

GPs: Give us Invisalign

Restricted technology has left general dentists out in the cold

IN SEPTEMBER 2000, Align Technology Inc., which manufactures the “invisible braces” system, Invisalign, launched a \$40 million marketing campaign directly at consumers, creating an enthusiastic demand for the product. However, company policy dictated that only board-certified orthodontists were authorized to provide the service.

Daniel Babiec, DMD, MAGD, a general dentist with a practice in Alexandria, Va., was turned away when he tried to attend a CE course hosted by Align Technology in October 2000. He’s performed orthodontic services in his practice for 18 years, but he was not allowed to attend the course because he is not board certified. “I think Align has put themselves in a deep hole over this board-certified issue,” Dr. Babiec said.

Last year Jon L. Richter, DDS, a general dentist practicing in Philadelphia, was turned away from a seminar hosted by Align Technology. “Align invited me to a seminar to learn the technique,” he explained. “Then, I was told that because I was not a card-carrying orthodontist I was not allowed to learn the technique.”

In response, Dr. Richter spearheaded a class-action lawsuit against Align Technology, alleging that the company is violating antitrust laws by selling their product to orthodontists exclusively. He also accuses the company of entering into secret agreements with orthodontists to prohibit sales to general practitioners. The company denies such action. “There is no reason why general dentists can’t use this product. By restricting treatment to orthodontists, they are limiting the availability of service and creating unfair competition,” he said.

While this action is arguably the most severe response to Align’s corporate policy, it is not the first. “I was very upset over Align marketing directly to consumers

because [general dentists] got no information beforehand,” said Carol Summerhays, DDS, MAGD, a general dentist practicing in San Diego. “Patients would come in and ask about Invisalign and we wouldn’t have any information for them.”

“General dentists technically and legally should be able to do what we want as long as we are competent to provide the procedure,” said John Chandler, DDS, MAGD, secretary of the Academy of General Dentistry. “I think Align, by cutting out general dentists, is going to experience a financial backfire. I think they have a procedure that is limited in scope, which needs more involvement from the dental community.”

Dr. Chandler’s disappointment in Align Technology’s policy lies in that the company eliminated his choice to incorporate or reject a product for his practice. “I want the [opportunity] to say ‘yes’ or ‘no’ to a new product or technique.”

Inline Orthodontics

Though Align Technology prohibits the direct sale of its product to anyone other than board-certified orthodontists, a group of specialists in Atlanta started a company called Inline Orthodontics and have found a way to bring the technology to general dentists who want to include Invisalign in their practice.

Ron Cooper, DDS, and Gene Witkin, DDS run Inline Orthodontics.



According to Dr. Cooper, the company employs 30 people, has 65 consulting orthodontists and more than 300 member general dentists, with about 25 new members joining every week. “The demand has been incredible and we are very ecstatic,” Dr. Cooper said. Inline Orthodontics exhibited at the Academy of General Dentistry’s Annual Meeting in New York.

Inline marketing materials state: “By starting just seven patients a month, you could increase your yearly revenues by at least \$100,000.”

The group provides what consultant Lee Silverstein, DDS calls Orchestrated Adjunctive Orthodontic Therapy, and is fairly straightforward. For a \$3,800 one-time membership fee, general dentists are trained by Inline Orthodontics to recognize patients who qualify for the Invisalign treatment.

According to Dr. Cooper, the membership fee provides general dentists with a Nikon digital camera (dentists who already have a camera pay a membership fee of about \$2,700), Align Technology storage boxes, flash cards and access to Inline-hosted seminars and training sessions.

The general dentist prepares the necessary data from the patient, including radiographs, diagnostic casts and digital photographs, and sends it to Inline Orthodontics, which forwards it to a board-certified consulting orthodontist certified by Align Technology and licensed to practice in the patient's state. After a diagnosis has been established, the prescription is sent to Align Technology to be molded. According to Dr. Witkin, Inline Orthodontics also assists general dentists with marketing, which includes signage and buttons for staff.

It is the consulting orthodontist, not the general dentist, who makes the diagnosis and writes the prescription. (According to Dr. Cooper, the consulting orthodontist shares liability with the general dentist.) The job of the general dentist includes making the required arch and bite impressions, taking the digital photographs and recognizing potential Invisalign candidates. "The general practitioner is a fancy assistant, in a sense," Dr. Silverstein said.

While some dentists are happy to work with Inline Orthodontics, others are skeptical. Dr. Summerhays attended a seminar hosted by Inline Orthodontics in June. She was interested in using the system in her practice to handle mild orthodontic relapse cases. But she left the meeting dissatisfied. "The information was very basic and there was minimal education. Most of the presentation was geared toward marketing—it was a joke," she explained. "You could see where [this product] could be abused if someone had no experience in orthodontics."

Dr. Summerhays said the starter kit she received from Inline Orthodontics had good marketing supplies, but training materials were sparse. The kit stated that participants could receive an instructional CD-ROM,

but it was unavailable at the time. She sought information from the company's Web site, <http://www.inlinedental.com>, but it was under construction.

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Jon L. Richter, DDS

Inline hopes to eventually have a complete multimedia training package available to its members. An Inline spokesperson said the CD-ROM should be available by mid-August; in the interim, there are other training materials available to member dentists. The Web site should be up and running by August, he said. However, it will initially serve as a marketing and informational tool. The spokesperson added that intranet capabilities to transfer patients' records will come later, after safeguards are installed in accordance with the Health Insurance Portability and Accountability Act of 1996. There is no set timeline in which this is to be accomplished.

Mark Ritz, DDS, MAGD, chair of the Academy of General Dentistry's Council on Dental Care, is concerned that Inline Orthodontics will not provide adequate training for dentists with little or no orthodontic experience. "It is wrong to place general dentists who are qualified by education and experience to make a proper orthodontic diagnosis and offer appropriate treatment options in the position of serving as a 'fancy dental assistant'," he explained. "Do we want to set a precedent that general dentists involved in orthodontic treatment need to outsource the orthodontic diagnosis? Do general dentists want to assume partial responsibility for a diagnosis that they don't have

the necessary education and experience to make? I do not believe that a middleman serves the best interest of the public."

Willing to pay

Some general dentists complain about the mark-up in price working through Inline Orthodontics. This includes lab fees and fees incurred by the consulting orthodontist, which costs up to \$360 per case. The cost of the Invisalign System can be double that of traditional metal braces. Align suggests orthodontists charge a base fee of \$4,800 for the treatment. Also, Align can charge an additional \$1,100 to \$3,300 in processing, delivery and manufacturing fees. Long-term treatments can cost patients upwards of \$9,000. Operating via Inline Orthodontics, that price can increase by 30 percent to 60 percent.

"It's amazing how many adults are willing to pay for these braces. I have had colleagues who've referred patients to orthodontists, giving them two choices: the Invisalign System or traditional metal work, which is faster and cheaper. And these patients are willing to pay almost double; patient after patient, we see this," Dr. Summerhays said.

"It appears the patient might lose out in the end," Dr. Chandler said. "And I think that is unfortunate because we are here to serve the patient, and they are going to have to pay more to go through a middleman. I'll be surprised if the majority of patients with problems Invisalign could solve would opt to go that route because of the cost."

Positive results

General dentists complain that there is a lack of clinical research about Invisalign, but results are just beginning to surface and seem positive. Vicki Vlaskalic, an assistant professor at the University of the Pacific, is one of several researchers Align has sponsored to study the Invisalign System. Clinical studies are being conducted at the University of the Pacific School of Dentistry, Indiana University, University of Florida and the University of Washington.

Good, but limited

According to Dr. Vlaskalic, preliminary research data show that the product is effective for what it was designed for, which is treating mild spacing and crowding. While it is slower, more limited in function and more expensive than metalwork, the Invisalign System does have a distinct advantage over its traditional counterpart. She said oral hygiene is improved, since the invisible braces can be removed for meals, brushing, flossing and routine dental cleaning. However, any restorative work must be completed before or after the treatment—any changes in tooth shape or position renders Invisalign obsolete. Another problem is that, unlike metalwork, it is difficult, if not impossible, to change or tweak the system after treatments have begun. This is because the system is so exacting.

And though many orthodontists are concerned over the idea of the patients' ability to remove the braces, thereby increasing the likelihood of derailing the treatment, Dr. Vlaskalic said patient compliance is actually pretty sound.

The future

Why did Align Technology open its doors to orthodontists and not to general dentists? Though the company has maintained a "no comment" policy (several employees of Align Technology declined to comment for this story) since the class-action lawsuit was filed, the breadth of speculation in the dental profession is as impressive as it is far-reaching. Talk to a dozen dentists and you are likely to get a dozen theories.

Few general dentists believe Align Technology can continue to withhold its product from such a large segment of the dental profession. Most agree it is only a

matter of time before the floodgates are thrown open.

Dr. Vlaskalic, who has been in contact with Align for the three years she has researched its product, says the company plans to open its doors to general dentists possibly as soon as October or November. "Align knew they had something new and that it would be greeted with skepticism. Invisalign was still under the guise of the FDA [in the late 90s]; it was a trial product," she said. "And they wanted their product to have credibility, so they offered it to clinicians, specialists in orthodontics and researchers to get results. Align figured that if the specialist couldn't make it work, then no one could."

When asked to deny or verify Dr. Vlaskalic's statement, Ken Vargha, Align Technology's vice president of marketing, declined to comment.

Rather than agreeing to a significant mark-up price by going through Inline Orthodontics, Dr. Summerhays said general dentists should enroll in orthodontic courses, be patient, and wait for Align Technology to make the next move. Attending the Inline Orthodontics seminar made her realize how important it is for general dentists to seek education in orthodontics, to be properly trained, to be able to diagnose a case, develop a treatment plan and execute it. Dr. Summerhays plans to enroll in a 15-day orthodontic course soon.

Dr. Ritz said the Dental Care council has repeatedly sent letters to Align Technology, requesting that they discuss the general dentist issue. Though Align has yet to respond to the request, Dr. Ritz said the council would remain diligent in its efforts to reach a "reasonable and equitable solution" with the company. AGD

NIH calls for more studies

Participants of the Consensus Development Conference on the Diagnosis and Management of Dental Caries Throughout Life, proposed the development of new diagnostic techniques to detect early stages of dental caries, providing more options to stop or reverse decay using noninvasive techniques.

The conference examined the current state of dental caries research to help health care providers and the general public make informed decisions. Nearly 20 percent of children between the ages of two and four have experienced dental caries, and by the age of 17 almost 80 percent of young people have had at least one cavity. More than two-thirds of adults between the ages of 35 and 44 have lost at least one permanent tooth due to dental caries, and one-fourth of those aged 65 to 74 have lost all their natural teeth.

Periodontal disease linked to arthritis

An Australian study that appeared in the *Journal of Periodontology* showed that people who have rheumatoid arthritis were more than twice as likely to have periodontal disease with moderate to severe jawbone loss. They also averaged 11.6 missing teeth, compared to 6.7 in the control group. Researchers are not saying if the relationship between the two diseases is causal, but some scientists think a bacterial infection may trigger the disease process in some of the estimated 2.1 million people with rheumatoid arthritis. For additional information, contact the American Academy of Periodontology at their Web site at <http://www.perio.com>

At press time ...

Align Technology Inc. reached an agreement in principle to settle a class action lawsuit filed against it on behalf of all licensed dentists (excluding orthodontists) July 25. The company has agreed to pay \$400,000 in settlement costs, as well as train 5,000 general practitioners each year for the next four years.

More information about the settlement is available on the Academy's Web site at <http://www.agd.org>.