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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.

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INVISALIGN REVISITED

In our June 2000 issue, we published an article entitled “The Congress laughs, sings and dances”. The irony was that this report, written home by one of the diplomats attending the Congress of Vienna, the assembly destined to redraw Europe’s borders while Napoleon was advancing unopposed to Paris, matched the spirit of some of the participants to the 100 years jubilee of the AAO. Indeed, a month before, Time magazine listed orthodontics as one of the professions that will disappear, the brackets being replaced “by a series of

disposable, clear-plastic aligners that will shift teeth into position”.

At that time, we published the opinions of several manufacturers. After two years, we have asked that of several clinicians, and subjected them to Prof. Dr. MM Kuftinec of NYU, an orthodontist [MK], and to Prof. Asst. Dr. M. Radu, a general practitioner using Invisalign [MR]. After analyzing the pros and cons, they presented their opinion, as it will be seen below. We asked then Prof. Dr. T.M. Graber of UIC, a pioneer in both removable and fixed appliances, to draw the conclusions.

Before the analysis, we would like to show how open minded the orthodontists can be:

“Ladies and gentlemen, welcome to the new millennium! Orthodontics is changing! Rapidly! We should “embrace” and support those changes with open arms—a positive and encouraging attitude—while at the same time maintaining a totally objective and scientific approach. We should be so thankful that a commercial enterprise was able to raise the vast sum of money required to develop such an awesome technology...that is only in its infancy. Who else was going to do this for us? The AAO? A traditional orthodontic supplier? My only regret is that it wasn’t my idea! I’m sure none of you have heard of Lasik or MRI’s or Cardiac Cath Labs... Where has orthodontic technology been? The costs involved to develop this technology are mind-boggling... and our patients and we are the direct beneficiaries of this exciting process. We could not have afforded to develop this technology via the status quo. Rest assured more is yet to come”... Dr. Lester Kuperman.

Q: Is there a difference in the principle of treatment between bracket and Invisalign treatment?

MR: The principle is the same. The practitioners diagnose the occlusal problem, plan future teeth position, and hopefully in harmony with the muscles and joints, and the appliances are fabricated accordingly to bring the teeth to the desired position. The differences are in the computerized simulation



Are today’s fixed appliances... edgewise?

of the treatment plan in the case of Invisalign and in the appliances themselves.

MK. Here I expect to differ in my views with my colleague, Dr. Radu. The essential difference is that the fixed appliance system incorporates the 3-D [three-dimensional] control of tooth movement. If I can be just a little boisterous, I will state that we can achieve a tooth movement in any direction, to almost any degree. Invisalign is still far from such a claim and possibly will never get that “good”. Generally, only mild or simple problems are suitable. This simple malocclusion must be confined to the individual arch irregularities, while the interarch relation must be fairly harmonious. Examples of malocclusions suitable for correction include: mild crowding, simple spacing, mild rotations with loss of proper contacts between the teeth, malposition of a tooth or a small group of teeth that can be corrected by the simple tipping.



View of the Align Co. stand at AAO's 102nd Annual Session

Q. Have orthodontists not previously had similar appliances that were capable of such simple tooth movements?

MK. Historically, such simple corrections were being made with the use of inexpensive removable plastic appliances, positioners and more recently with the Essix type of retainers. It is important to make a point that all these simple appliances have been used in preparation of, in addition to or after the use of the fixed appliances. Also, all these appliances are significantly less expensive than the current form of Invisalign.

Q: What is the main benefit of this new type of orthodontic treatment?

MR: There are some benefits of great value to the patients. The “invisibility” factor is huge. People want to look good, but, with bracket orthodontics, they first they have to go through a period of looking ugly. Not so with Invisalign. The increased comfort in chewing, speaking, and oral hygiene are also significant with Invisalign.

Another significant factor is the principle itself. I hope to not attract disdain of my colleagues if I dare to say that presently, the tooth movement induced by the appliances is often not controllable and perfectly predictable. If we could incorporate in the computerized treatment plan all data (age,

sex, growth, tooth size and position, tongue size and habits, lip type, mandibular position in relationship to the maxilla, desired result, etc.), we will get an intelligent system that could get us the ideal appliance to bring the teeth within the arches, the arches on the bone bases, and the two jawbones in perfect alignment! This is, in my opinion, the potential of this “computerized” treatment plan. The “invisibility” is almost secondary! Obviously, the present “Invisalign” is not doing most of these things, but the principle is there.

On the other hand, even in the present form, Invisalign may allow an easier alignment of the teeth in the desired occlusion. If the practitioner subscribes to the concept that maximum intercuspation should happen with the condyles seated in their respective fossae (centric relation), it is possible to record the interarch relationship before treatment and ask the fabricator of the aligners to move the teeth in that position.

MK: It would be both foolish and closed-minded not recognizing certain benefits of the Invisalign system. Absence of corroding metals is just one: no one can argue that point. Similarly, esthetics of the new system is superior. Next, we are assigning or delegating a degree of control to our patients, who may chose to wear an Invisalign device, or not to wear it at any given time. Clearly, such an option is not available to a patient wearing the conventional fixed orthodontic appliances.

Q: Given these advantages, will Invisalign replace orthodontics, as we knew it?

MR: No, or not for a long time. No, because not all cases can be solved with this treatment. In the long run, I can imagine lots of changes and additions that could be incorporated into an “invisible” appliance to make it more versatile than the present Invisalign.

MK: Not in its present form. It is still the work in progress, with numerous limitations. The concepts on which Invisalign is based will likely survive and make a major impact on orthodontic treatment, as we have known it for a long time.

Q: Which are its limitations?

MR: Aside from the limitations of indication, another issue may be compliance of the patient. Cost of the appliances from the manufacturer to the doctor is another disadvantage, making it somewhat of a niche market. On a lighter note, a disadvantage may be if unqualified practitioners will start treating a lot of patients and will prove unable to finish them. It is not an “over-the-counter” treatment like purchasing bleaching strips; this is another issue altogether.

MK. The words ‘quality’ and ‘quantity’ come to mind. Obviously that is the main reason why the Invisalign system poses limitation on the kind and the severity of the problem attempted to be treated. There are many examples where these two characteristics come to play. Let’s first look at the quality of the movement or correction. Interarch discrepancies, be they in sagittal, transversal or vertical plane, essentially cannot be corrected with Invisalign devices. Orthopedic forces, such as growth modifying appliances, functional appliances, various headgears and similar, presently cannot be used with Invisalign. Generally, only mild or simple problems are suitable. This simple malocclusion must be confined to the individual arch irregularities, while the interarch relation must be fairly

harmonious. Examples of malocclusions suitable for correction include: mild crowding, simple spacing, mild rotations with loss of proper contacts between the teeth, malposition of a tooth or a small group of teeth: these can be corrected by the simple tipping.

Let's now visit the quantity. For treatments of a variety of malocclusions we need to set up or supplement the anchorage. This is done with various trans-palatal arches [TPA], lingual arches, cervical anchorage, and very often with the properly prepared opposite dental arch. Invisalign, in its present form, simply does not provide for such planning and treatment execution. To put this differently, invisalign allows only the intra-arch corrections.

Q. Can I interpret your answers to mean that perhaps the present form of Invisalign would be best used in conjunction with the fixed appliances and the other devices you mentioned?

MR. There are limited such indications for Invisalign at this time. When the fixed appliances would be needed, the cases may be finished with an inexpensive retainer. It is hard to make patients pay for Invisalign at the end of a fixed appliance treatment, unless the price of the aligners will drop significantly.

MK. Yes, you can draw that conclusion. Fixed appliances are still biomechanically superior, because we have full control of tooth movement in all 3 dimensions. Adding Invisalign to our armamentarium of orthodontic tools or devices will make our ability to make our treatments more efficient and esthetically more pleasing for our patients.

Q: What will be the impact of Invisalign on the general dentist? Do you think more general dentists will pick-up orthodontics using this new modality?

MR: I believe more general dentists will do orthodontics this way, because it is simpler for the practitioner to be given the aligners fabricated by the computer, than to get involved with bracket bonding and wires. In addition, the treatment plan is made easier by the computer simulation. We have a feasibility factor incorporated into the treatment planning.

Q: What about the public? Do you think more people will seek orthodontic treatment?

MR: Absolutely! The public wants to look good and feel good while getting there.

Q: How do you see the future of orthodontics?

MR: I have never been more optimistic for the future of orthodontics! I see an important role of the "invisible" modality of treatment, especially after incorporating changes to allow a complete range of treatment, for all age groups. It is easy to bash a new modality of treatment as being in its infancy. The motorized carriage was at first discarded as being unreliable, noisy, dangerous, expensive, and without a future. Not too many horse breeders jumped on the bandwagon and got into the car manufacturing business. Let's hope that now, the more qualified, more experienced, and better positioned insiders, i.e. orthodontists, will help out and not be an obstacle to this new development.

MK. That is an interesting question. I have no doubt that the fixed orthodontic appliances, although different from the current versions of the preadjusted brackets, will be used in orthodontics. Invisalign, on the other hand, in its current form probably will not survive. Some other, improved version of

invisible devices may be developed. Such a new development, however, would need to have a more predictable and more powerful method of correcting malocclusions, thus eliminating many of its current limitations.



View of the Align Co. stand at AAO's 102nd Annual Session

TMG. The concept of computerized diagnosis is firmly entrenched in orthodontics, but computerized treatment is still controversial. One approach that has received public press coverage is the Invisalign appliance, referred to above. The study models are made per instructions from the manufacturer and sent to technicians in Pakistan for fabrication of a clear plastic appliance. Multiple appliances are made, each time with computerized changing of irregular tooth position a minute degree, with ultimate correct alignment the goal. To achieve correct position, usually interproximal stripping or slenderizing is needed. Contact points become contact surfaces, as arch length is gained through proximal tooth surface reduction. The appeal has been the excellent appliance cosmetic appearance, ability to remove such appliances that are under patient control, and lack of arch wires and brackets, headgears, palatal arches, implants, onplants, etc. The cost factor is considerable, so that fees for such alignment are generally greater than conventional fixed appliances.

The answers to the questions by Drs. Kuftinec and Radu cover some important considerations and raise some questions before the predictions of Time magazine, that this will be the ultimate approach for orthodontic appliances coming to fruition.

First of all, the primary utility for Invisalign is with individual tooth irregularities, particularly in the lower anterior segment. Properly chosen cases can show excellent results. But diagnosis is the name of the game for all orthodontic mechanotherapy, and particularly for this limited approach appliance—at least in its present form. A large proportion of patients treated by orthodontists have basal or skeletal malrelationships, with the teeth reflecting this condition (i.e. Class II, Class III, deep bite, open bite). The teeth are where they are because the jaws are where they are, aided and abetted by motivating musculature. Thus the problem is multi-system; i.e., skeletal, dental, neuromuscular. Merely aligning teeth does not

correct the morphogenetic pattern or skeletal malrelationship, no matter how much interproximal tooth enamel reduction is done. For such patients, growth guidance is a major approach with fixed appliances, extraoral appliances and functional appliances. This immediately limits use of Invisalign, which cannot replicate such needed correction. Most patients are not anxious to have both Invisalign and fixed appliances to produce the achievable optimum. Indeed, the vast majority of patients are adults with “crooked and unsightly teeth”, seeking a cosmetic correction. The choice of tipping the teeth off basal bone without enamel reduction is not usually a viable alternative. Slenderizing by interproximal enamel reduction can achieve 4-6 mm of arch length in many cases, depending on tooth size, shape, etc. However, replacing tooth contacts, as designed by nature, with broad contact surfaces has potential iatrogenic implications, particularly in the lower anterior segment—the reason most patients seek orthodontic care: i.e., crooked lower front teeth. Dr. R.L. Vanarsdall, who is both an orthodontist and periodontist, points out that too much reduction jeopardizes the health and longevity of interproximal bone. Broad contact surfaces make prophylaxis more difficult. Alveolar bone can recede and gingival recession is also a potential consequence. The nice gingival scallop disappears and periodontal problems may be enhanced. In other words, “What price cosmetic orthodontics?” What about the periodontal problems created? Is this iatrogenic potential worth the improvement in looks? You can be sure from the exponential increase in malpractice cases these days that legal vultures are

circling overhead right now! Failure of this approach to solve many orthodontic problems, covered subsequently in the press, hurts all of orthodontics. It is not the appliance, but why you use it, how you use it, when you use it, for how long you use it, and how you finish cases where only partial correction is achieved by Invisalign.

Another limitation is that patient compliance is critical. Most adults pay enough money for this service to be motivated, but not all. And with children, if this approach indeed replaces fixed mechanotherapy, the challenge is infinitely greater. Like expensive hearing aid losses, such appliances can easily “disappear.”

Yet, with properly chosen cases, comprehensive diagnostic study, which only an orthodontic specialist can truly provide, normal TMJ conditions, judicious slenderizing, optimal compliance, soft tissue care, protection of altered contact surfaces, and patience, there are many adult patients that can benefit from this approach. Not by general practitioners with weekend, tailgate, motel, quickie weekend courses, or with handholding by Invisalign fabricators, or those desiring a means of increasing their income or enhancing their public image by doing orthodontics.

It is not new philosophically. Positioners and Sheridan type plastic appliances have been doing this job for a long time. The patient should be prepared for the limited change possible and the potential need for fixed appliances to produce the achievable optimum.

Orthodontics as a specialty is neither dead nor dying.

ARE THE DO-IT-YOURSELF TESTS QUESTIONABLE, OR UNDESIRABLE?

In 1995, the Orthodontic Materials Insider had its first article dealing with do-it-yourself (DIY) tests published: since then, several others followed. In this Editor’s mind, there is not enough information on the materials the clinician uses. According to Proposition 65, or the Safe Drinking Water and Toxic Act of 1986, he should not use any products that are toxic, mutagenic, carcinogenic and oestrogenic, a recommendation that today can hardly be taken seriously: most of these actually are so....

Dura lex, sed lex. (Latin: The law is tough, but it is the law.). Interestingly, since 1988, more than 2,600 60-Day Notice letters have been filed with the California Attorney General, affecting over 9,600 separate businesses, and among these, dental offices. More than 200 Proposition 65-related lawsuits have been formally litigated, including more than 175 enforcement actions; at least another 600 Proposition 65 cases have been resolved through either court approved or out of court settlements—most with citizen enforcers of Proposition 65.

More than \$250 million in fines have been levied through various applications of the Proposition. Its unique requirements, extreme penalties, national and international reach make it one of the most important and dynamic environmental laws in existence today.

According to paragraph 25249.6 of this law entitled Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive Toxicity, “*No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual*”. Among these chemicals may well be the retainers softened with phthalates, the aligners or the adhesives prone to hydrolyze freeing bis phenol A (Bis GMA and the polycarbonates),etc.

Searching the Internet for Proposition 65 under “dental” (www.prop65news.com/prop65-cgi/lit_index.cgi), we found the following lawsuits that hit home:

-Los Angeles vs. Consumer Cause v. Darby Dental Supply; Date 1/5/2001, Case No. 243039

-Los Angeles vs. Consumer Cause v. Western Dental Centers; American Orthodontics, Lancer Orthodontics. Date: 2/3/2000, Case No: 225425

-San Francisco vs. ELF v. Angress Dental Supply. Date: 11/14/2000, Case No.316647

-San Francisco vs. Kids Against Pollution v. American Dental Association. Date: 6/12/2001, Case No: 322109

-San Francisco vs. Tibau v. American Dental Association. Date: 6/12/2001; Case No.322110.

As the time passes, this law and some other related ones would be increasingly enforced. How many offices are compliant with specific demands such as:

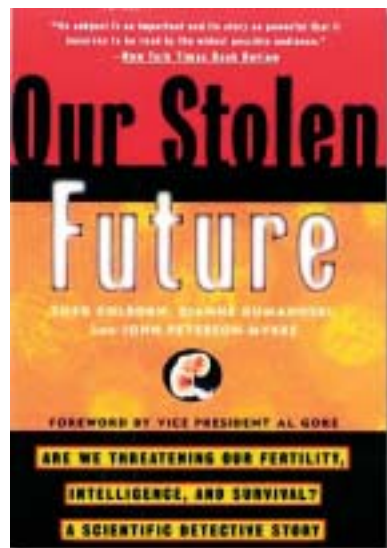
“Any company with ten or more employees that operates within the State or sells products in California must comply with the requirements of Proposition 65.

Under Proposition 65, businesses are:

1) Prohibited from knowingly discharging listed chemicals into sources of drinking water; and

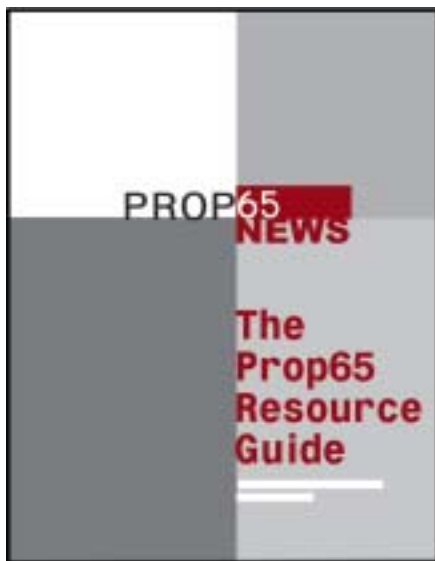
2) Required to provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, by posting signs at the workplace, or by publishing notices in a newspaper.”

The future. Inflammatory articles and books will continue to scare the public, obliging legislators to take measures, and determine law enforcers to act. Endorsed by Al Gore, at the time Vice President of the US, a book entitled “Our Stolen Future” was followed by



governmental organizations try their best to protect the public, it is unlikely that these will ever be able to catch with all the new products that are launched every year on the market. Even if this was possible, attention will always focus upon the most hazardous ones (Class I, according to FDA and ISO).

The need for do-it-yourself (DIY) tests will necessarily increase as the laws become stricter and the number of products launched become too large to be properly investigated, despite of the increased number of publications. Recently, the DIY testing has penetrated even into the inner sanctum of medicine, the prescription drugs. A new clinical-trial system promises to speed the trial-and-error process to find the drugs that work the best for a certain individual by testing how he responds to drugs.



“Hormonal Chaos”. Both report actual cases and ask for more control. Chances are that, like the hysteria that followed after Rachel Carson’s book “Silent Spring”, the indiscriminate banning of a series of pesticides, may happen again. In the medical field, for some twenty years, dimethyl sulfoxide was banned even as an ointment: today it can be taken even orally (jacobs@ohsu.edu).

While both governmental and non-

Opt-e-scrip (www.opt-e-scrip.com), a mail-order pharmacy in Morristown, NJ, releases patented test kits for up to 16 common chronic conditions, the patient doing the actual testing.

An example closer to home is the testing of heavy metals released from stainless steel brackets. According to the literature, “the maximum release of nickel in new brackets reaches a maximum in the first week, after which it declines”², and “the cumulative amounts of nickel and chromium released reaches a plateau after 6 days”³. This can be demonstrated by using a simple egg holder and hydrochloric acid from a pool supply. The following simple, in vitro experiment leads, to similar conclusions, as seen in Fig. 1-3. In each egg compartment, several types of brackets were subjected to the same diluted acid solution (5%) in three steps. After each step, the liquid was removed and replaced with the same, but unspent acid. In addition to a significant variation in color that indicates the brackets the most susceptible to corrosion, the test shows

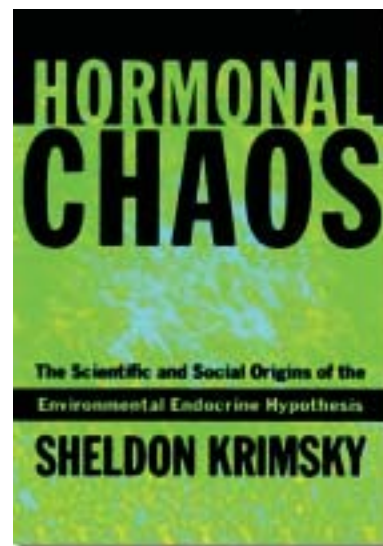
that while most metal active sites are quick to react, the attack takes, in time, a milder course. In other words, the brunt of the leakage occurs in the bearer of new brackets.

In our previous issue we have shown that with the help of a simple experiment and using a common disinfectant, it is easy to rank various acrylates in regard to their undesirable releases. To arrive to similar results, researchers at the University of Freiburg had to use sophisticated means such as high-pressure liquid chromatography (HPLC)⁴.

Attitudes versus DIY. Throughout the years, the American Association of Orthodontists has shown interest in methods that cannot but help the clinician protect his patients, or allow him to evaluate the products offered. Thus, at its 102nd Annual Session in Philadelphia, this writer has presented two posters^{5,6} and a lecture⁷ on related matters.

At the time being simple and instructive, some of these DIY tests have been used in universities as student projects both in the US and abroad, some of them being the basis of masters’ or doctorate level theses.

While, by and large, clinicians are too busy to try them, such simple tests have called the attention of few who





Twelve brands of brackets successively subjected to batches of 5% hydrochloric acid. **a.** After 24 h from the first addition. **b.** After 48 h since the spent acid has been replaced. **c.** After another 48 h since the last spent acid has been replaced.

Observe disintegrated brackets in compartment **b** 10

have developed also their own testing methods. Most clinicians have, however, shown interest in their results as these tests are appealing because of both their simplicity and ease of duplication.

Annoyed by the interference of the governmental organizations in their business, most manufacturers are understandably predisposed against any other influence or outside suggested tests, especially if these may bring or reveal problems. An example is the letter attached, where the signer refuses to provide samples and asks this investigator to stop “misleading the clinicians into thinking that they can select the least harmful polymer”, while recommending to leave the matter in the hands of

FDA: “Only its methods can measure toxicity and harm”. The sad and illustrative part of this is that the method referred to as “disturbing and technically unfounded”, the “Permanganate Index”, was based upon ISO tests, and is actually recommended by FDA⁸, a fact we didn’t mention in the article quoted. The only difference from the FDA test is that instead using a spectrophotometer for obtaining accurate values, a simple visual reading was found to be enough for comparisons.

Conclusions. Only through a cooperation between all the parties involved, the patient, the clinician, the manufacturer and the investigator, be it governmental or not, the present untenable situation can be resolved. To be forced to use materials that have been found to be hazardous requires from the clinician extra measures that may vary from case to case in balancing benefits versus risks, and any help should be welcomed. DIY tests should be used at least for screening. Otherwise, the list of those infringing upon Proposition 65 and the future other, similar laws will continue to grow, while the patients will continue to suffer.

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A LEACHING TEST FOR PLASTIC RETAINERS

No matter which are the leached substances, leaching plastics are detrimental both to the appliance and to the patient. As shown above, it is a preoccupation of both FDA and ISO, who each has developed sophisticated methods for its detection. Aside from the sophisticated means and labor, the procedures recommended by these organizations require also the honest cooperation of the plastic's manufacturer, who is free to supply any samples as long as these have the required sizes.

Reduction under liquid nitrogen. Used to disintegrate tissues in biology, the procedure renders the parts brittle by grinding them in a special, double walled stainless steel mortar at very low temperatures (-196°C). Liquid nitrogen can be obtained from air processing plants as long as large mouthed, metal cryogenic (Dewar) transfer vessels are used. When handling it, the operator should be protected against its droplets that spread and may freeze the skin, Fig.1. At such temperatures, where a latex glove



Fig. 1. Transfer of liquid nitrogen into a cryogenic container allowing the immersion of a steel tea-basket



Fig. 2. Reduction of the deep-cooled plastic materials and a stainless steel tea basket

Materials and method

Based upon the principles described in our previous issue (March 2002), we have applied the modified "Permanganate Index" to several retainers collected from various manufacturers during AAO's 102nd Annual Session, as well as from the neighborhood's drug stores. In doing so, the first hurdle was the difference in shape between what was needed for the test and what was supplied. Indeed, while the test requires particles fine enough to expose a large surface area to extraction, the samples were bulky and difficult to pulverize. Normal mechanical means (mortar and pestle) do not work due to the resiliency of the rubber-like materials, and any heating would alter their composition.

becomes hard and a lead bell sounds like crystal, the normal grinding of the various plastic appliances tested proved to be unsuccessful. It had to be replaced by crushing the cooled samples with a hammer immediately after their removal from the cryogenic vessel. For the operation, the plastic samples were contained in purposely-flattened stainless steel tea-baskets as shown in Fig. 2.

The eleven appliances tested, i.e., 1.Night Guard (Grinding Protector); 2.Essix "A"(Retainer); 3.Ortho Tain (Retainer); 4. Tru-Tain (Retainer); 5.Therabite (Wafer); 6.Tru-Fit Junior (Mouth guard with strap); 7.Essix Embrace (Retainer); 8.Invisalign (Aligner); 9.Myofunctional Research (Retainer); 10.Essix C+ (Retainer); 11.Tru-Fit Junior (Strapless mouth guard)

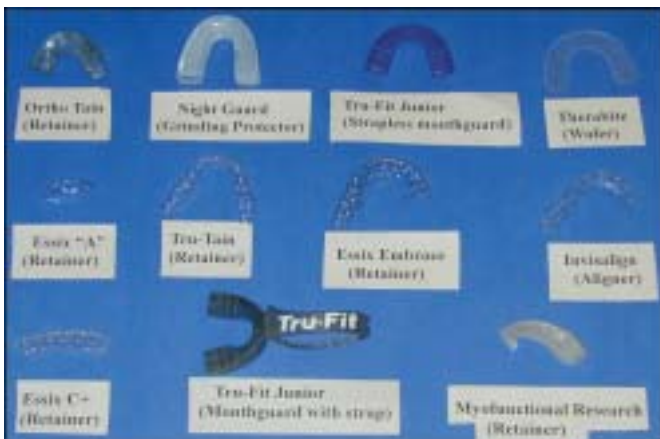


Fig. 3. The plastic appliances tested



Fig. 4. Particles obtained after the deep-cold reduction.

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are shown in Fig. 3. The particles of similar sizes obtained after reduction are shown in Fig. 4. From each reduced material, 0.2 g was immersed in 5 ml of a potassium permanganate solution hosted in the dents of an egg-holding platter: the solution was, as shown in our last issue, diluted enough to allow the reading of newspaper letters through a layer one inch thick. The arrangement where the number of each plastic was maintained is shown in Fig. 5a and b. The operation was repeated, as in the first time it was performed without any addition: the second time, the spent, neutral solution was replaced with a fresh one after being brought with phosphoric acid to a pH 1. After a 24 hour exposure at room temperature, in both cases the plastic particles were well hydrated, some even becoming submersed (No. 3, 4, 7, 8).

The photographs shown in Fig. 5, taken with a Nikon Coolpix 950 camera, show that No. 10, 4, 7 & 8 maintained well their color when compared with the control, an unaltered permanganate solution. The others suffered a marked discoloration, decreasing from No. 11 (maximum) to 1, 3, and 5. The least leaching, the C+

retainer from Essix is claimed to contain, or be based upon polypropylene, a polymer known for very little water affinity.

Discussion and conclusions

Some of the appliances tested were designed for a short exposure to the oral environment (the athletic ones, such as the Tru-Fit Junior (Strap or Strapless, No. 6 and 11 and the mouth guard), while others for a longer exposure, either singly or repeatedly (The number of Invisalign[®] aligners needed for a treatment may exceed 40).

For the first type there is not much concern. As it can be seen from their poor performance, however, some the appliances destined for a prolonged contact with the oral environment should draw attention. As it was expected, the soft ones (plasticized polyvinyl chloride, see past issue) leached the most, while the hard ones, the least. Although crude and reduced to maximum simplicity, this test is derived from FDA and ISO requirements that are enforceable: it is up to the clinician and the manufacturer to make the proper decisions.

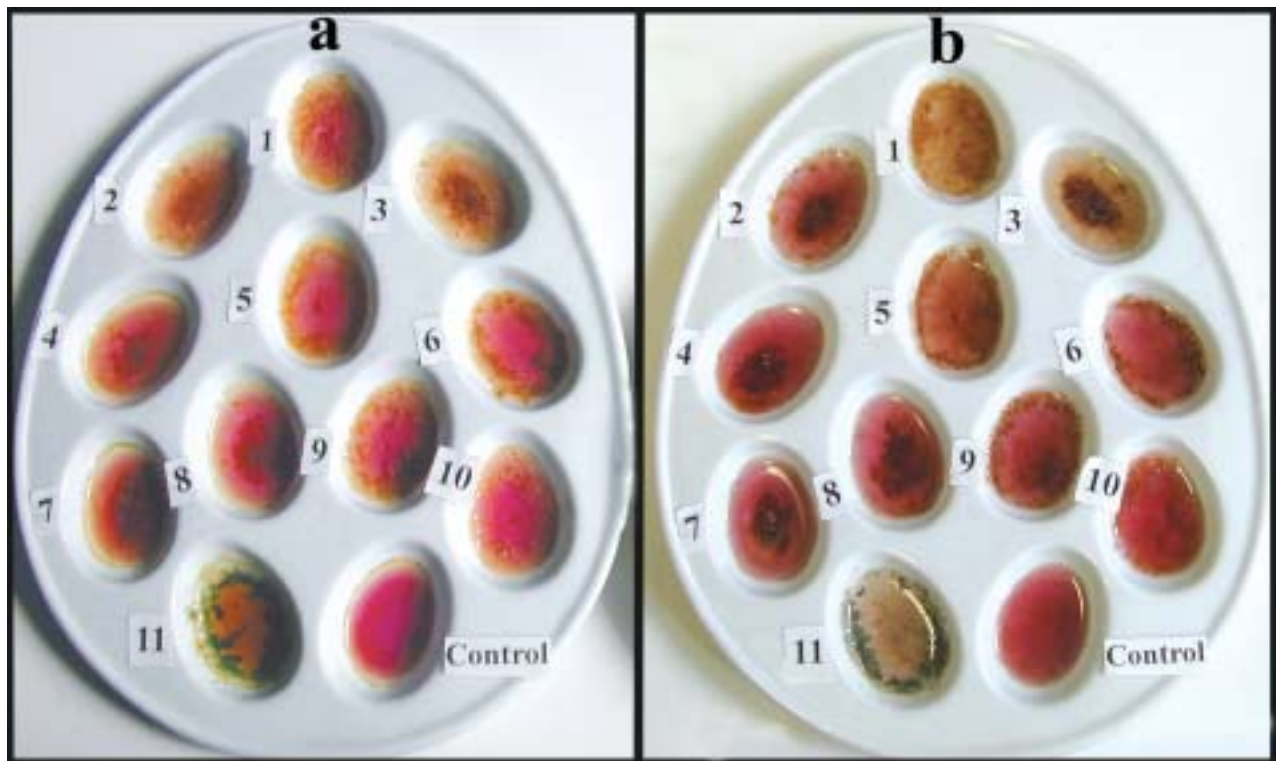


Fig. 5. Retainer particles in permanganate solution after a 24 h exposure. a. In neutral environment b. After replacing the spent solution with a new, acidulated one.