

A growing rise in the use of cheap alternative clear aligners has raised concerns among dentists and orthodontists. **Cameron Cooper** reports

Not all smiles

Just as Uber has disrupted the taxi industry and Airbnb has shaken up the accommodation sector, providers of direct-to-consumer clear aligners are taking on traditional teeth-straightening treatments.

Providers such as SmileDirectClub, EZ Smile and WonderSmile are promoting their alternative models as a more affordable and convenient choice than orthodontist-supervised options such as Invisalign. The trend has alarmed many dentists and orthodontists, who fear a rise in dental problems such as gum recession and tooth loss because of potentially poorly fitted and inadequately monitored DTC aligners.

Dr Marcus Tod, a specialist orthodontist with extensive clear-aligner experience at Ethos Orthodontics in Brisbane, notes that with DTC aligners people typically get a 3D scan or an impression kit to make moulds of their teeth from home. He is concerned about the absence of in-person physical assessments using diagnostic radiographs of patients before treatments begin, as well as a lack of ongoing in-clinic supervision from a specialist dentist or orthodontist. "Moving teeth is a complex medical procedure," he says. "They are not looking at radiographs or examining the patient, so no-one is actually verifying the health of the teeth."

Teleorthodontic platform

SmileDirectClub, a teledentistry company based in the United States, states that it has successfully served more than 1.5 million customers across 13 markets around the world, including tens of thousands of people in Australia. The company says its model "is intended for mild to moderate cases only" and that all clinical aspects of its aligner treatments in Australia—from diagnosis to the completion of teeth-straightening—are overseen by Australian-registered dentists using SmileDirectClub's telehealth platform.

Chief clinical officer Dr Jeffrey Sulitzer says traditional orthodontic procedures can be very costly and that many patients are especially concerned about going to dental clinics during COVID-19. "SmileDirectClub exists for that very reason to bridge the gap between cost and the inconvenience

of it all," he says. The company says its therapy model delivers savings of up to 60 per cent over traditional treatments.

Dr Sulitzer says SmileDirectClub's aligners are particularly popular in regional and rural areas of Australia "because orthodontists just aren't going to be located there. As the global response to the COVID-19 pandemic continues, telehealth and the delivery of remote care for medical needs from general medicine to dermatology and, now, orthodontics are needed more than ever. We're giving access to care in an environment where you can't get access otherwise."

Peak bodies raise concerns

The United Kingdom dental regulator, the General Dental Council, has expressed concerns for patient care and safety around the use of DTC clear aligners. It states that:

- DTC orthodontic treatment using clear aligners is a dental procedure and should only be performed by registered dentists and dental care professionals,
- In-person examinations are crucial for orthodontic treatment,
- Informed consent can only occur with direct doctor-patient interaction."

The Australian Society of Orthodontists (ASO) has called for the Australian Health Practitioner Regulation Agency (AHPRA) to provide clear guidance and warnings to the Australian public and dental providers regarding DTC clear aligner products.

"The ASO, like many other dental and orthodontic associations around the world, is concerned that direct-to-consumer aligner treatment models fall well short of the minimum standard of care required to adequately assess, diagnose and treatment plan an orthodontic patient and then provide safe and predictable orthodontic treatment outcomes," ASO president Dr Howard Holmes says.

He is particularly worried about issues related to patient consent for such treatments. "To give valid, informed consent, patients need to have been given detailed information about what the treatment involves, what alternative treatment options are available and the risks and benefits of the different treatment options. Direct face-to-face interaction with a

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Dr Jeffrey Sulitzer, chief clinical officer, SmileDirectClub

dental healthcare provider such as a specialist orthodontist or dentist who has considerable experience in orthodontics before committing to treatment plays a critical part in the informed consent process. This is deficient with many DTC aligner products.”

Dr Holmes says inadequate diagnosis or misdiagnosis, followed by improperly applied orthodontic treatment, can potentially cause irreversible damage to teeth and gums and worsening of bite problems, “leading to even more costly remedial treatment and, in the worst-case scenario, complete orthodontic retreatment and/or corrective surgery”.

While acknowledging that SmileDirectClub has been the subject of criticism from peak orthodontic bodies in the US, the UK and Australia, Dr Sulitzer hopes to keep liaising with such bodies. “We’ve brought a very disruptive technology to the forefront and whenever you bring a disruptive technology—something that has a strong value proposition for the customer—you’re going to get some push back.”

He maintains that clinical studies have proven that teledentistry is just as effective as treatment through a traditional brick-and-mortar setting for mild to moderate cases of malocclusion.

Dr Sulitzer rejects some industry and media portrayals of SmileDirectClub’s products as ‘do-it-yourself’. “Our model is dentist-prescribed and dentist-directed rather than DIY,” he says. “To claim otherwise only harms and misleads the thousands of Australian customers who could benefit from this technology during these challenging times.”

Price war

While he agrees that telehealth services have an increasing role to play in the delivery of dental and orthodontic services, Dr Tod says the orthodontists’ embrace of artificial intelligence-based solutions through platforms such as DentalMentoring still involves in-person consultation and the reading of radiographss.

“But that’s not the case with the direct-to-consumer companies,” he says.

Dr Tod has two other concerns. First, he says DTC clear aligner treatments do not utilise attachments that orthodontists put on certain teeth in order to help move these individual teeth more efficiently and accurately. Second, he says some people who have used DTC aligners are now presenting at his clinic to request bonded retainers, an important element of teeth-straightening that

DTC companies do not provide.

Dr Tod also questions the price advantages of DTC aligners given that the cost of orthodontic treatment is becoming more affordable as technology continues to improve. He notes, for example, that most orthodontists now have their own software and in-house fabrication facilities for aligners. “So we can turn out in-house aligners on our own 3D printer at a fraction of the cost that the big companies charge us. So with straightforward (teeth-straightening) cases people are often pleasantly surprised when we come under the cost of the DTC model.”

In conclusion, Dr Holmes advises consumers to consider the risks of using DTC clear aligners compared with orthodontic treatment from a specialist orthodontist. “Even in what seems like simple or ‘minor’ misalignment cases, things can, and do, go wrong, and the final treatment outcomes may be sub-optimal,” he says. “When treatment commences without a full clinical and radiographic examination and ongoing radiographic involves no in-person assessment and review by an orthodontist, the risks of poor treatment outcomes and patient harm from the treatment increase significantly.” **Bite**