread was, on average, 1.9 ± 0.4 m. from the operative field, including most oral and orbital retractors' tips (81.8% and 72.7%) and no virus was found at 3 m from the operative field, but no significant difference was found between 2 osteofixation types. On binary adjustments, significantly broader contamination was linked to centrolateral MFR ($P = 0.034$; 95% confidence interval [CI], 0.05 to 1.02), and displaced MFR > 45 min ($P = 0.022$; 95% CI, 0.1 to 1.03).
Conclusions: USaRP, albeit presumably heavily aerosol-producing, cause similar SARS-CoV-2 distribution to CTiP. Non-surgical operating room (OR) staff should stay ≥ 3 m from the operative field, if the patient is SARS-CoV-2-positive. Enoral and orbital instruments are a potential virus source, especially during displaced MFR > 45 min and/or centrolateral MFR, emphasising an importance of appropriate patient screening and OR organisation.

1. Introduction

In April 2020, *Zimmermann* and *Nkenke* [1] first mentioned craniomaxillofacial surgical (CMFS) care during the COVID-19 pandemic. Three months later, a group of plastic and maxillofacial surgeons, namely the "AO CMF COVID-19 international task force", launched their congruous recommendations [2]. Surgery involving COVID-19 patient's nasal/oral mucosa increase an exposure to respiratory droplets and aerosols containing SARS-CoV-2. The AO CMF thus limited CMFS procedures during the pandemic only to emergent airway management, epitaxis, severe bleeding, open reduction and internal fixation (ORIF) of facial fractures, and oncologic procedures in relation to reduced survival chance [2]. The primary author (P.P.) and her colleague recently published triage guidance on head and neck cancer and trauma care in Germany during this pandemic [3].

These three abovementioned recommendations are opinion-based (*i.e.* German AWMF's S1 guideline) with the UK's Oxford Centre for Evidence-Based Medicine (OCEBM) Level of Evidence (LoE) 5. The American Society of Plastic Surgeons advised clinicians to be alert to new evidence, if only LoE 5 is available. An expert opinion is often biased by personal experience without control of confounders [4]. For example, the AO CMF suggested low-speed drilling with limited/no irrigation [2], despite the risk of thermal bone necrosis, and subsequent screw loosening and osteofixation failure [5]. Self-drilling screws is an option to solve this problem, but may be unavailable in resource-restricted nations. Besides, a recent case-control study by

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Hiriyanna et al. [6]. could not demonstrate superior advantage of self-drilling screws over conventional screws in terms of screw failures and fragment stability (OCEBM's LoE 3b). Although a systematic review of all LoEs ranged contamination risks of high-powered devices, *e.g.* ultrasonic scaling, piezosurgery, to be high [7], ultrasound-aided resorbable plate (USaRP) system has become popular and may better suit young patients with simple (2-fragmented and non-comminuted), non-displaced fractures.

This study's purposes were to evaluate inanimate surface contamination of SARS-CoV-2 during midfacial fracture repair (MFR) in asymptomatic COVID-19 patients, and to identify relevant aggregating factors. Our primary null hypothesis discarded differences in viral spread between conventional titanium plate (cTiP) and USaRP systems. The specific aims were to (1) conduct a prospective non-randomised comparative study (OCEBM's LoE 2b/Therapy, Prevention, Aetiology, Harm), (2) compare viral spread on 4 different surfaces after using osteofixation, (3) determine factors precipitating viral dissemination, and (4) append clinical evidence to the abovementioned AO CMF's LoE 5 recommendations.

2. Materials and methods

2.1. Study design and sample description

The sample of this prospective non-randomised study derived from a cohort of asymptomatic COVID-19 patients with MFR on an emergency/urgency basis, *e.g.* retrobulbar haematoma, or as a part of polytrauma surgery. Patients were included if they (1) aged ≥ 18, (2) were SARS-CoV-2-positive confirmed twice by a rapid antigen test and a nucleic acid amplification test (NAAT) using real-time reverse transcription polymerase chain reaction (RT-PCR) [3,8], (3) had asymptomatic COVID-19, and 4) underwent MFR with cTiP or USaRPa performed by the first author (P.P.) during a one-year interval. Exclusion criteria were subjects with (1) multiple craniofacial fractures, (2) reconstruction using both osteofixation systems, and (3) incomplete documentation.

Institutional board approval was granted for this work. The World Medical Association's Declaration of Helsinki, the TREND (Transparent Reporting of Evaluations with Nonrandomized Designs) protocol, and the aforementioned AO CMF recommendations were followed throughout the study. Patients gave consent for study participation and for the use of their anonymous data in future research.

2.2. Study variables

The primary predictor variable was osteofixation (CTiP, 0.6 mm-thick LevelOne® Midface Ti implant *vs.* USaRP, 0.6 mm-thick SonicWeld®; both by KLS Martin, Tuttlingen, Germany). The osteofixation selection depends on clinical-anatomical factors: USaRP for simple, non-displaced fractures, especially in young patients.

Because of no negative-pressure operating room (OR) available, video laryngoscopy was used to better visualise the vocal cords, and subsequently, reduce the risk of exposure to aerosols generated during intubation [9]. The surgical team entered the OR 10–15 min after intubation ended [1–3]. To reduce intraoperative viral load, the oral cavity was cleaned with 10% povidone iodine solution (Betaisodona Lösung™, Mundipharma GmbH, Frankfurt/Main, Germany), or 0.1% octenidine dihydrochloride solution (Octenisept™, Schülke & Mayr GmbH, Norderstedt, Germany) if iodine-allergic, after throat packing [1,3].

Owning to low morbidity/mortality rates in asymptomatic SARS-CoV-2-positive patients, we used the standard surgical techniques, *i. e.* an intraoral Le Fort I approach for midfacial ORIF [10], a transconjunctival approach [11] or the *Meningaud* and *Pital-Arnnop*'s endoscope-assisted retrocaruncular approach [12,13] for orbital wall fracture repair with 0.25-/0.5-thick non-porous PDS® sheets (Johnson&Johnson Medical GmBH Ethicon, Norderstedt, Germany) with/without orbital rim or nasoorbitoethmoidal fracture (NOEF) osteofixation. The zygoma was re-anatomised by a Stromeyer's zygomatic hook via a 2-to-3-mm transdermal incision. The orbital incisions were left unsutured. All OR staff donned standard personal protective equipments (PPEs), *i.e.* water-resistant surgical gown, gloves, eye protection or face shield, hair cap, leg covering, and N99 masque without exhalation value (FFP 3 Nobaprotect®, Nobamed Paul Danz AG, Wetter, Germany) [1].

The outcome of interest was the presence or absence of SARS-CoV-2 on four different surfaces: 1) patient's drape or table at 1, 1.5, 2, 2.5, and 3 m from the operating field, 2) tip of Langenbeck retractors used intraorally, 3) tip of orbital retractors, and 4) single-use plastic lamp-handle covering. Viral RNA was extracted from swabbed surfaces, using CopanFLOQSwabs™ flocked swabs without medium (Mast Diagnostica GmbH, Reinfeld, Germany), and treated with real-time RT-PCR targeting RNA-dependant RNA polymerase and E genes. Virus isolation from positive samples was attempted *in vitro* on Vero E6 cells [14]. The swabbed surfaces were treated cautiously, *e.g.* adequate post-intubation interval before the surgical team and instruments entered the OR, no contact with contaminated gloves until the surfaces were swabbed.

Other study variables were classified into 3 groups: (1) demographic – age (as a continuous scale, and dichotomised by the median) and gender (female/male), (2) anatomical – fracture side (left/right), displacement (yes/no) and location (centrolateral [*i.e.* Le Fort I/ II with zygomatic complex fracture, ZMCF] *vs.* other [ZMCF, or NOEF only]) and (3) operative time from incision making to complete would closure (≤ *vs.* > 45 min). The cut-off value of 45 min was used because the operator (P.P.) spends *ca.* 30–45 min on simple, non-displaced MFR (unpublished data).

2.3. Data collection and analysis

Data were iteratively recorded over the course of the study and analysed using the biomedical statistic software MedCalc™ (MedCalc Software Ltd., Ostend, Belgium). Descriptive statistics and non-parametric bi- and multivariate statistics were computed as appropriate. We reported *P*-values, adjusted matched odds ratios ($OR_{adj.}$) and associated 95% confidence intervals (CIs). All statistical tests were 2-sided using a standard alpha of 0.05. *Post hoc* power analyses were performed by using a validated software package (G Power 3 for Windows, Düsseldorf, Germany) for a two-tailed *t*-Test study with an effect size of 0.5, α error probability of 0.05, and a sample size of 11.

3. Results

We included 11 asymptomatic COVID-19 patients undergoing MFR (27.3% females, 63.6% right side, 72.7% displaced fractures) with a mean age of 52.7 ± 20.1 years (range, 19–85). No otherwise eligible patients were excluded. Five patients had lateral midfacial fractures (ZMCF with orbital floor fracture) only, 5 other suffered from centrolateral fractures (Le Fort and/or NOEF with lateral midfacial fractures), and the other received ORIF for a *Markowitz* and *Manson*'s type I NOEF.

The average viral spread was 1.9 ± 0.4 m. from the operative field and indifferent between both osteofixation systems. Most intraoral and orbital retractors (81.8% and 72.7%) were contaminated, while no contamination was found at 3 m. After binary adjustments, in the event of displaced MFR > 45 min, SARS-CoV-2 detection may be as far as 2.2 ± 0.3 m. from the operative field ($P = 0.053$ when compared to non-displaced MFR with operation time ≤ 45 min, 1.5 ± 0.3 m.; $P = 0.022$; 95% CI, 0.1 to 1.03 when compared to no contamination or contamination on 1–2 surfaces: 1.6 ± 0.4 m.). Moreover, centrolateral MFR caused farer contamination than central/lateral MFR ($P = 0.034$; 95% CI, 0.05 to 1.02) (*Tables 1 and 2*). Multivariate analyses excluded differences between both osteofixation systems after adjusting other study variables (*Table 3*).

Table 1
Cohort characteristics grouped by osteofixation types.

Parameters	Overall	Conventional Titanium plates	Ultrasound-aided resorbable plates	P value ($OR_{adj.}$; 95% CI)
Demographic				
Sample size	11 (100)	7 (63.6)	4 (36.4)	N/A
Average age at MFR	52.7 ± 20.1	62.6 ± 18.1	35.5 ± 17.5	**0.039 (N/A; 1.67 to 52.47)**
Age at MFR ≥ 56 years[§]	6 (54.5)	5 (83.3)	1 (20)	0.24 (7.5; 0.46 to 122.7)
Female gender	3 (27.3)	2 (66.7)	1 (33.3)	1.0 (1.2; 0.07 to 19.63)
Clinical				
Right side	7 (63.6)	5 (71.4)	2 (28.6)	0.58 (0.4; 0.03 to 5.15)
Displaced fractures	8 (72.7)	6 (75)	2 (25)	0.49 (6; 0.34 to 107.42)
Centrolateral midfacial fractures	5 (45.5)	3 (60)	2 (40)	1.0 (0.75; 0.06 to 8.83)
Operative time				
> 45 Min.	6 (54.5)	5 (83.3)	1 (16.7)	0.24 (7.5; 0.46 to 122.7)
Outcome: viral presence at				
1 m.	11 (100)	7 (63.6)	4 (36.4)	1.0 (N/A)
1.5 m.	10 (90.9)	6 (60)	4 (40)	1.0 (0; 0 to NaN)
2 m.	8 (72.7)	5 (62.5)	3 (37.5)	1.0 (0.83; 0.05 to 13.63)
2.5 m	2 (18.2)	1 (50)	1 (50)	1.0 (0.5; 0.02 to 11.09)
3 m.	0	0	0	1.0 (N/A)
Average distance in m.	1.9 ± 0.4	1.9 ± 0.5	2.0 ± 0.4	0.63 (N/A; −0.79 to 0.5)
Retractor used intraorally	9 (81.8)	6 (66.7)	3 (33.3)	1.0 (2; 0.09 to 44.35)
Orbital retractor	8 (72.7)	5 (62.5)	3 (37.5)	1.0 (0.83; 0.05 to 13.63)
Lampe handle	6 (54.5)	4 (66.7)	2 (33.3)	1.0 (1.33; 0.11 to 15.7)

Note: § – median; MFR – midfacial fracture repair; $OR_{adj.}$ – adjusted odd ratio; 95% CI 95% – confidence interval; N/A – not applicable. Continuous data are listed as mean ± SD. Categorical data are presented as number (percentage). Statistically significant P-values are indicated in **bold** typeface.

The patients were kept isolated postoperatively. No health care provider contacting with patients in this cohort developed a COVID-19 infection, or was tested positive for SARS-CoV-2, until 2 weeks following the surgery.

Overall, our findings supplementing/modifying the AO CMF's LoE 5 recommendations [2] are presented in *Table 4*.

4. Discussion

This study highlights inanimate surface contamination of SAR-CoV-2 after MFR in asymptomatic COVID-19 patients. Apart from patients' ages between 2 osteofixation groups, most bi- and multivariate analyses could not refute the null hypotheses. Two exceptions requiring particular attention are the highly remote spread of SAR-CoV-2 during displaced MFR > 45 min and centrolateral MFR. Anyhow, the distance of 3 m away from the operative field was a safe zone for anaesthetists and other personals such as circulating nurses, as well as, for anaesthetic machines and other OR materials. To answer our 4th specific aim, the comparison of the AO CMF recommendations with our findings and other previously published data was intensively performed and is presented in *Table 4*.

At the early pandemic stage, 29% of healthcare workers involving in head and neck ORs had the nosocomial SARS-CoV-2 infection [1]. The transmission risk is assumedly increased because cervicofacial mucosa and/or the airway contain high viral loads in the upper aerodigestive tract [15–17]. A Brazilian series showed an infection rate of 75% (15 of 20) amongst front-line CMF surgeons during April and June 2020, and the "post-COVID-19 syndrome" or "long COVID" persisted up to 5 months [18]. Experimental data, however, discarded the spread risk during several head and neck procedures, such as tracheostomy [16], craniotomy/craniostomy [9], nasogastric tube insertion, swallowing testing in dysphagia patients (including endoscopy and fluoroscopy), upper airway suctioning, endoscopic sinus surgery (ESS), cautery, and nasendoscopy [19], if standard PPEs are used. Moreover, some techniques, *e.g.* use of two high-powered suctions with/without barrier [20,21] (at least one suction should be *ca.* 3 cm from the operating field) [20], and the OR's ventilation system with laminar air flow (LAF; a low-turbulence, vertical air flow directed from the ceiling to the floor) [17], could reduce viral spread. Another *in vitro* study revealed that microdebridement of nasal polyps at a specific irrigation rate and suction pressure did not intensively produce droplets or splatter, *e.g.* 2,000 rpm oscillation mode with irrigation 5–20 mL/min and suction pressure 100–240 mmHg, or with irrigation 25 mL/min and suction pressure 200–240 mmHg; or 6,000 rpm oscillation mode with irrigation 25 mL/min and suction pressure 100–240 mmHg In contrast, high-speed drill and/or irrigation rates, *e.g.* 12,000 rpm high-speed drill with a diamond bur and irrigation 25 mL/min; or 2000–6,000 rpm oscillation mode with irrigation 40 mL/min, caused contamination, regardless of the suction pressure [22].

We used low-speed drilling with slow/minimal irrigation for our MFRs in an isolated septic OR equipped with LAF. Our findings confirm significant associations between procedural complexity (*i.e.* long surgery, complicated fractures) and remote surface contamination, and thereby, support the aforesaid recommendations that CMF procedures are septic [1–3]. Contrary to a systemic review's findings by *Innes* et al. [7], the high-powered USaRP system did not cause higher viral contamination than cTiP. Procedures with high-speed oscillation and high irrigation rates, *e.g.* orthognathic/oncologic osteotomies, without LAF could have elicited more intensive contamination.

One particular concern is viral transmission via (*peri*)orbital tissue amidst nasal and/or oral mucosa. An Argentinean ophthalmic surgical guideline (OCEBM's LoE 5) rejects huge amounts of aerosols during oculoplastic/orbital surgery, compared to those from the patient's respiratory tract, unless general anaesthesia and electrocautery are utilised [23]. However, we found that orbital retractors were a potential viral source of remote viral spread, and contamination of intraoral retractors and lamp-handle coverings (OCEBM's LoV 2b). A possible explanation is that we used bipolar electrocautery to control bleeding during oculoplastic/orbital surgery, and all MFRs were performed under general anaesthesia. This finding is consistent with those of our recent meta-narrative review [24] and other studies [25,26], which emphasised that ocular surfaces and tear are sources of SARS-CoV-2, regardless of patient's COVID-19 severity (including asymptomatic SARS-CoV-2 carriers). The virus can be transmitted to ocular surfaces through hand-eye contact and aerosols, and transfer to other body systems via nasolacrimal and/or haematogenous routes. This also stresses the fact that opinion-based guidelines may not always be evidence-based.

Some study limitations merit consideration. First, this study appears to be a "not so meaningful" negative clinical trial because of its low sample size. *Post hoc* calculation demonstrated the power of

Table 2
Bivariate analysis after binary adjustment.

Parameters	Viral presence ≥ 2 m. (*n* = 8)	*P* value ($OR_{adj.}$; 95% CI)	Average distance of viral presence in m.	*P* value ($OR_{adj.}$; 95% CI)	Viral presence on retractor used intraorally	*P* value ($OR_{adj.}$; 95% CI)	Viral presence on orbital retractor	*P* valu ($OR_{adj.}$; 95% CI)	Viral presence on lamp handle	*P* value ($OR_{adj.}$; 95% CI)
Demographic										
Age at MFR										
≥ 56 years[§] (*n* = 6)	4 (66.7)	1.0	1.75 ± 0.4	0.2	5 (83.3)	1.0	5 (83.3)	0.55	4 (66.7)	0.57
< 56 years (*n* = 5)	4 (80)	(0.5; 0.03 to 7.99)	2.1 ± 0.4	(N/A; −0.92 to 0.22)	4 (80)	(1.25; 0.06 to 26.87)	3 (60)	(3.33; 0.2 to 54.53)	2 (40)	(3; 0.25 to 35.33)
Gender										
Male (*n* = 8)	6 (75)	1.0	2.0 ± 0.4	0.28	6 (75)	N/A	6 (75)	1.0	4 (50)	1.0
Female (*n* = 3)	2 (66.7)	(1.5; 0.08 to 26.86)	1.7 ± 0.6	(N/A; −0.33 to 0.99)	3 (100)		2 (66.7)	(1.5; 0.08 to 26.86)	2 (66.7)	(0.5; 0.03 to 7.99)
Clinical										
Side										
Right (*n* = 7)	4 (57.1)	0.24	1.8 ± 0.5	0.23	6 (85.7)	1.0	5 (71.4)	1.0	4 (57.1)	1.0
Left (*n* = 4)	4 (100)	(0; 0 to Nan)	2.1 ± 0.3	(N/A; −0.94 to 0.26)	3 (75)	(2; 0.09 to 44.35)	3 (75)	(0.83; 0.05 to 13.63)	2 (50)	(1.33; 0.11 to 15.7)
Displaced fractures										
Yes (*n* = 8)	7 (87.5)	0.15	2.1 ± 0.3	**0.0504**	7 (87.5)	0.49	7 (87.5)	0.15	6 (66.7)	0.061
No (*n* = 3)	1 (33.3)	(14; 0.58 to 338.78)	1.5 ± 0.5	**(N/A; −0.001 to 1.13)**	2 (66.7)	(3.5; 0.14 to 84.69)	1 (33.3)	(14; 0.58 to 338.78)	0	(∞; NaN to ∞)
Centrolateral midfacial fractures										
Yes (*n* = 5)	5 (100)	0.18	2.2 ± 0.3	**0.034**	5 (100)	0.45	4 (80)	1.0	4 (80)	0.24
No (*n* = 6)	3 (50)	(∞; NaN to ∞)	1.7 ± 0.4	**(N/A; 0.05 to 1.02)**	4 (66.7)	(∞; NaN to ∞)	4 (66.7)	(2; 0.13 to 31.98)	2 (33.3)	(8; 0.5 to 127.9)
Operative time										
≤ 45 Min. (*n* = 5)	3 (60)	0.55	1.7 ± 0.4	0.16	4 (80)	1.0	2 (40)	0.06	1 (20)	0.08
> 45 Min (*n* = 6)	5 (83.3)	(0.3; 0.02 to 4.91)	2.1 ± 0.4	(N/A; −0.18 to 0.94)	5 (83.3)	(0.8; 0.04 to 17.2)	6 (100)	(0; 0 to NaN)	5 (83.3)	(0.05; 0 to 1.07)

Note: § – median; MFR – midfacial fracture repair; $OR_{adj.}$ – adjusted odd ratio; 95% CI 95% – confidence interval; N/A – not applicable; NaN – not a number. Continuous data are listed as mean ± SD. Categorical data are presented as number (percentage). Statistically significant *P*-values are indicated in **bold** typeface.

Table 3
Multivariate analysis of study variables *versus* osteofixation systems on different surfaces.

Viral presence at	Age ≥ 56 years[§] (*n* = 6)	*P* value ($OR_{adj.}$; 95% CI)	Male gender (*n* = 8)	*P* value ($OR_{adj.}$; 95% CI)	Right side (*n* = 7)	*P* value ($OR_{adj.}$; 95% CI)	Displaced fractures (*n* = 8)	*P* value ($OR_{adj.}$; 95% CI)	Centrolateral midfacial fractures (*n* = 5)	*P* value ($OR_{adj.}$; 95% CI)	Operation > 45 min. (*n* = 6)	*P* value ($OR_{adj.}$; 95% CI)
≥ 2 m.												
Ti-plates (*n* = 5)	3 (60)	1.0	4 (80)	1.0	3 (60)	1.0	5 (100)	0.38	3 (60)	1.0	4 (80)	0.46
US-aided resorbable plates (*n* = 3)	1 (33.3)	(3; 0.15 to 59.89)	2 (66.7)	(2; 0.08 to 51.59)	1 (33.3)	(3; 0.15 to 59.89)	2 (66.7)	(∞; NaN to ∞)	2 (66.7)	(0.75; 0.04 to 14.97)	1 (33.3)	(8; 0.31 to 206.37)
Average distance in m.												
Ti-plates	1.7 ± 0.4 (*n* = 5)	N/A	2.0 ± 0.4 (*n* = 5)	1.0 (N/A;	1.8 ± 0.6 (*n* = 5)	0.92 (N/A;	2.0 ± 0.3 (*n* = 6)	0.38 (N/A;	2.2 ± 0.3 (*n* = 3)	0.79 (N/A;	2.0 ± 0.4 (*n* = 5)	N/A
US-aided resorbable plates	2 (*n* = 1)		2.0 ± 0.5 (*n* = 3)	−0.73 to 0.73)	1.75 ± 0.4 (*n* = 2)	−1.1 to 1.2)	2.25 ± 0.4 (*n* = 2)	−0.89 to 0.39)	2.25 ± 0.4 (*n* = 2)	−0.99 to 0.82)	2.5 (*n* = 1)	
Retractor used intraorally												
Ti-plates (*n* = 6)	4 (66.7)	0.52	4 (66.7)	1.0	4 (66.7)	0.52	5 (83.3)	1.0	3 (50)	1.0	4 (66.7)	0.52
US-aided resorbable plates (*n* = 3)	1 (33.3)	(4; 0.21 to 75.66)	2 (66.7)	(1; 0.05 to 18.91)	1 (33.3)	(4; 0.21 to 75.66)	2 (66.7)	(2.5; 0.1 to 62.6)	2 (66.7)	(0.5; 0.03 to 8.95)	1 (33.3)	(4; 0.21 to 75.66)
Orbital retractor												
Ti-plates (*n* = 5)	4 (80)	0.46	4 (80)	1.0	4 (80)	0.46	5 (100)	0.38	2 (40)	1.0	5 (100)	0.11
US-aided resorbable plates (*n* = 3)	1 (33.3)	(8; 0.31 to 206.37)	2 (66.7)	(2; 0.08 to 51.59)	1 (33.3)	(8; 0.31 to 206.37)	2 (66.7)	(∞; NaN to ∞)	2 (66.7)	(0.33; 0.02 to 6.65)	1 (33.3)	(∞; NaN to ∞)
Lampe handle												
Ti-plates (*n* = 4)	3 (75)	1.0	3 (75)	1.0	3 (75)	1.0	4 (100)	1.0	2 (50)	0.47	4 (100)	0.33
US-aided resorbable plates (*n* = 2)	1 (50)	(3; 0.08 to 107.45)	1 (50)	(3; 0.08 to 107.45)	1 (50)	(3; 0.08 to 107.45)	2 (100)	(NaN; NaN to NaN)	2 (100)	(0; 0 to NaN)	1 (50)	(∞; NaN to ∞)

Note: Ti – conventional Titanium plate system; US – ultrasound.
§ – median; $OR_{adj.}$ – adjusted odd ratio; 95% CI 95% – confidence interval; N/A – not applicable; NaN – not a number. Continuous data are listed as mean ± SD. Categorical data are presented as number (percentage). Statistically significant *P*-values are indicated in **bold** typeface.

Table 4
Summary of the 2021 AO CMF recommendation [2] regarding midfacial repair (MFR), our findings, and relevant literature [9,16,19,24,32−39].

AO CMF recommendations (LoE 5)	Our findings (LoE 2b)	Relevant literature
1. Surgical procedures involving the nasal-oral mucosal regions increase the risk of infection for medical personnel due to the aerosolisation of SARS-CoV-2.	1. Ocular surface is also a potential viral source; thereby, contamination to the orbit must be treated as same as nasal-oral contact.	1.1 It has been hypothesised that ocular surface is infected via the nasolacrimal duct as the transmission route. Minimally invasive techniques for ocular/orbital surgery such as transconjunctival approach, endoscopic orbital wall repair is therefore recommended in order to minimally manipulate the globe and reduce intraoperative contamination (LoE 2a) [24]. 1.2 COVID-19 patients may suffer from acute-onset neuroophthalmic diseases such as optic neuritis, vision loss, diplopia, bulbus pain with movements. Hence, ophthalmological outcome assessment in MFR patients might be more difficult if the patients have SARS-CoV-2 (LoE 2a) [24].
2. Asymptomatic patients may be infected with SARS-CoV-2.	2. All of our patients were SARS-CoV-2-positive, but asymptomatic.	2. A German big data study (n > 1.7 million) showed that 42% of COVID-19 patients are asymptomatic. SARS-CoV-19 screening in all patients at hospital admission and/or before surgery is therefore very important (LoE 2b) [32].
3.1 Decisions should be taken locally, as factors vary by location; this includes incidence, prevalence, patient and staff risk factors, community needs, resource availability, and PPE. It is imperative to accurately determine the disease burden and curve trajectory. 3.2 During times of potentially high incidence, elective procedures and routine ambulatory visits should be cancelled, until guidance is provided by government or hospital officials, and professional organisations permitting reopening for elective clinical services.	3. If PPE and operative environment/personnel are available, MFR, especially that with emergency/urgency basis such as retrobulbar haematoma, visual change, or as a part of polytrauma surgery, can be performed. 3.2 Otherwise, it can be postponed after the COVID-19 heals (*i.e.* two negative SARS-CoV-2 tests in $a \geq$ 24-h interval are confirmed).	3. We refer interested readers to guides of facial trauma triage supposed by Hsieh et al. (LoE 5)[33] and Wunsch and Pitak-Arnnop (LoE 5) [3].
4. Intraoperative measures which limit the generation of aerosolised particles that may harbour virus are recommended.	4.1 The distance of ≥ 3 m from the operative field is a safe zone with no contamination. 4.2 We usually used electrocautery during orbital floor exploration, which could cause intensive viral contamination.	4.1 A cadaver study (n = 4) demonstrated that the contamination distance ranged from 0.15 to 1.98 m from the operative field (LoE 3b) [34]. However, data from mock surgical procedures suggested that stepping 2 m away from the operative field would *"not"* protect personnel in ORs (LoE 3b) [35]. 4.2 Concentrations of air particles were found to be greater along OR walls than at the instrument table at the centre of the OR (LoE 3b) [35]. Coupled with our results, the non-surgical OR personnel and anaesthetic machine should not only step ≥ 3 m away from the operative field, but also be far from the OR wall. Instrument containers that are not necessary for the surgery should not be slid next to the walls (*i.e.* it is better to place them outside the OR). 4.3 Aerosol dispersion is reduced if a high-powered suction and/or a smoke evacuating electrocautery hand piece are used (LOE 3b) [34]. 4.4 Robortic surgery with the surgical console outside the OR may be a useful option, if the COVID-19 pandemic remains long-persisting (LoE 3b) [35].
5. There are 3 categories of PPE: (1) *Standard PPE* is a surgical cap and masque, gloves, gown, and eye protection, (2) *Special PPE* is minimum requirement FFP2/N95 masque plus face shield or goggles (or masque with attached shield over FFP2/N95), gloves, nonporous gown, disposable surgical cap, and (3) *Enhanced PPE* is minimum requirement FFP3 masque plus face shield, gloves, nonporous gown, disposable hat. If the COVID-19 status of the patient is unknown, or cannot be determined, then *Special PPE* is strongly encouraged. It is generally accepted that *Enhanced PPE* with FFP3/N99 provide better protection and should be used in place of FFP2/N95 masks if available.	5.1 There was no SARS-CoV-2 infection amongst healthcare providers participating in patient care in this study. However, it is important to note that FFP3 was used intraoperatively, and FFP2 was used during postoperative patient visit in the cohort ward. 5.2 The patients must wear at least FFP2 during patient transport (from the ward until intubation, and from extubation back to the patient room) in order to eliminate the SARS-CoV-2 transmission risk during patient transport.	5.1 Health care providers may have undiagnosed COVID-19, and those previously infected may not have long-lasting immunity (LoE 3b) [36], emphasising the essential role of infection control practice and immunisation. 5.2 Surgical and cloth/cotton masks cannot effectively block the escape of droplets and aerosols ejected during sneezing and coughing. FFP2 masks completely prevent the particles from leaking forwards, but leakage could still occur sideways and could move up to 0.6 m backwards. Without a masque, particles from a common sneeze can be projected for approximately 0.76 m in almost 22 s (LoE 3a) [37]. Thus, COID-19 patients should wear *"at least"* FFP2 *"all the time"* they are outside their isolated patient room. 5.3 Not only direct human protection but inanimate surface is a very important reservoir of the virus. The aerosolised form of the virus can persist for up to 3 h in the air and 48 to 72 h on selected surfaces (*in vitro* study; LoE 5) [33].

(*continued*)

Table 4 (*Continued*)

AO CMF recommendations (LoE 5)	Our findings (LoE 2b)	Relevant literature
6. Based on an OR air exchange rate of 20 exchanges per hour (standard for most operating rooms), 99% of pathogens should be clear in 14 min, and 99.9% by 21 min.	6.1 Our surgical team entered the OR 10–15 min after intubation ended. The waiting time of 10–15 min after intubation appear to be adequate for clearance of air particles (*e.g.* SARS-CoV-2 or cautery). 6.2 Intubation (with video laryngoscopy) and extubation were performed in the operating room.	6.1 Increasing OR air exchange (from the single large diffuser to the multiple diffuser array, and from 20 to 26 air exchanges per hours) reduce time for air clearance (LoE 3b) [35]. 6.2 It has generally been accepted amongst anaesthetists and intensivists that the use of video laryngoscopy, preferably with an external monitoring screen, during endotracheal intubation increases the distance between the face of the intubating person and the patient's mouth, and thus enhance the protective effect on the exposed personnel (LoE 5) [38]. However, the use of video laryngoscopy could not reduce air particles generated during intubation. The waiting time for air clearance remains unchanged before non-anaesthetic staffs (*e.g.* surgeons, OR nurses) enter the OR.
7.1 Self-drilling screws for monocortical screw fixation. When drilling is required, limit or eliminate irrigation. If drilling is required, consider a battery powered low speed drill. 7.2 Consider using Carroll-Girard screw for reduction, and avoid intra-oral incision, if 2-point fixation (inferior orbital rim and zygomatic-frontal buttress) is sufficient for stabilisation.	7. Low-speed drilling with minimal irrigation, coupled with intraoral and transconjunctival approaches (2-point fixation at the inferior orbital rim and zygomaticomaxillary buttress), seems to be safe, regardless of the osteofixation methods (either titanium or ultrasound-assisted resorbable plates).	7. *In vitro* studies pointed out that several head and neck procedures, such as tracheostomy[16], craniotomy/craniostomy [9], nasogastric tube insertion, swallowing testing in dysphagia patients (including endoscopy and fluoroscopy), upper airway suctioning, endoscopic sinus surgery (ESS), cautery, and nasendoscopy[19] were not associated with an increase of transmission risk of SARS-CoV-2 (LoE 5).
8. There is neither mention of antiseptics for skin and oral-oropharyngeal tissue preparation nor recommendations on the sequence of anaesthetic-antiseptic performance.	8.1 In our study, the skin and oral cavity were cleaned with 10% povidone iodine solution (Betaisodona), or 0.1% octenidine dihydrochloride (Octenisept) if iodine-allergic, after throat packing. 8.2 Although cuffed endotracheal tubes were used in this study, throat packing could help minimise undesirable fluid accumulation over the cuff, which could cause aspiration during/after extubation. The intraoral lavage should therefore be performed after throat packing.	8.1 Many guidelines recommend preoperative chlorhexidine or povidone iodine swish and spit (LoE 5) [33]. 8.2 Consideration should be given to securing the airway with a cuffed endotracheal tube especially for the longer duration procedures and when theatre staffs are in close proximity to the upper airway. This may reduce staff exposure to any aerosols generated during the procedure (Level 3a) [39].

Note: LoE – Level of Evidence according to the UK's Oxford Centre for Evidence-Based Medicine (OCEBM); PPE – personal protective equipment; OR – operating room.

3.3% only, when considering viral presence ≥ 2 m. in each osteofixation groups (*i.e.* cTiP 71.43% *vs.* USaRP 75%, α = 0.05). Calculation using *t*-statistics and non-centrality parameters suggested the sample size requirement of 252 in each osteofixation group to eliminate the false negativity chance of the comparison on viral spread distances (*i.e.* cTiP, 1.9 ± 0.5 m. *vs.* USaRP, 2.0 ± 0.4 m.). Some analyses would therefore have been statistically significant, for example, average viral spread between displaced *vs.* non-displaced MFR (actual results: *P* = 0.0504; 95% CI, −0.001 to 1.3 [*Table 2*]; after adjustment according to the *post hoc* calculation, *i.e.* cTiP with *n* = 441 and USaRP with *n* = 252, displaced fractures with *n* = 504 and non-displaced fractures with *n* = 189: *P* = 0.0001; 95% CI, 0.54 to 0.66). If so, the study interval of 45.8 years would have been necessary. A multicentric study design can shorten the study length, but confounders, *e.g.* inter-operator and viral sampling discrepancies, would pollute the study's internal validity. Second, the study was not randomised *a priori*. The decision to use the CTiP or USaRP was anatomical-, and operator-based. Simple, non-displaced MFRs, compared to lengthy displaced MFRs, could produce fewer respiratory particles. In other words, USaRP should be used only in case of simple, non-displaced MFRs. Third, we cannot answer which respiratory particles (droplets [> 10 μm] *vs.* aerosols [1–10 μm] *vs.* fine particles [< 1 μm]) produced surface contamination in this study, and whether this surface contamination leads to disease transmission in humans. It seems highly possible that other factors such as very close and prolonged contact with respiratory secretions may play a bigger role in viral transmission [19]. Lastly, our findings raise interesting questions for future research, including CMFS procedures in symptomatic COVID-19 patients with high viral load and shredding. The role of viral loads as a driver of contagiousness has been documented in the literature. Asymptomatic SARS-CoV-2-positive cases often have lower viral load [27–30]. The larger viral load levels in critically ill patients could lead to a relative increase in the probability of transmission of 24% to 58% in household contacts, and of 15% to 39% in non-household contacts [28]. Contrary to low concentrations of serum C3 and C4, which indicate compliment activation [29], the viral load of SARS-CoV-2 in nasopharyngeal swab appears insignificant for predicting COVID-19 severity and prognosis [8,24,30], and may not be related to surface contamination. Last but not least, our study was performed before the pandemic of the Omicron (B1.1.529) variant. We cannot predict the maxillofacial operative environments in relation to this viral variant, whose transmissibility has up to now been found to be much higher than those of other variants such as Wuhan (wild type), alpha, beta, or even delta variants (WHO's data on November 28, 2021) [31].

5. Conclusions

We look at inanimate surface contamination of SARS-CoV-2 during MFR in asymptomatic COVID-19 patients. As ORIFs > 45 min of displaced or centrolateral midface fractures enhance the viral spread, non-surgical OR personnel should stay ≥ 3 m. away from the operative field. Instruments for orbital/oculoplastic surgery should be treated in the similar manner with intraoral instruments, if the patient is SARS-CoV-2-positive. Our findings confirm those of our previous publication [24] and other studies [25,26,30] that ocular surfaces are SARS-CoV-2-septic. Our previous meta-narrative review (OCEBM's LoE 2a) [24] and the present study (OCEBM's LoE 2b) provide higher LoEs than expert-opinion guidelines (OCEBM's LoE 5) [1–3] (and along with data from relevant literature [9,16,19,24,32–39], are shown in *Table 4*), as well as according to Burn et al. [4], could attract far more citations and public attention.

Declarations

Financial disclosure/funding

Nil.

Availability of data and material

Deidentified individual participant data are not available. The datasets generated and analysed during this study are available from the first author (P.P.) upon reasonable request.

Authorship disclosure

Conception and study design: P.P., N.S., C.T., P.S., J-P.M., A.N.
Acquisition of (blinded) data: P.P., N.S., C.T., P.S.
Statistical analysis and interpretation: P.P., N.S., C.T., P.S.
Drafting the work: P.P., N.S., C.T., P.S., J-P.M., A.N.
Final approval: P.P., N.S., C.T., P.S., J-P.M., A.N.

Declaration of Competing Interest

Prof. Jean-Paul Meningaud is the Immediate Past President of the European Association for Cranio-Maxillo-Facial Surgery (EACMFS). Prof. Andreas Neff is the Head of the TMJ Section of the Strasbourg Osteosynthesis Research Group (S.O.R.G) and the Immediate Past President of the European Society of TMJ Surgeons (ESTMJS), as well as has received remunerations as a design surgeon for Medartis (Basel, Switzerland) for the development of midfacial and mandibular osteosynthesis systems. All of the authors indicate full freedom of investigation and manuscript preparation without potential conflict of interest as regards this study, except Prof. Andreas Neff who has involved in LevelOne® and SonicWeld® (KLS Martin, Tuttlingen, Germany) as a part of the S.O.R.G.'s tasks.

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