

CED Position

“DIRECT TO CONSUMER ORTHODONTICS”, ARTIFICIAL INTELLIGENCE (AI) AND DENTISTRY

November 2023

Introduction:

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dentists across Europe. The association was established in 1961 and is now composed of 33 national dental associations from 31 European countries. The CED's core mission is to promote the interests of the dental profession in the EU.

With this paper, the CED would like to outline its main concerns and recommendations in relation to “do it yourself” / “direct to consumer” (DIY/DTC) dentistry, and in particular DIY/DTC orthodontics, and the consequences that Artificial Intelligence (AI) may have in this area in the near future. The document was produced because there is an increased marketing of DIY/DTC orthodontics, potentially placing patients at risk since the procedure does not involve a comprehensive orthodontic diagnosis and treatment progress is not adequately supervised by a qualified dentist and/or specialist orthodontist. This is becoming an issue of concern in different countries and also interplays with the ongoing developments in EU legislation on eHealth and AI.

The dental profession wishes to highlight that it is imperative to push for further action to prevent future issues of endangering patient health but also of liability of dentists. Furthermore, there are a lot of variations and discrepancies in how this issue is handled at a Member State (MS) level. While handling this issue must be tailored to each country's individual circumstances, it is crucial that a dentist and/or specialist orthodontist must always be involved in the process.

DTC Orthodontics: Overview

The orthodontic discipline: Before beginning orthodontic treatment, a comprehensive in-office clinical examination by a qualified dentist and/or specialist orthodontist is considered the minimum acceptable standard to assess orthodontic needs. This is the basis for formulating a treatment plan and for completing the appropriate treatment. Such examination encompasses diagnostic imaging with radiographs, impressions or occlusion scan and photographs. It provides the opportunity to evaluate the health and position of the teeth, jaws, temporomandibular joints, periodontal tissues, and their functioning together. Through this examination process, a personalised treatment plan is developed based on health and aesthetics alike¹.

It is imperative to note that a qualified dentist has the training to identify any issues occurring during treatment and to implement the necessary changes for a successful treatment outcome. Such training includes expertise regarding growth and age-related developmental factors. This allows for providing patients with a healthy, beautiful smile while also avoiding any potential unintended harmful consequences that can result from DIY/DTC treatment.² It is important to note that a failed treatment through a DIY/DTC process may have potential repercussions through teeth loss, difficulty eating, loss of self-esteem, neuromuscular disorders, depression.

DIY/DTC approach: DIY/DTC orthodontics entails fabrication of orthodontic appliances (mainly aligners) with no personal contact with a qualified dental professional. There is

¹ Description taken from and based on the World Federation of Orthodontists (WFO) *Statement on Do-It-Yourself (DIY) and Direct-to-Consumer (DTC) Orthodontics*, <https://www.wfo.org/news-gazettes/2023/8/2/a-statement-on-do-it-yourself-diy-and-direct-to-consumer-dtc-orthodontics/>

² Ibid.

commonly no clinical examination and no radiographic examination; dental impressions are taken either by the patients themselves or at a company outlet, by dental auxiliaries at best. Although most companies assert that a dentist oversees the treatment plan and treatment progress, the patient never meets the dentist in person. Communication between patient and dentist is only on patient request, and then by text messages. Noteworthy is the fact that some companies may request the patient to sign a non-disclosure agreement (NDA), thus limiting publication of potentially negative comments and reports.

The recent significant advances in AI may exacerbate the problem in the near future. AI applications that allow faster and less expensive turnaround for the companies, may lower prices and make DTC orthodontics more affordable to the public. On the other hand, AI, if implemented prudently, could increase diagnostic quality and enhance treatment results. AI in the hands of qualified dentist and/or specialist orthodontist could allow them to be more competitive and claim a larger market share from DTC companies.

The CED's overall concern on this topic focuses on the potential lack of involvement of dentists and/or specialist orthodontists in the process but also ensuing issues of liability – namely, the possibility for a dentist to be liable even though they were bypassed or not fully involved in a DIY/DTC orthodontics process. When a patient visits a dental practice following a problematic/failed DIY/DTC process, dentists and/or specialist orthodontists are placed in a precarious situation, both ethically and legally, in terms of any remedial steps required.

Furthermore, it is important to note that this lack of involvement from a dentist and/or specialist orthodontist would ultimately and most importantly lead to endangering patient dental health (mainly periodontal and TMJ (temporomandibular) health). In light of this, it is imperative not to commercialise orthodontics, therefore turning them into a type of consumer service rather than a dental treatment.

Main recommendations:

- **It is imperative that this process remains within the field of dentistry, performed either by a dentist and/or a specialist orthodontist;** a full clinical examination by a qualified dentist/specialist orthodontist is necessary to assess whether orthodontic treatment is in the best interest of an individual and that orthodontic treatment is truly needed; the patient cannot be solely responsible for this process. The DIY/DTC companies should not be allowed to provide such treatment without the direct involvement of a qualified dentist and/or specialist orthodontist across all relevant steps of the diagnostic and treatment process. Otherwise, it is unclear what safeguards are in place for those patients who may seek this form of treatment if there is no direct contact and clinical examination of the patient's mouth and assessment of their dental health by a dentist.
- **Patient safety must be top priority** – dental health must not be treated as a commercial, “conveyor belt” activity without involvement of an actual dentist. This is important because no one can assess the health of a patient's mouth by viewing photographs that are taken on a phone or using a dedicated camera. As such, all orthodontic procedures must originate from a comprehensive examination including a clinical assessment, a qualified diagnosis and dentists must be engaged in the step-by-step supervision of the orthodontic treatment.

- **The role of the dentist as the leader in providing dental care and deciding on treatment and diagnosis must be respected:** other technologies or professionals can assist dentists but cannot replace them. The advent of 3D scans imaging (digital impressions) on patients who have not seen a dentist means that the process constitutes a “grey area” in terms of the clinical tasks that are within the scope of practice of people who are not supervised by dentists. A failed treatment combined with the lack of responsibility from the DIY/DTC service providers could have irreversible consequences for the health of the patient.
- **When care is provided by a dentist and/or specialist orthodontist there is no doubt that if there is a problem with the care, the treating dentist is responsible for their patient** in relation to the regulatory and legal system. As the DIY/DTC system does not involve direct treatment by a dentist, it is unclear who is clinically responsible for the treatment. In case of overtreatment or malpractice the insurance premiums will rise exponentially and the patient may not be able to access financial support for a clinical negligence claim.
- **A similar principle is followed with patients: they must be engaged and guided to give informed consent to treatment by their dentist and/or specialist orthodontist,** so that risks, benefits and options for care are fully explained. Otherwise, when care is provided with limited protection of the public in the absence of a health care professional an important ethical issue is raised.
- Initiatives that increase access to dental care are welcomed. However, **if these initiatives involve reducing the direct input of adequately trained healthcare practitioners, then the price to pay for increased access may be greater risk and limited protection for the public and the patient.**
- **It is imperative that illegal practice of DIY/DTC orthodontics is proactively challenged as illegal and monitored and acted upon:** the relevant national authorities must intervene whenever the engagement of the dental profession is bypassed.
- Finally, it is important to note that **all dentists should be aware of their ethical responsibilities and should refrain from working with DIY/DTC orthodontics companies where they do not have overall responsibility for the treatment and ongoing care of the patient.**

Adopted at the CED General Meeting in November 2023

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