

# Why OrthoDots® CLEAR is Poised to Replace Dental Wax



Dental Wax

OrthoDots®  
**CLEAR**

**A White Paper By:**

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## TABLE OF CONTENTS

## PAGE

Abstract	2
Background and Market Size	3
Adherence	4
Pliability & Tear Resistance	4
Use on Appliances Other Than Braces	5
Aesthetics	6
Hygienic Use	7
Quality & Safety	8
Summary	9
References	10
Author Bios	11

## ABSTRACT

Orthodontic professionals know that pain and abrasions from orthodontic treatment is an issue for most patients. Pain from orthodontic treatment indexes high relative to other types of treatment and virtually all patients experience bleeding (oral mucosal tears) from braces and other orthodontic appliances, particularly at the start of treatment. Pain and abrasions are also known to be among the top reasons for resistance to treatment, patient complaints, and unscheduled office visits.<sup>1</sup>

For many decades, commodity “dental wax” has been the only broadly available product on the market for both orthodontic practices and patients, despite an **ongoing desire for a better solution**. This paper provides an in-depth comparison between dental wax and OrthoDots® CLEAR based on the key product features highlighted below and explores other reasons why OrthoDots CLEAR is positioned to achieve significant market share in both the professional and consumer retail channels.

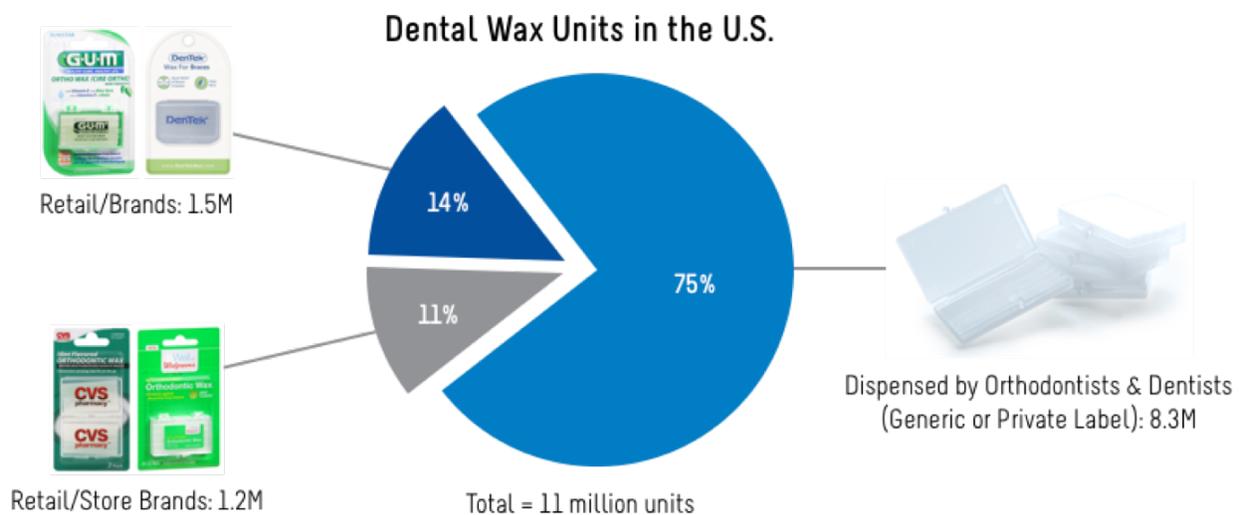
Product Benefits	OrthoDots® CLEAR	Dental Wax
Sticks and stays the best (with moisture activated adhesive)	✓	X
20x more pliable than dental wax (easier to mold)	✓	X
Best for use on all appliances (including Invisalign® trays and attachments)	✓	X
Clear (transparent)	✓	X
Individually packaged for hygienic use (for consumer and in-office use)	✓	X



## BACKGROUND & MARKET SIZE<sup>2-8</sup>

In the U.S. alone, 9,100 orthodontic specialists treat about 5.5 million patients. It is estimated that an additional 2.7 million patients receive treatment from general practitioners (dentists). Approximately 11 million packs of dental wax are dispensed or sold through the professional and consumer retail channels annually. Globally, it is estimated that the dental wax market is over 30 million units. Of the 11 million units in the U.S., only 2.8 million units (about 25%) are sold directly to patients at retail, while the majority (about 75%) is given to patients by their orthodontist or dentist.

The dental wax market is primarily generic, with a very small brand presence of only about 14% market share. Virtually all dental wax is universally packaged in plastic cases with 5 strips of “wax.” In the U.S., 86% of units are generic or store brand, and all of the leading brands and store brands (shown below) are imported from China. Among the leading brands in the retail segment, none have significant distribution or brand equity within the professional channels. Virtually all dental wax distributed through orthodontic and dental professionals is generic or private label.



Because dental wax is still the only widely available product for abrasions caused by orthodontic treatment, this paper explores the following aspects of dental wax vs. the new OrthoDots CLEAR product that is now on the market:

- Adherence (initial adherence and length of time it stays on)
- Pliability and tear resistance (moldability and resistance to crumbling)
- Use on orthodontic appliances other than braces
- Aesthetics (transparency)
- Hygienic use (for patients and chairside/in-office application)
- Quality and safety

## **ADHERENCE**

For a product to work properly for its intended use, obviously it must stick and stay in place. “Early on in our R&D efforts, one of the major opportunities our team identified was to be the first to add one of the common and safe adhesives used in other oral care applications,” according to Dr. Mike Silver, inventor of OrthoDots. “Although this was a very promising idea, it still presented an R&D challenge to add an adhesive component to a high-quality and malleable material. Development of this unique approach along with a scalable manufacturing process are the cornerstones of our IP and patent filings for our OrthoDots CLEAR product.”

The adhesive system used in OrthoDots CLEAR is moisture activated, meaning that it not only initially sticks the best in the very wet conditions around orthodontic appliances, but it also stays in place much longer than dental wax. Directions for traditional dental wax require the appliance to be dried before application, which is a very difficult task, particularly for areas toward the back of the mouth.

## **PLIABILITY & TEAR RESISTANCE**

“What especially makes OrthoDots CLEAR a novel invention is that it's the first product to combine the best material for this application with a moisture activated adhesive component,” according to Dr. Silver. “Traditional dental wax, typically a composite of hydrocarbon-based waxes and fillers, is not an ideal material from a malleability, tear resistance<sup>9</sup>, or transparency perspective, so we never considered using a similar “wax”-based composite. Instead, we selected a medical grade high-consistency<sup>10</sup> silicone as the ideal composite for this application. By its nature, silicone-based material doesn't stick to wet surfaces, but we addressed this by being the first to incorporate a moisture activated adhesive layer.”

The material is drastically superior to traditional dental wax for this application. Third-party testing confirmed that the medical-grade silicone is 19 to 21 times more pliable and 33 to 82 times more tear resistant than leading dental wax products on the market.<sup>11</sup> These characteristics make it extremely moldable (without breaking apart) and enables it to be easily removed in one piece – unlike dental wax, which often comes off in pieces and can leave a residue that some patients attempt to pick out. This is not only inconvenient but also – if done too vigorously – can break orthodontic appliances.<sup>12</sup> Additionally, the properties such as feel and viscosity of high-consistency silicone remains relatively unchanged through a much wider range of temperatures than traditional dental wax, resulting in longer-lasting comfort.

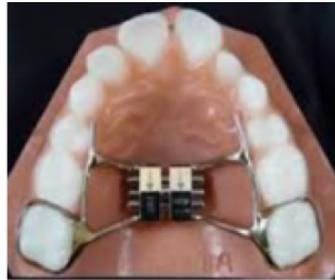
## USE ON APPLIANCES OTHER THAN BRACES

Although abrasions are typically thought to be caused primarily by braces, there are many other types of orthodontic appliances that can be a source of pain and irritation.

Given the superior adhesive properties, tear resistance, and malleability of OrthoDots CLEAR, it is the best option for use on all orthodontic appliances. Below are examples of other orthodontic appliances that commonly cause irritation.



Lingual (hidden) Braces



Expanders



Buccal Tubes



TAD (Temporary Anchorage Device)



Herbst Appliance



Invisalign® attachments can cause irritation or abrasions



Edges of Invisalign trays can cause irritation for some patients

Invisalign® (or clear aligners) has quickly emerged as a treatment option particularly for adults, given the benefits of being less noticeable. Unfortunately, attachments (or buttons) as well as the edges of the trays can cause irritation for some patients. OrthoDots CLEAR is superior for this application since the adhesive technology enables it to stick to attachments and is easily moldable across the edge of a tray that is causing irritation. It is also important to note that patients who have chosen the clear aligner treatment prefer the least noticeable option, which OrthoDots CLEAR also provides over the more opaque dental wax.

## AESTHETICS

Orthodontists are well aware that aesthetics is a major trend in orthodontics because patients strongly prefer the most discreet and unnoticeable treatment options.<sup>13</sup> This consumer need alone has been a major reason for the great success of products like Invisalign. And in response, the top players in the orthodontic industry are in a race to develop less noticeable options such as clear plastic brackets, tooth colored wires, and even linguals which are brackets bonded on the lingual (tongue) side to hide the brackets.<sup>14</sup> This placement, unfortunately, leaves the tongue very vulnerable to abrasions.

“In our previous generation of OrthoDots, we quickly learned how important the product transparency feature was to patients,” said Ron Schutt, CEO of OrVance. “Orthodontists and patients clearly preferred OrthoDots over dental wax – but when we asked patients what we could do to make the product better, the single, overwhelming response was that a transparent solution was extremely desirable. This was something we always knew was a preference, but we didn’t realize at the time how important it was to consumers.”

Dr. Mike Silver, director of technical affairs and R&D for OrVance, added, “We’ve always had transparency identified as an ideal feature, but it presented a very substantial R&D challenge to provide a transparent solution while also achieving the goal of sticking and staying in place better than dental wax.



But based on the overwhelming feedback from patients, we went back into the lab and figured it out. With OrthoDots CLEAR, we now have the best solution on the market for all the top features patients desire: It sticks onto wet surfaces, stays in place, is the most malleable product on the market, won't break apart into pieces, and is now also transparent and less noticeable.”

In light transmittance testing, OrthoDots CLEAR was shown to be 17-30 times more transparent (less opaque) than leading dental wax products on the market.<sup>15</sup> The image on the left shows a leading dental wax brand vs. OrthoDots CLEAR.

## HYGIENIC USE

“In addition to developing a more effective and transparent solution than dental wax, we also wanted to solve another problem – the need for more hygienic and convenient applications,” according to Dr. Eric Hannapel, co-inventor of OrthoDots and practicing orthodontist. “Before the launch of the OrthoDots ProPack, there really was no product on the market designed specifically for in-office use, which is why our profession has not historically used dental wax for chairside application. Dental wax is not packaged appropriately for the healthcare setting and it’s not practical to use for that purpose. As with any specialty healthcare practice, time is money. Even if we did use an entire box of wax for one patient application, properly drying the teeth and molding the product with gloved hands would take well over 30 seconds. By contrast, OrthoDots are applied in about 10 seconds because of the convenient packaging and the ability to skip the step of drying the appliance before application.”

According to Andrea Cook, an orthodontic clinical consultant, “OrthoDots not only offers a better product to maximize patient satisfaction, but it also offers a better option for more convenient and hygienic use. The ProPack provides the only single-use application which is fully compliant with CDC and FDA guidelines for products used on multiple patients in healthcare settings.”



VS.



Dental wax is not convenient or FDA and CDC compliant for application on multiple patients from one pack. OrthoDots® CLEAR is the only product in unit-of-use packaging designed for chairside application.



VS.



Unit-of-use packaging for more convenient and hygienic patient use

“Since products used for this purpose come in contact with saliva and even blood, dental wax is not appropriate to share among patients – and we know this occasionally happens,” according to Dr. Hannapel. “Safe and convenient use for our patients are the primary reasons why we chose to package OrthoDots in single-use applications. We OrthoDots CLEAR white paper | November 2017

believe dental wax is one of the last products used for a similar purpose in healthcare that is not packaged in hygienic unit-of-use packaging. As a result, we expect both practices and patients will quickly embrace how OrthoDots are packaged similar to bandages. When you stop and think about it, why has it taken so long for a product used for this purpose to offer adhesive properties and to offer single-hygienic applications much like bandages and virtually all other medical devices?”

## QUALITY & SAFETY

Dental wax and OrthoDots CLEAR are both regulated as a Class 1 medical device, product code EGD, in both the U.S. and Canada.<sup>16-17</sup> This regulatory classification does not require compliance with Current Good Manufacturing Practices (CGMP’s), which is required for most medical devices and pharmaceutical products. Additionally, all the leading retail brands of dental wax in the U.S. and Canada are imported from China without listing specific ingredients that make up the “wax” composite.



Dental wax as typically dispensed to patients by healthcare professionals: no directions for use or lot codes for traceability



OrthoDots® CLEAR includes directions for use and lot codes for traceability.

OrthoDots are made from a high quality medical-grade silicone and a common adhesive ingredient that has long been safely used in other oral care products. According to OrVance, in addition to manufacturing OrthoDots in the U.S., the company sources all of the product’s ingredients and packaging components from within the U.S. And although not required by the FDA or Health Canada, OrVance voluntarily complies with CGMPs required for most healthcare products.

Additionally, OrthoDots CLEAR is voluntarily manufactured with lot codes for traceability along with clear directions for use. While most retailers in the U.S. and Canada require lot codes, the dental wax given to patients by orthodontists and dentists generally do not contain lot codes.

According to Ron Schutt, president/CEO of OrVance, the company has taken the following voluntary measures to maximize quality and safety, even though they have not been the easiest or least expensive path to market:

- Source materials and manufacture the product within the U.S. – where we can best oversee and enforce quality
- Manufacture under CGMP conditions
- Provide lot codes on all packages for traceability
- Package in unit-of-use hygienic packaging
- **Provide clear directions for use on all packaging**

### **SUMMARY**

OrthoDots CLEAR is not only the best product on the market for the reasons cited in this paper, it is also the only brand that has aggressive marketing strategies that span both the professional and consumer channels.

Dr. Scott Tyler, orthodontist in Michigan and advisor to OrVance, commented “Given the many benefits the new OrthoDots CLEAR provides over wax, I can’t imagine why any ortho practice would continue to dispense bulk dental wax to their patients. All my patients prefer the new OrthoDots CLEAR over the old dental wax. There is also nothing like the OrthoDots ProPack in the market designed specifically for hygienic chairside application. This product is a nice addition to our orthodontic profession.”

## REFERENCES

1. "Efficacy of a wax containing benzocaine in the relief of oral mucosal pain caused by orthodontic appliances", G. Thomas Kluemper, DMD, MS, Douglas G. Hiser, DMD, MS, Mary Kay Rayens, PhD, and Michael J. Jay, PhD, National Center for Biotechnology Information, 2002, <https://www.ncbi.nlm.nih.gov/pubmed/12411880>
2. "Patient census surveys: Patients in treatment by AAO members in U.S. and Canada," American Association of Orthodontists (AAO), 2012
3. "IRI InfoScan Retail Data: Orthodontic Wax," IRI, 52 weeks ending May 17, 2015
4. Survey of orthodontist offices on dental wax usage, OrVance, 2015
5. Based on industry assumption that the global orthodontic market is approximately three times the size of the U.S. market.
6. Retail store checks in U.S. and Canada, OrVance, 2017. All leading dental wax brands and store brands specify "Made in China."
7. "Orthodontic services provided by general dentists", Shari L. Wolsky, DDS, MS, and James A. McNamara, Jr., DDS, PhD, <http://dent.umich.edu/sites/default/files/departments/opd/104.pdf>
8. "Study finds a 34% rise in dentists performing orthodontic treatments," Dentistry IQ Editors, October 8, 2013, <http://www.dentistryiq.com/articles/2013/10/study-finds-a-34-rise-in-dentists-performing-orthodontic-treatments.html>
9. Tear resistance is the measure of a sample's ability to resist tearing into pieces when under tension.
10. High-consistency silicone is high molecular weight silicone polymers that have been combined (compounded) with fumed silica to enhance tear resistance.
11. Testing done using test method ASTM D412C employing an Instron Mechanical Testing Machine and dogbone-shaped samples clamped at both ends with strain applied at 20 inches/minute.
12. "Four Steps to Fixing a Broken Braces Bracket," 2017, Tracey Sandilands, Colgate-Palmolive Company, <http://www.colgate.com/en/us/oc/oral-health/cosmetic-dentistry/adult-orthodontics/article/four-steps-to-fixing-a-broken-braces-bracket-0914>
13. "The Adult Orthodontic Patient: More Options than Ever Before!" N.E. Tarraf, Dentistry, vol. 5(2), 2015, <https://www.omicsonline.org/open-access/the-adult-orthodontic-patient-more-options-than-ever-before-2161-1122.1000278.php?aid=39079>
14. "Discomfort caused by bonded lingual orthodontic appliances in adult patients as examined by retrospective questionnaire," Shouichi Miyawaki, DDS, PhD, Mika Yasuhara, DDS, and Yasuhiro Koh, DDS, PhD, NCBI, 1999, <https://www.ncbi.nlm.nih.gov/pubmed/9878962>
15. Testing done using a dual-beam Hitachi U-2910 UV-Vis spectrometer; transmittance measured at 50 nanometer intervals from 700-350 nanometer and averaged, using 1.6 mm average sample widths
16. U.S. Food & Drug Administration, CFR – Code of Federal Regulations Title 21, 21CFR872.6890, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?id=1122>
17. Health Canada, Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices, File Number 06-120629-368, [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/md-im/keyword\\_motsclcs2-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motsclcs2-eng.pdf),

page 74

## **AUTHOR BIOGRAPHIES**

### **Michael E. Silver, PhD**

Mike has a PhD in chemistry from Cornell University and is a professor emeritus at Hope College. Mike has over 30 years of experience in academia and working with industry to develop novel materials and intellectual property in the healthcare arena. Mike is also the principal inventor of OrthoDots and author of numerous issued patents. He currently leads product development, intellectual property, and technical affairs for OrVance LLC in Grand Rapids, Michigan.

### **Dr. Eric D. Hannapel, DDS, MS, PC**

Dr. Hannapel has been a practicing orthodontist since 1996 and received his dental degree and orthodontic residency from the University of Michigan. Eric also donates his time on the Cleft Palate Board of Specialists at Helen DeVos Children's Hospital in Grand Rapids, Michigan and provides treatment. He also teaches at the University of Michigan in the Orthodontics & Pediatric Dentistry department as an adjunct clinical assistant professor.

### **Ronald J. Schutt**

Ron has over 20 years of experience in healthcare and previously served as vice president of consumer healthcare marketing at Perrigo Company (NYSE: PRGO), where he championed major healthcare initiatives and led several of the most successful product launches in the company's history. He is also the founder and principal of RJ Schutt & Associates and serves as the president/CEO for OrVance LLC in Grand Rapids, Michigan.