
Position Paper

Contact lenses are safe: don't misuse them.

Guidance on contact lens safety for wearers and professionals

05 June 2020

Contact Lenses (CLs) are regulated medical devices in the European Union (EU)

Contact lens materials and solutions are safe. They are regulated by EU Directives and the Health Authority in each member state; generally they are also FDA approved (USA).

CLs are labelled prescription (Rx) only, so they are not available as “free-sale” or over-the-counter (OTC) devices: they must be dispensed by a qualified professional,ⁱ as stated in the EU Regulation on Medical Devices.ⁱⁱ They are generally classified in the EU market as Class IIa medical devices (≤ 30 days). Only eye care practitioners (e.g. opticians, optometrists, ophthalmologists) are licensed to dispense CLs in the EU (there are minor differences between regulations of different member States).

With professional advice, CLs can be used at any age, from newborns to the elderly. Contact lenses can be fitted for many eye and vision conditions as an alternative to eyeglasses/spectacles or refractive surgery. There are some eye conditions, for example keratoconus, where contact lenses provide superior vision correction and where they may be the only useful option.

There are approximately 120 million CL wearers globally; with around 40 million in USA and 25 million in Europe. Therefore, CLs are a high volume, widely used device. This means that if a problem occurs, such a huge number of wearers will generate a significant number of cases, even if the problem is rare. For this reason all the following steps are important: special pre-market evaluation by *manufacturers* (when required), regular eye-check by *professionals*, correct wear and use by *wearers*, post-market vigilance by *professionals*.

CLs and other methods to correct refractive errors

Refractive anomalies (or defects of the eyeⁱⁱⁱ) are common: about 60% of population need refractive correction to see well. The following can be used to correct refractive errors:

- 1) eyeglasses/spectacles,
- 2) contact lens or
- 3) refractive surgery (including laser vision correction).

Spectacles are by far the most used device, followed by CLs and then refractive surgery. No method can really “cure” any errors, instead each one *optically compensates* for the defects. Methods can be used together, e.g. spectacles and CLs; spectacles or CLs after refractive surgery.

The method of refractive correction is an individual choice determined by individual needs and preferences, lifestyle, environment, job etc. .

CLs are frequently misused

It should be obvious that the misuse of any kind of medical device, including CLs, could give rise to problems and risks. Unfortunately, CL wearers don't always manage their CLs correctly: lack of compliance with proper use of CLs is rated at 40% to 90%^{iv}. Most of the problems with CLs are caused by improper use.^v

Common misuses of CLs are:

- (1) lack of proper cleaning and disinfection,
- (2) prolonged wearing time (time the CLs stay on the eye), exceeding the advice given by manufacturers and eye care professionals,
- (3) prolonged use (length of time before discarding CLs), exceeding the advice given, e.g. reuse of daily disposable CLs.^{vi vii}

Certain conditions can expose the wearer to increased risk. Some wearers have a personal propensity to take risks, based on their lifestyle. "Approximately 99% of contact lens wearers reported at least one risk behavior ever for eye infections or inflammation"^{viii} and the most "risky wearers" are young males.^{ix x}

Useful, free advice on safe CL use is available from the *Love your lenses* campaign by UK General Optical Council.^{xi} Similar advice can be found at the American Optometric Association.^{xii}

Water and CLs

It is very important not to use any kind of water with CLs. Neither tap water nor drinking water^{xiii} are suitable for rinsing or storing CLs: this "water" can contain micro-organisms that infect the eye. If you want to swim or take a shower with CLs on, then the use of goggles is recommended to avoid water entering your eyes. You should remove CLs immediately after any contact with water. The most suitable CLs for swimming are daily disposable contact lenses, removed immediately after swimming.

Solutions for CLs

Specific solutions for CLs are necessary to look after reusable CLs. It is important to use cleaning and disinfecting solutions as directed by your eye care professional. Don't change one solution for another that seems similar, without the advice of a professional, as the active agent and formulation of "similarly named" CL solutions could be very different. Solutions are not required for daily disposable (single-use) CLs: they are discarded after use.

Correct management and periodic check of eye, vision and CLs are necessary

The wearer of CLs can enjoy the good vision that CLs allow by following some important advice:

- single-use CLs should always be discarded after use,
- always clean and disinfect reusable CLs before and after use,
- follow advice on appropriate and safe wearing time,
- ensure safe storage and handling of CLs

A CLs wearer can contribute to a safe wear by carrying out a daily check on vision, comfort, and the appearance of their eyes.

However, a do-it-yourself check by the wearer alone is not enough, as subtle initial signs of a problem may be missed. Each wearer may react differently to the use of CLs, so they must be checked regularly by professionals to ensure the best outcome: usually a yearly check is sufficient, but a professional may advise more frequent checks if necessary. Initial signs observed by a professional could prevent discomfort or problems in the future.

Each optician and/or optometrist within the EU that dispense CLs should offer post-market surveillance^{xiv} as part of the Medical Device Vigilance System. This means every CL wearer has a place to go for a regular check or if they have a problem. Contact the optician or optometrist that fitted your CLs as soon as possible or your ophthalmologist if your CLs are part of a medical therapeutic plan.

CLs on-line?

Some CLs can be purchased on-line in the EU, even it is not fully clear which limitations apply. However, if you buy CLs on-line be careful because:

1. CLs can be misbranded, not sterile or even counterfeit^{xv} or present some other problems.^{xvi}
2. Both the wearer and the CLs must be checked by a professional on a regular basis, as stated before, even if you have purchased the CLs on-line and even if you already know how to insert and remove CLs.
3. Each wearer needs to be checked for post-market events. On-line commerce is not yet clearly regulated/controlled^{xvii}. So, if you buy CLs on-line, you don't have a place to go if you experience complications.

All of CLs need the same care and professional eye-check

Cosmetic CLs (e.g. for theatrical use, fancy dress, cosplay, etc.) are no different to other CLs^{xviii}: they need to be cleaned and disinfected on a regular basis, discarded after the planned use and must be dispensed and/or fitted under the supervision of a professional.

CLs and Coronavirus/SARS-CoV-2/COVID-19 risks

During 2020 the World Health Organization (WHO) declared the COVID-19 pandemic.^{xix} In many countries the service provided by opticians and optometrists is classed as a necessity. No specific contraindications to CL wear or spectacles in relation to COVID-19 have been given by either the EU or National Authorities thus far. Scientific evidence sources suggest that wearing CLs does not affect the risk profile of a wearer, provided the correct procedures on handling, cleaning and disinfection are strictly followed: "there is currently no evidence that [the wearers] are at any higher risk of developing COVID-19 infection than non-wearers."^{xx}

However, the widely accepted advice is that CLs should not be worn if the person is sick.^{xxi}

Professionals are conscious of many factors about the wearing of CLs and SARS-CoV-2 virus emergency:

- 1) Eyes contribute to the spread of virus because hands touch many surfaces and can pick up viruses. Once contaminated, hands can transfer the virus to your eyes, nose or mouth^{xxii} highlighting the risk of contaminated hands.
- 2) It has been suggested (without scientific data) that wearers probably touch their eyes more frequently when wearing CLs^{xxiii} and therefore it is particularly important to follow proper care when wearing CLs.^{xxiv}
- 3) Hand hygiene is a critical issue: a CLswearer must wash and dry hands prior to touching any CL, both in standard care and in an emergency setting.

- 4) CL wearers can have a tendency to not be fully compliant and skip necessary hygiene steps.^{xxv}
- 5) Wearers who buy CLs on-line (without professional control) are 3.8 times more likely to forget their aftercare schedule.^{xxvi}
- 6) The “ocular transmission of COVID-19 is uncertain”, given no SARS-CoV-2 virus detected in tears, “suggesting a low risk of ocular transmission.”^{xxvii} Another paper considers that there could be a chance that the virus could be detected in tears and conjunctival secretions,^{xxviii} and single case-reports claim caution.^{xxix}
- 7) Hydrogen Peroxide disinfecting solutions are also effective against viruses^{xxx} and preparations take effect in minutes on SARS-CoV-2 virus.^{xxxi}
- 8) Other useful factors to consider: despite anecdotal reports, conjunctival congestion seems rare,^{xxxii} nevertheless a “first case” of keratoconjunctivitis (associated with respiratory symptoms) has linked to COVID-19.^{xxxiii}

All factors taken in consideration, professionals could consider switching CL wearers to disposable/single-use CLs in planned replacement (monthly), or suspend CLs extended wear,^{xxxiv} or switch wearers to spectacles, on the base of specific condition and needs of the wearer.

However, many wearers use CLs as their preferred refractive correction and/or must use CLs in their work setting and/or CLs is the only device for their vision problem.

The situation with regard to COVID-19 is fluid and dynamic and must be continuously monitored. On this topic, optical and optometric centers have specific needs,^{xxxv} and show some analogies to pharmacies.^{xxxvi xxxvii} The Centers of Disease Control are continually providing updated advices.^{xxxviii xxxix}

ECOO Professional Services Committee – 2019-2020

Coordinator: Anto Rossetti, OD (SOPTI, ITA)

Acknowledgments: Sylwia Kropacz-Sobkowiak, Cindy Tromans, Ann Blackmore

An ECOO position paper on side effects of CLs (by prof. Judith Morris) is also available.

References and notes

ⁱ ...“any person authorized by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.”

ⁱⁱ Regulation (Eu) 2017/745 Of The European Parliament And Of The Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

ⁱⁱⁱ Myopia or shortsightedness, hyperopia or nearsightedness and astigmatism are properly call ametropias and influence both far and near vision. Another defect is presbyopia, it's an aspect of age physiology and influence near vision only.

^{iv} Cope J et al. Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections — United States, 2014. August 21, 2015 / 64(32);865-870. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a2.htm>

^v FDA. Contact Lens Risks. <https://www.fda.gov/medical-devices/contact-lenses/contact-lens-risks>, accessed 08-2019.

^{vi} FDA. Contact Lens Risks. <https://www.fda.gov/medical-devices/contact-lenses/contact-lens-risks>, accessed 08-2019.

^{vii} CDC (USA). Data Behind Contact Lens Wear and Care Recommendations. <https://www.cdc.gov/contactlenses/show-me-the-science.html>

-
- viii Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections — United States, 2014. Centers for Disease Control and Prevention CDC USA. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a2.htm>
- ix Nicole Carnt, Lisa Keay, Mark Willcox, Vicki Evans, Fiona Stapleton. Higher risk taking propensity of contact lens wearers is associated with less compliance. *Contact Lens & Anterior Eye* 34 (2011) 202–206.
- x Chalmers RL1, Keay L, Long B, Bergenske P, Giles T, Bullimore MA. Risk factors for contact lens complications in US clinical practices. *Optom Vis Sci.* 2010 Oct;87(10):725-35. doi: 10.1097/OPX.0b013e3181f31f68.
- xi General Optical Council GOC. Love your lenses, 2016. <http://www.loveyourlenses.com>
- xii American Optometric Association. Lens Care. <https://www.aoa.org/patients-and-public/caring-for-your-vision/contact-lenses/lens-care>. Accessed 11-2019
- xiii Rebecca L. Penland, Kirk R. Wilhelmus. Microbiologic Analysis of Bottled Water, Is It Safe for Use with Contact Lenses? *Ophthalmology* 1999;106:1500–1503
- xiv Zaki M et al. A review of international medical device regulations: Contact lenses and lens care solutions. *Contact Lens and Anterior Eye Volume 42, Issue 2*, April 2019, Pages 136-146. <https://doi.org/10.1016/j.clae.2018.11.001>
- xv This episode of Fake Britain BBC highlight the problem: <https://www.bbc.co.uk/iplayer/episode/m0007lqv/fake-britain-series-9-30minute-versions-episode-5>
- xvi FDA. Contact Lens Risks. <https://www.fda.gov/medical-devices/contact-lenses/contact-lens-risks>, Retrived 08-2019.
- xvii This could be fine for general products, but could be risky for CLs or other medical devices whose quality cannot be checked by wearer.
- xviii Contact Lens Risks. <https://www.fda.gov/medical-devices/contact-lenses/contact-lens-risks>, Retrived 08-2019.
- xix World Health Organization. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
- xx Jones L, Walsh K, Willcox M, Morgan P, Nichols J, The COVID-19 pandemic: Important considerations for contact lens practitioners, *Contact Lens and Anterior Eye* (2020), doi: <https://doi.org/10.1016/j.clae.2020.03.012>
- xxi American Optometric Association. Contact lens wear during COVID-19. <https://www.aoa.org/contact-lens-wear-during-covid-19> Retrived 31 March 2020.
- xxii World Health Organization. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>. Retrived 31 March 2020.
- xxiii Reena Mukamal (Reviewer Sonal S Tuli). (2020). Coronavirus Eye Safety. American Academy of Ophthalmology. <https://www.aao.org/eye-health/tips-prevention/coronavirus-covid19-eye-infection-pinkeye> Retrived 31 March 2020.
- xxiv David Turbert (Reviewer James M Huffman). (2020). Prevent Infection With Proper Contact Lens Care. <https://www.aao.org/eye-health/diseases/prevent-infection-with-proper-contact-lens-care> Retrived 31 March 2020.
- xxv Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections — United States, 2014. Centers for Disease Control and Prevention CDC USA. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a2.htm>
- xxvi Wu Y, Carnt N, Stapleton F. Contact lens user profile, attitudes and level of compliance to lens care. *Contact Lens & Anterior Eye* 33 (2010) 183–188 doi:10.1016/j.clae.2010.02.002
- xxvii Yu Jun IS, Anderson DE, Zheng Kang AE, Wang L-F, Rao P, Young BE, Lye DC, Agrawal R. Assessing Viral Shedding and Infectivity of Tears in Coronavirus Disease 2019 (COVID-19) Patients, *Ophthalmology* (2020), doi: <https://doi.org/10.1016/j.ophtha.2020.03.026>.
- xxviii Xia, J, Tong, J, Liu, M, Shen, Y, Guo, D. Evaluation of coronavirus in tears and conjunctival secretions of patients with SARS-CoV-2 infection. *J Med Virol.* 2020; 1– 6. <https://doi.org/10.1002/jmv.25725>
- xxix Colavita F, Lapa D, Carletti F, et al. SARS-CoV-2 Isolation From Ocular Secretions of a Patient With COVID-19 in Italy With Prolonged Viral RNA Detection. *Ann Intern Med.* 2020; [Epub ahead of print 17 April 2020]. doi: <https://doi.org/10.7326/M20-1176>
- xxx CDC. Chemical Disinfectants. Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html>
- xxxi EPA. List N: Disinfectants for Use Against SARS-CoV-2. <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2> Retrived 31 March 2020.
- xxxii Guan, W et al. Clinical Characteristics of Coronavirus Disease 2019 in China. *New England Journal of Medicine* DOI: 10.1056/NEJMoa2002032 <https://www.nejm.org/doi/full/10.1056/NEJMoa2002032>
- xxxiii Cheema M. et al. Keratoconjunctivitis as the initial medical presentation of the novel coronavirus disease 2019 (COVID-19): A case report. *Canadian Journal of Ophthalmology.* <https://doi.org/10.1016/j.cjco.2020.03.003>
- xxxiv Jones L, Walsh K, Willcox M, Morgan P, Nichols J. The COVID-19 pandemic: Important considerations for contact lens practitioners, *Contact Lens and Anterior Eye* (2020), doi: <https://doi.org/10.1016/j.clae.2020.03.012>
- xxxv Zeri F, Naroo SA. Contact lens practice in the time of COVID-19. *Cont Lens Anterior Eye.* 2020 Mar 19. pii: S1367-0484(20)30050-3. doi: 10.1016/j.clae.2020.03.007. [Epub ahead of print].

^{xxxvi} NHS England and NHS Improvement coronavirus. Novel coronavirus (COVID-19) standard operating procedure. <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-community-pharmacy/> Retrieved 7 April 2020.

^{xxxvii} Considerations for Pharmacies during the COVID-19 Pandemic. <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-resources/pharmacies.html> Retrieved 7 April 2020.

^{xxxviii} Centers for Disease Control and Prevention. For Healthcare Professionals. <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html> Retrieved 2 April 2020.

^{xxxix} European Centre for Disease Prevention and Control. Factsheet for health professionals on Coronaviruses. <https://www.ecdc.europa.eu/en/factsheet-health-professionals-coronaviruses> Retrieved 2 April 2020.