

# Figuring Out “Teen”

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Dr. Orhan Tuncay was the lead investigator on the study that led to the Invisalign Teen product. I recently had the opportunity to visit with Dr. Tuncay to get an overview of this project.

## Could you please tell me about the nature of this study?

**Tuncay:** For the longest time Invisalign was *de-facto* reserved for adult patients, but many of us adventurous clinicians were treating teenage patients with Invisalign anyway. Ultimately, the company thought that it could be a good product for the teenage patient. It is no secret that there are a number of teenagers who just don't want braces – they are mostly junior or senior students in high school. They are the ones who were left behind because their teeth developed slowly. It is no surprise when everybody else is getting their braces off, they don't want to be seen in braces. Hence, there was a need to address the specialized need of this non-adult comprehensive treatment patient population. That is why the product was launched. But in terms of effectiveness of the product, there was really not much known other than anecdotal experiences of the clinicians.

Once launched, we thought it would be a good idea to look at the performance of this teen product in a properly controlled clinical setting. Furthermore, as the principal investigator of the study, I did not want a university clinic-based study. I thought it best the investigation should be conducted in a private-practice setting.

## When did you start this study?

**Tuncay:** It officially began in January 2008. In this teen study, selection criteria were such that, when the cases were finished the patients still had to be teenagers. This meant, at the start of treatment, the patients had to be 18 years of age or younger.

## How many patients did you have in the study?

**Tuncay:** We thought that we should have 50 patients in all and right now we have 60. Also this is a multi-center non-randomized study. There are four practices: mine, Jay Bowman from Michigan, Jonathan Nicozisis in New Jersey, and Brian Amy in Oklahoma. The sample was drawn from our regular patients who were screened and were offered treatment with the Invisalign Teen product. Every office gave a nominal discount for the treatment fee. Also, on a six-month basis, these study patients received a little gift card. In return, they would agree to show up for the appointment for data collection intervals (every three months).

## How is the Invisalign Teen product different from the regular Invisalign product?

**Tuncay:** Invisalign Teen was designed with the input from a large number of clinicians. Basically, it is the same product (the same plastic) but it has some special features. I think the most important element is the compliance indicator. The biggest problem that any Invisalign practitioner might have is patient compliance. Thus, the compliance indicators were added. They are located on the molar tooth. Secondly, as you know, you put braces on patients and the second molars come in later. Because of the nature of the Invisalign appliance (it works as an occlusal plane) we incorporated eruption tabs. In other words, if the second molars are coming in, there would be a tab covering the occlusal surface so they would not supra-erupt. Also, Invisalign Teen lets you prescribe room for erupting cuspids and bicuspid. So if these teeth are coming in, you could specify in the treatment how many millimeters you want to allow for growth. Thirdly, and this is very significant, is the incorporation of the feature called Power Ridges. These are dimples are near the gingival margin of the appliance, on the upper incisor teeth. They push the roots to achieve palatal root torque.

## How have the compliance indicators worked?

**Tuncay:** We've published the initial findings of the compliance indicator part of the study and they are very encouraging because it showed that compliance indicators work. In other words, color fades over time. In order for the color to fade, there must be moisture present, which is saliva, and the environment must be a certain warm temperature, which is mouth temperature. For example, the patient can not put the aligner in a cup of water and expect it to fade. Because the colored compliance indicator is a polyvinyl alcohol material, which is a food-grade dye, it bleaches continuously similar to some blue bristle toothbrushes that fade over time. What we found in the initial set of data, is that the compliance indicator does fade over time. The interesting finding was there was a difference of fade rate between the male and the female patient but we don't know whether one group has more salivary flow than the other. So the compliance indicator worked, meaning it faded over time, but it was not predictable from one patient to the next. Different people's indicators faded at different rates. It works as the patient's own monitoring device. The patient is his or her own control, if you will.

## So could the parents just take a look at the aligners and get some idea about how the

**compliance indicator is fading and how the patient is wearing the aligners?**

**Tuncay:** Yes, no question. The beauty of the compliance indicator was instead of *policing*, the compliance indicator gave us a chance to *monitor* the wear.

**Teenagers tend to misplace things. What about lost aligners. Has that become an issue in this study?**

**Tuncay:** It has been observed, but only on few patients. Lost aligners are always a problem. With the Teen product, however, patients can receive up to three sets of aligners free of charge in the event of loss.

**How have the teenagers responded to this study and their parents?**

**Tuncay:** The parents and patients have been wonderful. But you might argue that you are looking at a biased sample, because they are the ones that agreed to take part in the study. So the Hawthorne effect cannot be entirely dismissed; because you are in the study, you behave better. But let me mention something apart from the study patient population; in my private practice, there is no price distinction between braces and Invisalign for the teenage patient. So, when I ask, “How do you want to be treated? Do you want me to push your teeth with metal or plastic?” Their eyes get bigger and they reply, “Oh yes. I want Invisalign.” But the parent states she/he’s not going to wear them. “Oh no, mom, I will. I am making a commitment.” Interestingly, once they get into treatment, because kids are basically making a bet with their parents, they are remarkably compliant.

**Was this surprising to you?**

**Tuncay:** In the beginning it was. Then I started to reflect on the conversation I had with the child and the mother in the same room and I realized that the children are more responsible than their parents give them credit for.

**What is the current status of the study today? Is it over or is it still going on?**

**Tuncay:** We have collected data for 12 months now and the rest is coming in. So by this time next year we will have collected just about all of our data for reporting.

**So you have about one year left before the end of the study?**

**Tuncay:** Just about. I don’t think it is going to take a whole year but we are finishing up the stragglers because not all patients started at the same time. The study was opened

officially in January 2008, but it took a while for us to collect all the patients.

**In your opinion, has the Teen product filled the need in your practice for having patients in treatment who possibly would have not gone into treatment if braces were the only option?**

**Tuncay:** Yes, indeed. The only difference is, if you are treating someone with braces and there are deciduous teeth present, you can still start the treatment. With Invisalign Teen, it works best if all primary teeth are gone. The start date of the treatment is a little bit different with the teen product than it is with fixed appliances. That said, if the permanent tooth has not yet erupted, the aligner creates a space – like a pontic area, for the tooth to drop into.



*The Invisalign Teen Investigators (from left): Dr. S. Jay Bowman, Dr. Brian Amy, Dr. Jonathan Nicozisis, and Dr. Orhan Tuncay.*

**What advice would you give orthodontists who have not yet started with this appliance?**

**Tuncay:** I can tell you about my own experience. When I meet with patients and their parents I help them understand that teeth don’t know what is pushing them. Teeth respond to finger pressure, tongue pressure, rubber band pressure, metal pressure just as they do to plastic pressure. The treatment is the same, the treatment plan is the same, treatment time is the same (and, in some instances, shorter) with Invisalign than braces. I educate them and based on that there is no competition, except for one thing: some kids want the different color elastic ties on their braces.

**The treatment times on average were about 10-12 months, is that correct?**

**Tuncay:** Ten months, yes, except for one or two cases, but most of them fall in the 14-18 month range. If we had to do some torquing or used Class-II elastics it might have taken longer. The selection criteria were Class-I or Class-II patients; not Class-IIIs.

**What about case refinement or mid-course corrections. Has that been involved with this Teen product?**

**Tuncay:** Absolutely! You can do case refinement just as well as with regular Invisalign. I seem to be on the far end of the case refinement. I do case refinement probably more than most of my colleagues.

**What final remarks do you have for our readers?**

**Tuncay:** My closing comment would be that everyone should use Invisalign Teen in their practices because it is a better product than people think it is. ■