THE ORTHODONTIC MATERIALS INSIDER

March 2006, vol. 18, Nr. 1

A quarterly dedicated to orthodontic professionals, and to the renewal of their habits and tools by ORTHO-CYCLE, A COMPANY THROUGH WHICH YOU CAN RECONDITION, BUY AND SELL ORTHODONTIC APPLIANCES.

ISO 9001: 2000

Editor: Claude G. Matasa, Dr. Chem. Eng., Dr. Techn. Sci., Professor of Oral Bio-Materials

CE 0510

Against all warnings, paste dual composites could and should be stored in close contact!

Introduction

For decades, the components of dental dual or chemically cured composites have been delivered in separate jars accompanied by instructions requesting that their cross-contamination should be avoided as it will result in hardening the material.

Yet, drug stores sell tooth pastes in which the squeezed stripes do not mix (Fig. 1), and hardware stores offer epoxy glues in which the two reactive pastes are in contact. In what follows it will be shown that this is also possible in the case of dual, acrylic adhesives.

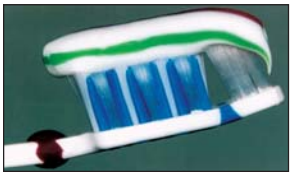


Fig. 1. Common, striped toothpaste

Theory

To achieve a good set, the polymerization starters (initiator and activator) must find each other and react. Homogeneity is seldom achieved, as it can be demonstrated by measuring the properties in various areas of the composite. Hydrodynamics teaches that laminar or streamline flow does not lead to mixing because the particles move in parallel layers, with no intermingling. In contrast, mixing, or the chaotic distribution of the components, occurs only when the average velocity of a particle is added with transverse and longitudinal variations in time, direction and intensity, a phenomenon known as turbulence. Paste mixing requires strong agitation to overcome the antagonistic effect of viscosity.

Therefore, it is reasonable to claim that if any dual-type adhesives are not thoroughly mixed, they will not bond well. Moreover, if reactive and highly viscous components of a composite are left in contact, in the absence of enough motion, no general setting will occur. This is due to poor diffusion, a mechanism by which components of a mixture are transported through and around the mixture by means of random molecular (Brownian) motion.

While gases diffuse very quickly, liquids diffuse much more slowly; solids are even slower. Diffusion progresses as long as a large concentration difference in the components exists on either side of the unit area. “Stuff moves from where you have lots to where you have little” is a popular description of Adolph Fick’s law, which states that the speed of diffusion increases with temperature and decreases with increasing pressure. Given enough time, flows will eventually stop as a result of homogeneity.

Whenever the two components of reactive composites are joined, their inter-diffusion should be hindered both by their high viscosity and by the polymeric membrane generated by the reacting components. In contrast with osmosis, this membrane should not only be impervious, but also self-mending. The experiments shown below confirm that this hypothesis is true.

Materials and methods

The two-paste (or dual) composites used were Phase II from Reliance Orthodontic Products (Itasca, IL 60143) and Bond Tite II from Anchor Adhesives (Pompano Beach, FL 33064).

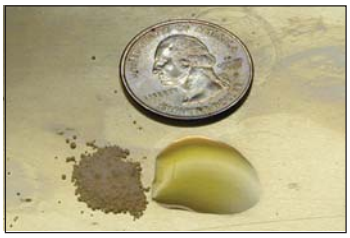


Fig. 2. Granules of benzoyl peroxide and a drop of N,N-dimethyl p-toluidine.

Fig. 3. Same as Fig. 2, but after the two reagents have made contact. Observe successive puffs of smoke

The reagents that initiate acrylic's polymerization were 75% benzoyl peroxide (initiator) and 99% N, N-di-methyl-p-toluidine (DMPT)*. Along with toluene and acetone, all were from Fisher/ Acros (Pittsburgh, PA 15275-9943).

To test the reagents and at the same time demonstrate the intensity of their reaction, a small pile of benzoyl peroxide granules was put in contact with a drop of DMPT. The photographs in Figs. 2 and 3 were made before and after contact. Since the peroxide comes in granules—not in block— contact with the amine generated a series of mini-explosions accompanied by puffs of smoke. To test if these reagents— commonly found in adhesives–would perform as required, 0.5 g of each couple of pastes was then well mixed and their setting time to set used as a control.

*Fig. 4 &5. Blobs of reactive pastes before (**a**) and after being pressed one againt the other (**b**).*

I. In an experiment designed to test the inter-diffusion of reactive composites, two paste blobs of the adhesive Bond Tite II were subjected to fretting while being pressed against each other (Figs. 4 & 5). A portion taken a week later showed a setting time of about a minute longer when compared with the control (original composite). After a month at 30° C, both components were found to be soft throughout the mass; most of the blobs were removed, starting from their ends, while their junction was immersed in toluene and then in acetone in order to dissolve the uncured adhesive. After few hours, a thin, friable film (Fig. 6) was recovered from the disintegrated composite.

Fig. 6. The thin, friable film formed at the contact surface of the two composite blobs shown in Fig. 4 & 5

II. The experiment was repeated using Reliance's Phase II adhesive. A Nalgene™ tube of ID 0.2", which was cut longitudinally and held open (Fig. 7), allowed the placement of a streak of Part A adhesive, (Fig. 8). On it was superimposed a streak of part B (Fig. 9). The tube was left to recover its initial shape; in Figs. 10 and 11 the superimposed streaks in the tube are shown both in length and in section. After being left for a month at 30° C, both pastes were found to be soft.

III. Superimposed stripes of Phase II Parts A and B were inserted into a lip balm tube, pushed out after a week and then cut into fine slices. Mixed, each of these gave apparently similar results in strength and delay in curing time.

IV. To duplicate what may happen inadvertently, blobs of the two parts of the same adhesive were added with portions of their counterparts, as shown in Fig. 12. This two- paste system was tested and found to be still soft after a month at 30° C.

V. To demonstrate the existence of a film formed when the components of a dual, reactive composite are joined, a streak of the peroxide containing Part B of the Phase II adhesive was immersed in a solution of 5% DMPT in toluene for 3 minutes, then left for 2 h. After immersion in toluene and then in acetone, the uncured adhesive was dissolved, and a thin, empty tube was isolated. Fig. 13 shows this tube along with a streak of Part B from Reliance's Phase II similar to the one treated.

Fig. 7. A cut open Nalgene™ tube along with the screw syringes containing parts A and B of the adhesive Phase II

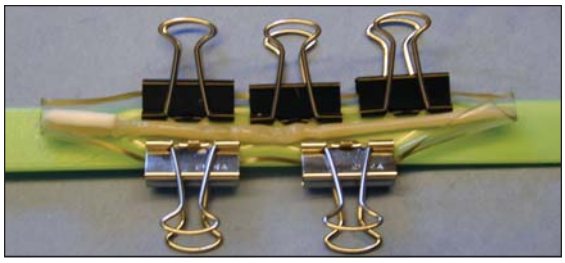


Fig. 8. A streak of the adhesives part A laying on the cut open tube having on it (right) a small amount of Part B.

Fig. 9. Superimposed streaks of the adhesives Phase II laying on the cut open tube

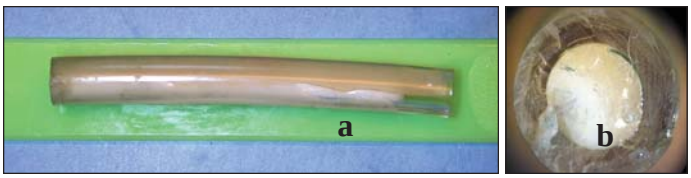


*Fig. 10 & 11. Tube closed on the superimposed streaks of the adhesive Phase II (**a**) and its section (**b**). Observe the yellow tint of Part A which contains the amine.*

**Along with N, N-dihydroxymethyl-p-toluidine (DMPT), N, N-dihydroxyethyl-p-toluidine and N, N-di-methyl-p-toluidine are common activators/kickers or reductants for peroxides*

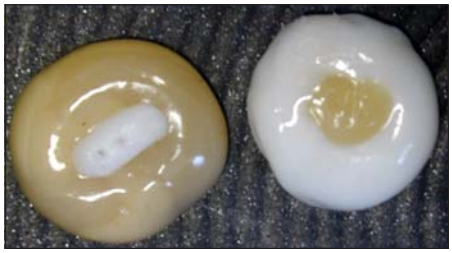


Fig. 12. Blobs of the components of the adhesive Phase II added with portions of their counterparts

Fig. 13. Strip of Part B of Phase II before (a), and after treatment with DMPT and dissolution (b). Observe tube.

Results

In all cases, the parts of the dual adhesives that were joined but not mixed were found to be soft even after a month's exposure to 30° C. The cured film separating the joined parts of the composites makes unnecessary the use of any separating or isolating hydrophilic film.

Being thin and friable, the film does not influence the properties of the cured adhesive. While the setting time of the portions cut and mixed showed an inherent increase, the aged composite was still usable for bonding.

Discussion

In the previous experiments, the joined pastes remained soft after a month's exposure at 30°C. In the absence of inherent decay of the curing reagents, this exposure is equivalent to three months at room temperature. According to Arrhenius's law, for most reactions occurring near room temperature, a temperature increase of 10°C speeds the rate of reaction two to three times. Kept refrigerated, i.e., extending the initiator's decay, the normal shelf life of these joined but not mixed systems should have been half a year.

These experiments show that the reciprocal diffusion of the polymerization initiators is not only slowed by the high viscosities involved but also stopped by the thin film generated by the components' own contact. Even if the film separating the pastes were locally penetrated by the active ingredients, self-mending would take place, being generated by interaction of the activators with the monomer. This phenomenon, along with normal decay of the initiator in time and the "wall effect" exerted by the chemically inert particles of the filler, leads to a decreasing probability of premature setting of the system.

While it is true that negligent handling (i.e., involuntary partial mixing) may indeed shorten a composite's life, an ad-literam interpretation deprives the dentist of a simpler delivery system such as the one shown in Fig. 14 (pastes in lip balm or striped toothpaste tube).

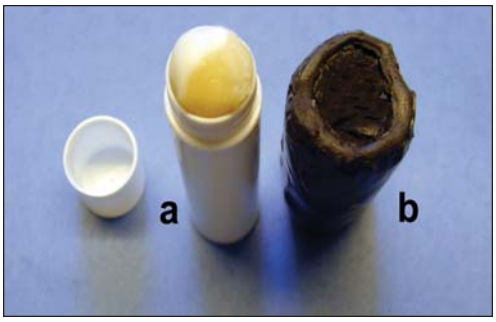


Fig. 14. Reactive dental composites can be delivered the same way as their industrial counterparts.
a. Streaks of a dual adhesive in a lip balm tube.
b. Concentric streaks of the epoxy putty Loctite

Devices in which a laminar, nonmixing flow of pastes is maintained are half a century old. In the US Patent 2,789,731 '57 and the many which followed, simple arrangements allow the pushing from a tube of several components without mixing them. When compared with toothpastes, dual dental composites would mix less, as diffusion is hindered by the generated self-mending film. Made of a thin and friable polymerized composite, the latter cannot affect the performance of composites that contain up to 80% mineral filler anyway.

Conclusions

Knowing how and when to mix and not to mix reactive pastes proves to be rewarding. If you mix them well, you reach the composite's ultimate strength. If you take measures that these don't mix during storage, you can simplify their application.

The belief that a burst of free radicals could, without further mass agitation, travel throughout the mass of a composite and cure it has been found to be both unjustified and counterproductive. As shown by industrial products already on the market, it is possible to store inter-reactive, viscous components in close contact with each other. If a simplified composite delivery, where a single, combined paste would be used instead of two, this would render the chemically cured composites as attractive as today's preferred photo-chemically cured ones. This would not just save money, but should lead to improved bonding and less messy applications.

We thank Reliance Orthodontics for providing the Phase II adhesive used in the above experiments

Dentistry's composites should outpace those from industry

Introduction

In an era when designer polymers can be assembled molecule by molecule, dental adhesives lag behind. Even copying those already common in industry doesn't fare better. The preceding article proves that there is still plenty of room for improvement: for half a century, reactive adhesives and dual composites were kept separated in dentistry and medicine, but not in industry.

By tinkering with their structure at the molecular level, designer polymers are a new class of polymers that are manufactured to perform specialized functions In fact, these can be assembled using a modular polymer scaffold on which smaller molecules are grafted. Today it is possible to control and predetermine the chemistry of both the adhesive material and the way it is handled.

Resin-based adhesives in dentistry

In dentistry, the basic monomer continues to be bis-GMA. In a past issue, [1] as well as in a full chapter, [2] we have shown that the resulting adhesives were found to be toxic, cytotoxic, mutagenic, carcinogenic and oestrogenic. A recent analysis of the properties of bis-GMA composites[3] has shown that their only advantage is their mechanical strength, due to a structure that is almost that of liquid crystal polymers (LCPs),[4] the strongest known. The bonding to dentin, known to exhibit a high protein content as well as retained water, is so poor that it has led the guru of dental materials, Dr. Gordon J. Christensen, to declare, "Long term dentin bonding is a myth."[5]

Particularly subject to shrinkage and loosening whenever applied too thick or in layers, a separation composite or substrate is likely to occur during the setting process. Aside from weakening the bond, it generates at the above-mentioned interface tiny gaps, or cracks, that harbor cavity-causing bacteria. Not being cariostatic and sometimes exhibiting an incomplete cure, adhesives can generate postoperative sensitivity.

Although dental LCP polymers have been studied for years at the Southwest Research Institute in San Antonio, Texas (an organization specializing, among others, in liquid crystals and micro-encapsulation),[6] no new resin or delivery system has yet reached the market. Both developments are critical for the adhesives of tomorrow.

Adhesive delivery systems in dentistry

Whether cured chemically or photo-chemically, today's composites have a limited shelf life. Unless kept refrigerated, their properties are maintained for less than two years; any accidental exposure to more intense light could cause setting.

The current delivery systems for multicomponent adhesives used in dentistry are also lagging behind. Despite being up to 30% weaker than their reactive, chemical counterparts, [7] the single-component and light cured-adhesives are preferred because of a simpler and less messy delivery. When using light, orthodontists face the problem of attachment opacity, which can lead to incomplete curing. Whether using chemical (reactive) or photo-chemical systems, the application should take no more than two minutes, otherwise the gel generated before the adhesive cures will reach a viscosity high enough to markedly decrease its ability to penetrate the microfissures (Tromsdorff effect).[8] No better off are the dentists who must cure their composite layer by layer, because active light cannot penetrate deeply enough (layering is also necessary to allow relaxation of the interfacial stress generated by polymerization shrinkage).

Although advancing from powder-liquid to paste-paste and from separate jars to dual screw syringes, reactive systems used in dentistry are still messy. Suggested improvements are minimal, such as single-dose delivery in which the adhesive is precoated on the attachment in a quantity no greater than that needed for a single application.[9] In another system[7] the attachment is scraped along the pattern of adhesive found in vicinal transfer areas. When using a multiple-part adhesive, successive scraping and removal of the two parts is considered sufficient mixing for a proper cure. As we can see from the previous article, this statement is quite debatable.

Despite the succession of many generations of these adhesives or related variations that combine conditioner and primer, bonding composites are still multicomponent and technique sensitive. Aside from not providing the claimed bond strengths, one-step or one-bottle products are misnomers because they are often applied in two steps.

The future of dental adhesive resins

It is true that, although designed for industrial purposes, today's commercial LCPs are not yet ready for use in dentistry. LCs (liquid crystal–based polymers) are the strongest polymers known to man, and they can be derived from natural sources, solving many of the problems listed above. Today's derived adhesives and composites have been the object of past articles, [4, 11] and they are successfully used to join textiles, electronic parts and printed circuits.

In another direction, researchers at the Georgia Tech School of Chemistry and Biochemistry are attaching various small molecules to a polymer backbone and obtaining materials with interesting properties.[11] In England, chemists at the University of Warwick have patented a process that generates polymers in a controlled way, tailoring their properties to particular applications. A spin-off company, Warwick Effect Polymers (WEP), manufactures designer polymers for adhesives.[12]

The future in delivering and handling adhesives

Today, monoblock assemblies of multicomponent epoxy glues abound in hardware stores (Fig. 1), and microencapsulated, anaerobic thread-locking compounds are readily available. Thus, the adhesive in 3M's Scotch-Grip™ is coated on the fastener; the shearing action of engaging the fastener into a nut breaks the capsules and allows the adhesive to cure at room temperature. Capsule contents can be released by melting the wall, or dissolving it under particular conditions, as in the case of an enteric-drug coating. In other systems, the wall is broken by solvent action, enzyme attack, chemical reaction, hydrolysis, slow disintegration or even by small temperature differences.

Plastics that mend themselves when heated have been developed at the University of California, Los Angeles.[13, 14] Other plastics, made at the University of Illinois at Urbana-Champaign, self-heal when fractured.[15, 16] An approaching crack ruptures the embedded microcapsules, the contents of which, along with the catalyst (initiator), are released into the crack plane through capillary action. The advantage of this damage-induced triggering mechanism is that it provides a site-specific, "autonomic" control of repair.

Inspired by advances in industry, a recent idea has expanded Kaelble's film.[17] The patent, offered by 3M Innovative Properties Company, claims to be a multilayered dental adhesive that can be precoated on an orthodontic appliance. [18] Is the ideal "peel–and-stick" era getting closer?

Conclusions

Perhaps the most important reason why dental adhesives lag behind is that industry makes enough money to continue to be interested in investing in research. If an adhesive from a reputable manufacturer is sold for $2/g (no accessories such as bottles, brushes were taken into account) and the price of gold bullion is $580/oz ($20/g), then the price of adhesive is 10% that of gold. When we consider that some 80% of the adhesive is an inexpensive filler such

Fig. 1.Single pack, two paste epoxy adhesives that can be found in hardware shops

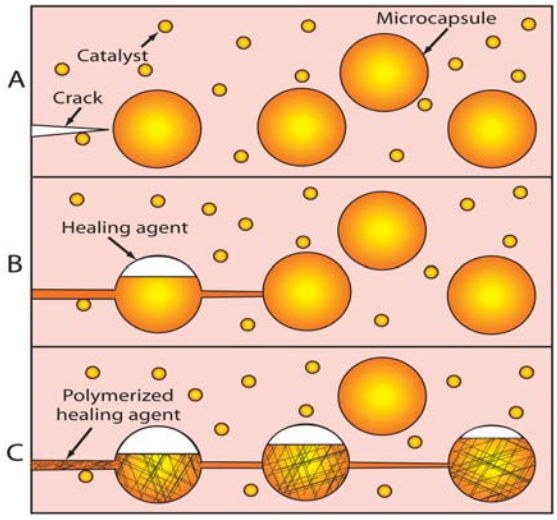


Fig. 2. Plastics self-healing: the crack breaks microcapsules containing monomer. In contact with the catalyst (initiator), it polymerizes, generating thus new bonds

as glass, alumina or silica, then the price of the "chemistry" involved in its manufacture is almost as expensive as gold.

This leaves the development of new resin adhesives and delivery methods in the hands of universities and research institutes such as Southwest Research Institute, San Antonio, Texas, or federal agencies such as the National Institute of Standards and Technology, Gaithersburg, Md. If the profession doesn't cry havoc, the advancement of dental biomaterials will have to compete with other, more pressing, demands.

References

1. Matasa CG, Do you really know the resins you use? The Orthod. Mat. Insider 2000; 13 (1): 5-8
2. Matasa CG, Polymers in orthodontics: a present danger? In: Graber TM, Eliades T, Athanasiou AE (eds). Risk Management in Orthodontics: Experts' Guide to Malpractice. Quintessence, Chicago, 2004.
3. Matasa CG, Balaban AT, Challenges in medical in-situ biomaterial polymerization, The Orthod. Mat. Insider 2004; 16 (4): 2-8
4. Matasa CG, To have great composites, we'll have to look ... down. The Orthod. Mat. Insider 2005; 17(1): 4-8
5. Christensen JG, Current controversies in esthetic dentistry: Esthetic & restorative update 2005, American Acad. Esthet. Dentistry meeting, April 9, Lake Buena Vista, FL
6. http://www.swri.edu/3pubs/ar2000/nano.htm
7. Dixon DR, Andreiko CA, Individual dose dental adhesive delivery system and method, US Patent 6,482,003 '02
8. Matasa CG, A simple bond strength testing device and the Tromsdorff effect, The Orthod. Mat. Insider 2005, 17 (2): 6-8
9. Pranitis LJ Jr., Ng D, Single dose dental adhesive delivery system and method and adhesive therefor, US Patent 5,860,806 '99
10. Matasa CG, Resin-based composites, today. The Orthod. Mat. Insider 2005 17 (3): 1-3
11.www.electroline.com.au/elc/feature_article/item_062003b.asp
12. www.warwickeffectpolymers.co.uk
13.www.sciencedaily.com/releases/2002/03/020301071136.htm
14. .Scott A., Designer polymers, on the cheap, Chemical Week, March 13, 2002
15. White SR et al., Autonomic healing of polymer composites, Nature 2001; 409: 794-797
16. Brown EN et al., Microcapsule induced toughening in a self-healing polymer composite, Journal of Materials Science 2004; 39, 1703-1710
17. Kaelble DH, US Patent 4,204,325 '80
18. www.freshpatents.com. Multi-layer-adhesives-and-methods-for-bonding-orthodontic-appliances -to-toothstructuredt20050623ptan 20050136370.php

What extra value is there for clinicians who deal with our top-certified company?

Using high-tech procedures, Ortho-Cycle Company is committed to making every effort to satisfy the needs of our customers. It delivers defect-free, reprocessed orthodontic attachments through continual quality improvement. Orthodontic recycling can be much more than "from trash to mouth." Meeting exacting standards (FDA, ISO, CE and BBB), Ortho-Cycle offers you the following:

Quality

-A quality assurance system that is continually maintained and controlled; its implementation improves not just the product but also the process.

-Attachments that are superior to those released by our non-certified competition that use adhesive charring and metal removal through electro-polishing.

-"Safe and effective" attachments, according to the AAO president (*The Bulletin*, Annual Report, 1997-1998).

-Attachments that have not been "repaired," an activity often leading to poor quality.

-Total decontamination: the adhesive-removal process that breaks vital carbon-to-carbon bonds in any chemicals or microorganisms.

-No metal loss; burnishing is a procedure used by all manufacturers.

-Our -cutting edge, sophisticated processes have been described in scientific journals.

-Eco-friendly processing that does not dump harmful pollutants (Cr, Ni).

-Thorough inspection of attachments, more rigorous than those of the original manufacturers.

-Renewed attachments good enough to make many customers desire to buy similar ones.

-Constant dialog through feedback questionnaires [toll-free number (800/82-CYCLE), fax (954/92104174), Web site (www.OrthoCycle.com)].

Company reputation

-Deal with a legal manufacturer that has been in business for 30 years, with a solid track record. It has never been charged or sued by a customer (except by frustrated, competing manufacturers!).

-Backed up by a modern research laboratory.

-Be part of a loyal customer base that grows every year because referral is our constant source of new customers.

-See what we do: visit us and tour our facility. We are open five days a week!

-Enjoy our highly attractive area.

A dedicated management

-Extensive experience and research in the field with over 100 papers, some 30 patents, scientific books and chapters in text books translated into many languages (see www.Matasa.net).

-Share an in-depth perspective recognized by attachment manufacturers; despite being competitors, some consider our knowledge of brackets "unmatched by anyone" (Advanced Orthodontics Co.).

-Benefit from surveys and audits that are continually used to improve quality and reliability.

-Expect continual improvement not only in finding defects and mistakes, but also in preventing their recurrence. Reports on weaknesses are welcomed. Feedback and complaints are encouraged.

-Depend on the results of a "zero-defects" policy followed despite the immense variety of attachments.

Useful information

-A detailed description of Ortho-Cycle and its news and activities can be found both on the Internet and in its trimestrial newsletter, *The Orthodontic Materials Insider* and at www.OrthodonticMaterials.com. Ideas expressed in this newsletter are often a source of inspiration for major manufacturers.

-Use it for understanding your everyday tools: "… a scientific beacon for the orthodontic community" (T. M. Graber) that "educates manufacturers" (Pyramid Orthodontics Co.).

Low price

-For most of our customers, price is not the primary buying factor. Nonetheless, take advantage of our highly competitive price per attachment, despite the superior, costly, high-tech processing and inspection.

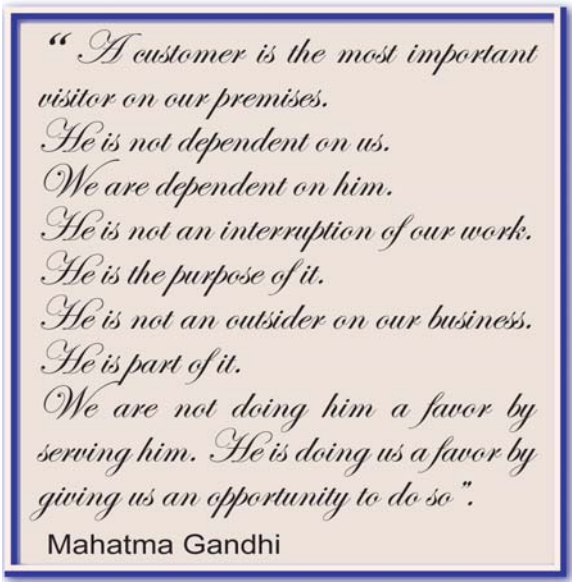
-Compare what you pay for a new attachment and what is asked for the same item (e.g. a molar band with multiple tubes or a modern, self-ligating bracket can cost over $10; we sell them for $2.00 or less!

Friendly, professional staff

-Enjoy interacting with people who are dedicated to follow Gandhi's customer-service precepts (**see box below).** We are happy to make money by saving you money.

-Communicate with employees familiar with international business and who speak several languages.

-Deal with customer-friendly professionals in the field who have the authority to make decisions and are empowered to improve our policies and procedures. They have remained loyal to the company for decades!



Is our CE Mark a testimony for quality?

Introduction

You can find the CE Mark on such diverse products as computers, x-ray machines and dental equipment—actually on some 22 groups of products that include medical devices. Without the guarantee of a CE Mark, European customs officials would not allow a product to enter. It has therefore been called the "trade passport to Europe," becoming a mandatory mark for some 70% of the products sold in European Union (EU) and European Free Trade Association (EFT) countries, and in countries to be included in the future enlargement of the EU in eastern Europe. Actually, all devices being put on the market in the EU after June 1998 must bear CE Marking.

Short history

The CE Mark started in 1957 when a group of European countries generated a single European market by signing the Treaty of Rome. Financial transactions, services and goods started to move freely across borders within the member states.

The mechanisms to overcome barriers by harmonizing standards and imposing consistent requirements for safety were called "directives." Failure to meet a certain directive became a criminal offense resulting in fines, impounding of product or imprisonment. The Treaty of Maastricht (1992) introduced new forms of cooperation between member state governments, leading to the EU.

In 1993, the EU introduced the Medical Devices Directive (MDD) 93/42/EEC. At that time and during the transition period, compliance with the directive was voluntary. By the summer of 1998, however, the MDD had become the basis of mandatory regulatory requirements for all medical device manufacturers selling their products in the EU. The letters *CE*, an abbreviation of *Conformité Européenne*, French for *European conformity*, were intended only to give companies access to the European market to sell their products without adaptation or rechecking. A CE Mark on products was intended initially to show only mandatory compliance with the appropriate health and safety requirements. By ensuring that a device presented no danger to the patient or end-user from a number of possible hazards, it became in fact a mark of quality.

Tough requirements

The International Organization for Standardization (ISO) standards for business management and quality systems are not only accepted throughout the world, but also held everywhere in high esteem. If being certified by the ABO represents the crowning of an orthodontist's efforts, then for a company that strives for excellence, the ISO has become compulsory.[1] To get a CE Mark, one has first to fulfill the conditions set by the ISO; because Ortho-Cycle has them both, this puts us in a league with any major company. Long considered a manufacturer, Ortho-Cycle has joined the major players that feel they cannot ignore the prestige, corporate image and marketing edge it has acquired.

This was not easy: the EU Product Directives include many additional product-specific requirements that must be met. At a minimum, this usually includes certain kinds of design, testing and validation records to demonstrate conformance to established EC standards for safety requirements. In other words, while an ISO 9000 registration only certifies that one has established an acceptable quality management system and does not signify the acceptance of products manufactured under the system, a CE mark certifies compliance. To demonstrate the European commitment to risk analysis as a design control tool, a guidance standard for risk analysis of medical devices was published in 1997.[2] It contains specific references to the two risk analysis tools as well as the international standards for their use. [3, 4]

Intended for human treatment, orthodontic appliances are usually placed by the Directives in Class I, which comprises non-active, unpowered devices that do not penetrate the body. In most cases, Class I devices pose little hazard to patients as they carry few hazards. This is not the case when the use of a device requires sterilization: the processing then implies an assessment by a Notified Body, an organization that checks whether appropriate conformity assessment procedures have been carried out according to the Directives. It performs evaluations and tests of certain products falling under regulatory control based on Product Directives issued by the EEC (the governing bureau of the EC).

Theoretically, to avoid legal interferences, ISO should deal with quality systems in management, while the CE Mark should focus on maintaining and improving product safety and performance. It is easy to understand that overlaps occur whenever the latter requires that the manufacturer of medical devices keep an efficient quality system. What other than quality is required by the Medical Devices Directive when it requests both adequate clinical data concerning the product's characteristics and performance under normal use and an evaluation of any undesirable side effects? Sentences such as "the physical characteristics and quality of the devices should not be adversely affected" followed by requirements that these should "meet all claimed performance criteria, and continue to function as intended" are eloquent...

How is the CE mark perceived?

Not a mark of quality in the traditional sense, it is next to it, as can be seen from the realistic reaction of many CE Mark–certified companies. Some trade on the definition by showing that "it serves its customers with the most current regulatory and quality assurance information available"[5] or that "it provides them with the assurance that a quality system is in place and that its products meet the stringent safety and labeling requirements of the Directive."[6] Others indicate that "the CE mark is a recognized symbol of quality assurance and indicates that a specific product is compliant with the requirements set forth by the parliament of the European Union"[7] or that "compliance with the European directives and regulations ensures a standard level of performance for device function, safety, and health protection for users, patients."[8]

Commenting on the CE certification of his company (Henry Schein, a company well known for its dental products), Stanley M. Bergman, CEO and president, stated: "We are very excited about receiving these approvals which further promote customer confidence in the quality and value of our Henry Schein brand name products and in our strong reputation as a world class leader in the healthcare distribution market. These approvals also enhance our sales and marketing efforts in the European Community as we continue to raise the standards of value and service in each country we enter."[9] Other manufacturers are even blunter in claiming quality: "The uses of materials that do not have the CE mark, whether imported or not, threatens the health and safety of personnel in the workplace."[10]

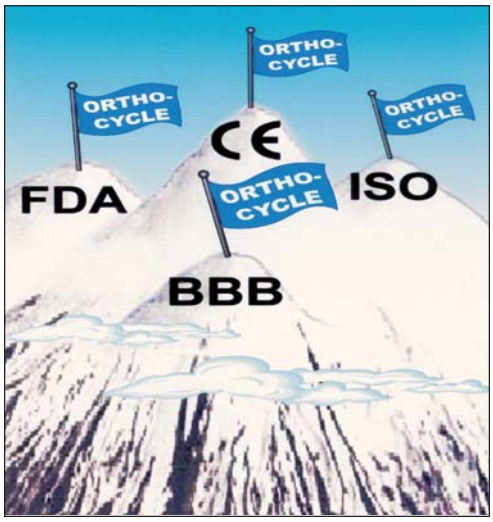
Ortho-Cycle and its certifications

The Food and Drug Administration, the US's watchdog for the health of its citizens, has accepted the marketing of Ortho-Cycle's reconditioned attachments since 1991. In addition, the company is a member of the Better Business Bureau (http://search.bbb.org) which provides information and reliability reports on more than 2 million organizations.

To be certified in Europe, Ortho-Cycle could have selected any of the Notified Bodies; most of these handle a wide variety of domains of activity and are less exigent. In contrast, to evidence its ability to comply with the most severe demands, it has selected for the purpose the Nordic Dental Certifications, former NIOM, branch of the Nordic Institute of Dental Materials (http://www.niom.no, Norway). The stated main goal of this institute is to ensure that dental products are safe to use and that they last as long as possible. Known for the many related publications released throughout the world, this institute continues to certify year after year Ortho-Cycle Company with all the necessary warranties such as ISO 9001:2000 (Quality Manual Systems-Requirements), and ISO 13485:2003 (Quality Systems, Medical Requirements).

ORTHO-CYCLE CO.
2026 Scott Street
Hollywood, FL 33020-2417 U.S.A.
1-800-82-CYCLE; (954) 920-9074
Telefax: (954) 921-4174
E-Mail: Matasa@aol.com
http://www.OrthoCycle.com
http://www.OrthodonticMaterials.com

PRSRT STD
U.S. POSTAGE PAID
PERMIT NO. 427
SO. FL. FACILITY



Nec plus ultra: Ortho-Cycle won them all...

To ensure, year after year, the conditions leading to certifications under the supervision of a highly specialized institution from another continent doesn't come cheap: at Ortho-Cycle we are committed to satisfying our customers and delivering defect-free, reprocessed orthodontic attachments. The continuous exposure to certifying organizations has paid off: the attachments we process are better inspected than the new ones, as witnessed by the many brand-new—but defective—attachments we continue to find and expose.[11-15]

References

1. Kuftinec M, Matasa CG, ISO 9002 Certification, Am. J. Orthod. Dentofac. Orthop. 2000; 118: 583-585
2. Medical Devices - Risk Analysis, EN 1531, Annex D
3. Procedure for Failure Mode and Effects Analysis (FMEA), - IEC 812
4. Fault Tree Analysis (FTA), IEC 1025
5. Lone Star Medical Products, www.lsmp.com/html/products/cemark.html
6. Oxoid Co., www.laboratorytalk.com/news/oxo/oxo184.html
7. SCL, http://www.schleicher-schuell.com/icm11be.nsf/ (html)
8. Philips, www.medical.philips.com
9. www.prnewswire.co.uk/cgi/news/release?id=22017
10. www.manufacturingtalk.com/news/trw/trw100.html
11. Matasa CG, Flaws in bracket manufacturing, J. Clin. Orthod. 1990; 24(3): 149-152
12. Matasa CG, Fallas sistematicas en la fabricacion de los brackets de pegado directo (In Spanish: Systematic errors in the manufacture of direct bonding brackets), Ortodoncia, Buenos Aires, 1991; 56 (109): 5-10
13. Matasa CG, Defend yourself against faulty appliances. I. Faults due to poor manufacturing. J. Gen. Orthod. 1991; 2(4): 5-9
14. Matasa CG, Defend yourself against faulty appliances. II. Alterations produced by wear, debonding and poor reconditioning, J. Gen. Orthod. 1992; 3(2): 13-17
15. Matasa CG, Orthodontic brackets: Should the new ones be considered a standard? (In French and English) Revue d'Orthopedie Dento Faciale, Paris, 2000; 34: 459-476.