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In This Issue:

Letter from the Editor – David C. Sarrett, DMD

It's been more than 20 years since clinicians routinely began reaching for exam gloves. While the ability of dental gloves to prevent disease transmission is vital for patients and dental personnel, there is some inherent risk in using any infection control product. Although data indicate that the risk of transmitting bloodborne pathogens in health-care settings—including dental offices—is low, some risk is unavoidable.

In this issue, we take a look at the integrity and performance of gloves in two articles: A Laboratory Analysis of Latex Examination Gloves and Evaluating the Water Tightness of Powder-Free Natural Rubber Latex Exam Gloves Following Simulated Clinical Use: A Pilot Study.

The performance standards for regulatory approval of dental gloves are well established, but they don't address wear performance or simulated use. The only testing necessary to meet the standard is conducted on products taken right from the box. It may surprise you to learn that a certain level of glove failure "out of the box" is allowed in standardized laboratory glove testing. And, in a sample test size of 125 gloves, seven may fail and the overall sample still can be deemed acceptable. I think you'll find the laboratory and clinical simulation results interesting.

Also in this issue is the first of two articles on Bisphenol A (BPA) in dental materials. In the past year, there's been increased media attention on BPA and its potential impact on health and human development. Sensational headlines have linked BPA to everything from heart disease, coronary artery disease, and obesity to diabetes and immune system and reproductive disorders. The *Update: Bisphenol A in Dental Materials* explores the question, "Why would BPA appear in 'BPA-free' dental materials?" It also examines BPA exposure levels and how to address patient concerns. In a future issue, we'll report on the ADA Laboratory's evaluation of BPA in dental materials.

Lastly, we've included *Palliative Over-the-Counter (OTC) Treatments for Oral Dryness and Associated Inflammation*, an overview of clinical approaches for managing oral dryness with over-the-counter products. The article includes examples of the various types of products available on the U.S. market.

If there's something you'd like to see in the ADA Professional Product Review, drop me a line at pprclinical@ada.org.

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Update: Bisphenol A in Dental Materials

Stephen E. Gruninger, Amer Tiba, PhD, Nina Koziol

The issue. The controversy about Bisphenol A (BPA) and its potential impact on health and human development received increased media attention in the past year. Headlines have linked BPA to heart disease, coronary artery disease, obesity, diabetes, and immune system and reproductive disorders.

BPA is a common component used to make polycarbonate plastic and epoxy resins. Polycarbonate plastics are found in countless everyday items such as food and beverage containers, eye glasses, cell phones, bike helmets, children's toys, plastic tableware, some types of receipts, self-adhesive labels and a host of other consumer products. Epoxy resins are often used as protective coatings inside metal food cans. The primary source of exposure to BPA for most people is assumed to occur through the diet[1] although industrial and household wastes released into the environment are other sources.

BPA, which has been used in consumer products since the 1960s, was used in the manufacture of some dental materials.[2-4] Dental sealants were identified in 1996 as a source of very low-level BPA exposure[5] and a recent study published in the Journal of the American Dental Association reports that "placement of resin-based composite restorations was associated with detectable increases in saliva of BPA and other study compounds within one hour after restoration placement and increased concentration of BPA in urine nine to 30 hours after restoration placement."[6]

Some manufacturers of dental composites and sealants market their products as "BPA-free," yet some studies have detected BPA in the saliva of patients within minutes following placement. BPA-free usually means that no BPA is added to the product, or that residual BPA is below the detection limit of the analytical method used to make the claim.

So, why would BPA appear in "BPA-free" dental materials?

Composite restorative materials are made from a mixture of ingredients where bisphenol A glycidyl methacrylate (bis-GMA) is the major component. BPA is a critical starting material used to manufacture bis-GMA and many other methacrylates used in sealants and bonding materials.

Looking at the structures of BPA and estradiol (Fig.1) you will find similar features between the two compounds that impart at least some ability for BPA to bind to mammalian estrogen receptors.[5]
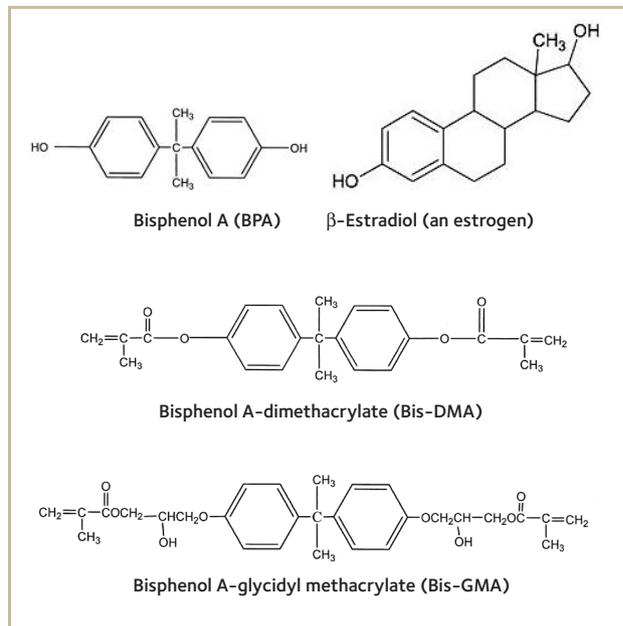

Figure 1. Major compound structures involved in the issue of BPA toxicity

Bis-GMA is an extremely viscous material making inclusion of polymerization initiators very difficult without adding modifiers to change its handling properties. An example of one of these modifiers is bisphenol A dimethacrylate (bis-DMA), which, when mixed with bis-GMA, reduces viscosity sufficiently to allow the addition of stabilizers and polymerization initiators resulting in a homogeneous mixture that is easily handled. BPA also is used to synthesize bis-DMA.

Materials containing bis-DMA can release very small quantities of BPA after coming in contact with salivary enzymes (esterases) (Fig.2).[7]
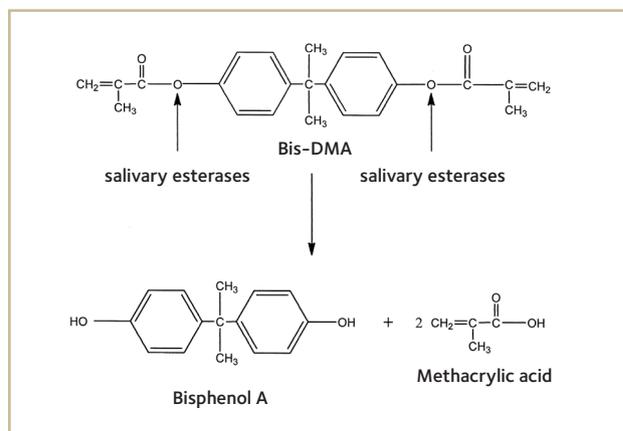

Figure 2. Hydrolysis of bis-DMA to BPA by salivary esterases

Several alternative aliphatic viscosity modifiers often are used instead of bis-DMA. One of these alternatives is TEGDMA, which is not synthesized from BPA, nor does it decompose to BPA (Fig 3).
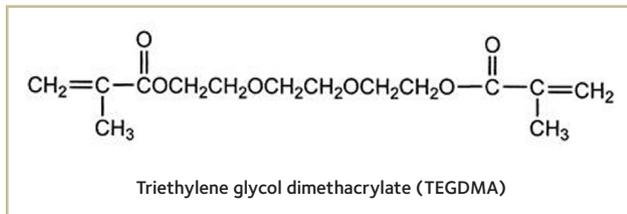

Triethylene glycol dimethacrylate (TEGDMA)

Figure 3. Triethylene glycol dimethacrylate (TEGDMA)

Materials made with bis-GMA do not undergo esterase hydrolysis.[7] Sealants, bonding agents and composite resins developed with bis-DMA and/or bis-GMA may contain trace amounts of BPA as a byproduct of the manufacturing process. Careful formulation during the manufacturing process for bis-GMA keeps the unreacted levels of BPA to a minimum, but some residual trace levels of BPA can remain. Manufacturers of materials containing dental resins do not manufacture bis-GMA themselves. Bulk bis-GMA is purchased from at least 22 worldwide suppliers of bis-GMA.[8] Four suppliers are based in the United States, 11 in mainland China, three in Hong Kong, three in Germany and one in the United Kingdom. It is unknown how well residual levels of BPA are controlled among these manufacturers.

Polymerization of bis-GMA containing materials involves free-radical chemical reactions. Oxygen in the air interferes with this process causing incomplete polymerization at the bis-GMA/air interface. Thus, any newly placed restoration or sealant will have a thin surface layer of incompletely polymerized material, which is rapidly lost within hours post-placement. This could be the reason that the Kingman study[6] detected higher levels of composite components (including BPA as well as bis-GMA) in saliva and urine after placement than before placement. However, as in other studies, component release became significantly reduced or undetectable within hours,[6] and exposure to these substances seems to be acute, not chronic.

What level of BPA exposure produces harmful effects in humans?

This is a key question and the subject of active research today. A decade or more ago, several studies showed that clinical levels of BPA in various body fluids were transient and rapidly fell below the detection limit of 1.0 to 5.0 ng/mL (1.0 - 5.0 ppb) by the high pressure liquid chromatography (HPLC) methods used at that time.

However, a proliferation of subsequent studies using more sensitive liquid chromatography/mass spectrometry (LCMS) analytical methods reduced BPA detection limits to 0.02 ng/mL (50 times lower). The more sensitive methods appeared capable of detecting BPA at significantly lower levels than the earlier methods. Furthermore, other studies implicated dental resins as a potential cause of harmful effects such as neurobehavioral disorders[10] or obesity in children.[10] In an apparent response to concerns surrounding potential harmful effects of dental resins, many dental resin manufacturers have stated that their product contains no detectable level of BPA. However, manufacturers often do not state the detection limit or the analytical method employed. Any dental material made with bis-GMA potentially can contain trace levels of BPA.

The fact that the presence of a perceived harmful material can be detected does not mean the material is harmful at that detection limit. More than 500 years ago, a German physician, Philippus von Hohenheim, better known as Paracelsus, stated:

> *"All substances are poisons; there is none which is not poison. The right dose differentiates a poison from a remedy."*[11]

In other words, the dose makes the poison. This is an extremely important concept that the dental professional always must be mindful of when evaluating studies or reports claiming that a toxic substance was found in a dental material.

Patients may be alarmed by media reports of environmental exposure to BPA from a multitude of common items, and the media reports usually mention dental materials in the same breath.

Acceptable BPA exposure limits are:

> **EPA:** *<0.05 mg/kg body weight/24 hours, which is the same as <50,000 ng/kg/day*
>
> *Thus for a 70 kg man = 3.5 x 10⁶ ng/day, and for a 10 kg child = 0.5 x 10⁶ ng/day*

> **The National Toxicology Program (NTP)** *suggested: 10,000 ng/kg/day*

The recent Kingman study[6] measured BPA concentrations in the saliva of study subjects before and after placement of a composite resin restoration. Salivary concentrations of BPA should represent the highest measurable indicator of BPA exposure from composite resin, since saliva is in direct contact with the resin. Salivary concentration should thus be

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ABBREVIATION KEY Bisphenol A (BPA): A chemical produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins. **Bis–GMA:** Bisphenol A-glycidyl methacrylate. **Bis–DMA:** Bisphenol A-dimethacrylate. **TEGDMA:** Triethylene glycol dimethacrylate. **UDMA:** Urethane dimethacrylate.

a good indicator of exposure. Salivary BPA measured before placement accounts for any BPA exposure from pre-existing sources and serves as a baseline level. Subtracting the BPA concentrations following placement is an indicator of the amount of BPA originating directly from the composite.

Geometric means were calculated for three sampling periods post-placement: 0–1; 1–8; and 9–30 hours. The geometric mean average of BPA in saliva within the first hour of placement was 0.21 ng/mL. Following composite placement from one to 30 hours, BPA was not detected in saliva at levels above baseline.[6] This indicates that BPA exposure from composite placement is very short and does not persist in saliva in detectable amounts after 60 minutes.

Therefore, these data suggest that the estimated oral BPA exposure from one composite resin restoration over 24 hours is 0.00875 ng/mL saliva/hour. A nanogram is one-millionth of a mg. If we assume average saliva production of 0.5 mL/minute or 30 mL/hour, and an average body weight of 70 kg for each study participant, then the BPA exposure following composite placement is about 6.3 ng/70 kg within the first hour. Since salivary BPA levels were not significantly different from pretreatment baseline levels after one hour and up to 30 hours post-treatment, the average adult daily dose of BPA from one composite resin restoration was 6.3 ng. Another study looked at BPA in saliva following sealant (no bis-DMA) placement in adults. Analysis found an average of 0.32 ng/mL of BPA in saliva immediately following treatment, and essentially no BPA was detected in saliva in excess of pretreatment levels one hour after placement of sealant on an average of six teeth.[13]

The above two clinical studies show that BPA exposure from current bis-GMA based composites and sealants is more than 500,000 times lower than the EPA acceptable daily exposure limit for adult humans. If the more conservative NTP exposure limit is used, then BPA exposure from one composite is more than 100,000 times lower. The margin of safety is several orders of magnitude lower than either exposure limit. Trace levels of BPA from dental resins do not appear to present a health hazard based on current exposure limits, especially when one considers that the exposure predominantly is acute only during the first hour post-treatment.

Urethane modified methacrylate restorative resins (UDMA) are available and are not manufactured from BPA (Fig. 4). However, 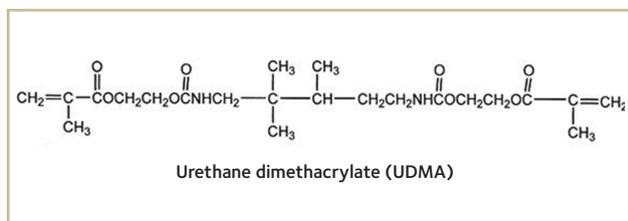their use as a bis-GMA resin alternative is limited because they do not develop equivalent stiffness and hardness characteristics as bis-GMA based restoratives.[14] Consequently, use is restricted primarily to low-stress surfaces.

Some earlier studies in rodents suggested significant harmful reproductive effects from very low levels of BPA exposure, much lower than the EPA acceptable level, and may have raised concerns that similar exposure levels could have the same effect in humans. However, recent studies have challenged that notion by showing that primates metabolize ingested BPA differently from rodents. Newborn monkeys were found to have a high capacity for inactivating BPA in contrast to newborn rodents. Blood levels of equivalent BPA exposures were found to be 10-fold lower in rhesus monkeys than in rats and mice.[15] Another study showed that people who ingested high levels of BPA in their diet did not show high levels of BPA in their blood, which supported findings in the primate studies.[16]

Despite an absence of documented adverse health risks related to these dental materials, some patients may be concerned. Nevertheless, the benefits of composite resin materials for restoring oral health and preventing caries is well established, while any health risks from their use is not. In 2007, the U.S. Department of Health and Human Services stated that, "Dental sealant exposure to bisphenol A occurs primarily with the use of dental sealants [containing] bisphenol A dimethacrylate. This exposure is considered an acute and infrequent event with little relevance to estimating general population exposures."[17] Furthermore, the medical community continues to support the use of resin-based dental materials based on their proven benefits and brevity of BPA exposure.[18]

(Editor's note: A future issue of the ADA Professional Product Review will feature "An Evaluation of Bisphenol A found in Dental Materials," in which we will report ADA Laboratory test results of BPA and bis-DMA levels from a variety of dental composites, sealants and bonding materials. Although these data will not use human subjects, they will give insight to the potential patient exposure levels of BPA from known amounts of product resin.)

Urethane dimethacrylate (UDMA)

Figure 4. Urethane dimethacrylate (UDMA)

BPA and Dental Materials: Addressing Patient Concerns

Here are some key points that can help you answer patient questions about BPA:

- According to manufacturers, BPA is not an added ingredient in dental composites or sealants currently on the market.

- The main ingredient in most commonly used composites and sealants is bis–GMA, which has been shown to be stable within the mouth and does not decompose to BPA over time.

- Trace amounts of BPA present in raw bis–GMA are a residue of its manufacturing process.

- Some products contain added bis–DMA as a bis–GMA viscosity modifier. Bis–DMA is known to decompose to BPA in the presence of salivary esterases (enzymes). However, many current dental resins severely limit or eliminate all bis–DMA from their formulations.

- Although trace levels of BPA can be detected in dental products containing bis–GMA, the potential exposure level is at least 100,000 times lower than current exposure limits.

- BPA exposure from dental materials likely lasts only a few hours after placement of a composite or sealant. Therefore, any BPA exposure is brief and transient.

- The preponderance of scientific data over the past 15 years indicates that the amount of BPA exposure from dental restoratives does not present a health hazard.

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A Laboratory Analysis of Latex Examination Gloves

Kristy L. Vogt, Amer Tiba, PhD, and Diana G. Lin

Introduction

When the Occupational Safety and Health Administration (OSHA) published the Bloodborne Pathogens Standard in 1991, the use of gloves became a requirement for dental personnel when there is hand contact with blood or other potentially infectious material, including saliva.[1] By 1993, the U.S. Centers for Disease Control and Prevention (CDC) had disseminated recommendations for practicing dentists. However, the American Dental Association was advising dentists on glove use prior to 1986.[2,3,4] As a result of the OSHA requirement, examination gloves are worn during all dental procedures to protect both provider and patient against infection.

It is estimated that the usage rate of gloves in dental practice is about 100 pairs (two boxes) per staff member per week.[3] Three types of examination gloves are available to dental healthcare workers: latex, vinyl (polyvinyl chloride), and nitrile. Each glove type is typically available in powdered and powder-free varieties. Powdered gloves offer easier donning and removal, but powder-free gloves aim to reduce the dispersion of latex particles into the air as well as reduce the residue left on hands and objects. One Web-based poll surveyed glove use trends in clinical practice and generated the following responses from a 242-clinician convenience sample. According to the survey results below, slightly more than half of the clinicians polled use exam gloves made from latex.[4]

- 48.3% use non-latex gloves exclusively in their practice

- 85.9% use ambidextrous gloves while only 8.3% use hand-specific fitted gloves

- 54.1% are free to work with the glove of their choice

- 9.5% are expected to use what is provided, regardless of size or personal preference

- 51.5% reported hand fatigue from wearing improperly fitted gloves

In terms of barrier effectiveness, durability, and tear resistance, latex and nitrile gloves have been reported to be superior to vinyl.[5-7] While many physical properties, such as strength and durability, are comparable between latex and nitrile, latex is believed to provide better dexterity and tactile sensitivity.[7]

Since powder in latex gloves has been recognized as an aerosol carrier of allergenic natural rubber latex (NRL) proteins as well as an irritant to patient and provider, it is no surprise that a search of dental supply catalogs revealed that there are more than twice as many powder-free gloves in distribution as powdered gloves. Gloves have now been used routinely in clinical practice for more than 20 years and performance standards that are used to grant regulatory approval are well established. However, standards do not address wear performance or simulated use conditions. Hence, the only testing necessary to meet the standard is conducted on products taken right from the box.

Numerous raw material sources and considerable latitude in proprietary ingredients of latex gloves result in slightly different formulations.[8] One example of variation in formulation is the amount and the type of filler used. Hence, glove quality could range from superior to barely adequate under unworn conditions, and the effects of wear on performance attributes is not established. There are numerous studies on the physical properties of latex and non-latex gloves under different use conditions.[6, 9-14] However, past studies of use were not designed the same; for example, the water tightness test methods used were different in some cases, the length of time the gloves were worn varied or was not specified, and not all procedures performed are relevant to a dental practice.

Measuring the ash content, an indicator of the amount of inorganic filler in a glove: Dr. Amer Tiba removes porcelain crucibles from an ADA Laboratory oven heated at 750±25°C during gravimetric determination of total residual powder according to ASTM D6124-06.

The ADA Laboratory evaluated powdered and powder-free NRL exam gloves with the primary aim to determine the general performance of the gloves as a whole, prior to wear. The ash content, an indicator of the amount of inorganic filler a glove contains, was also measured.

The Sample Selection Process

Owing to the overwhelming number of products, sizes, manufacturers' claims and varying discounting practices, in this report we focused on the NRL examination gloves' general performance by aggregating samples from 29 brands of powdered gloves (n = 125) and from 68 brands of powder-free gloves (n = 200). According to Table 3B in ANSI/ADA Standard No. 76, the sample size for a batch size of 2900 is 125 gloves and the sample size for a batch size of 6800 gloves is 200 gloves.[15] These sample sizes were used to evaluate the aggregate sample of powdered gloves and an aggregate sample of powder-free gloves for water tightness, tensile strength and elongation. A different sampling strategy was necessary for protein and powder determinations.

A randomized number list was generated for water tightness, tensile strength and ultimate elongation tests. Gloves were selected according to this list to obtain a composite sample. For protein tests, one sample consisted of three gloves from each brand. The amount of residual powder was determined from a sample of two gloves for each powdered brand, and a sample of five gloves for each powder-free brand. To simplify the scope of testing, all gloves evaluated were size medium, ambidextrous.

Due to the multitude of brands and glove sizes, the following limitations exist because there was no practical way to control for them in this study:

- While every effort was made to include all currently marketed gloves, including different colors, scents, and/or flavors of the same brand, it is possible that some brands were not included. Because the aim of this study is to provide observations about a general category, enough brands were included to make such a generalization. The location of the exact manufacturing facility is not easily traced by our labs. Therefore, we likely included several brands that were derived from the same manufacturing facility, as is the case with private-label brands.

- Using only one box or lot could produce a test result that is higher or lower than what is truly representative of the product, and may or may not pass the performance standard. Increasing the sample size to three lots and averaging the values provides a number that is more reflective of the brand of gloves. The objective of this evaluation was to determine if a pervasive quality problem exists and not to discriminate between individual manufacturers. Thus, a brand or two with failing performance attributes will not impact representation of the data because numerous gloves make up a composite sample.

Summary of Tests

Water Tightness

Test Summary

Researchers have used some very elaborate means to assess the barrier effectiveness of all types of gloves, including artificial contamination and subsequent detection by a tracer dye, a water inflation test, a viral leakage test, and other in vitro tests.[10,16-18] The water tightness test as described in ASTM D5151-06 is a reference method recognized by the FDA as a means to evaluate the barrier effectiveness of gloves. Its premise is simple: the glove is filled with water and observed for a time period much shorter than that in which a clinician might wear them. If the glove can hold one liter of water for two minutes, it passes the test.[19] This test aims to determine if pinhole leaks occur due to suboptimal latex formulation or a problem in the manufacturing process. The test does not determine if the glove is water-tight after bodily contact and use.

Test Method

Water tightness of powdered and powder-free gloves was tested according to ASTM D5151-06, "Standard Test Method for Detection of Holes in Medical Gloves."[19] For this test, 125 powdered gloves and 200 powder-free gloves were selected at random. Each glove is clamped at the wrist to suspend it with the fingers facing downward and one liter of water is poured into it. Over the course of two minutes, the entire glove is checked for leaks. If water droplets or a stream was detected, the glove failed the test. If no water was detected, the glove passed the test.

Results and Observations

- Four of the 125 powdered latex gloves tested for water tightness exhibited leakage (failure rate = 3%). In a sample size of 125 gloves, seven gloves can fail and still be deemed acceptable. Failures occurred in the following areas: on the palm close to the thumb, between the middle and ring fingers, and top of palm near middle finger.

- Two out of 200 powder-free gloves tested for water tightness exhibited leakage (failure rate=1%). In a sample size of 200 gloves, 10 gloves can fail and still be deemed acceptable. Failures occurred between the thumb and index finger, and between the ring and little finger.

Clinical Significance

ANSI/ADA Standard No. 76, Non-Sterile Natural Rubber Latex Gloves for Dentistry, permits a small number of failures in a glove batch.[15] For example, if three boxes of 100 gloves each from a single batch are tested, the batch size is 300 gloves, the sample size for general inspection level is 50 gloves, and three out of 50 failures are permitted. Assuming three failures would occur for every 50 gloves sampled, in a batch of 300 gloves, one would expect 18 gloves to fail.
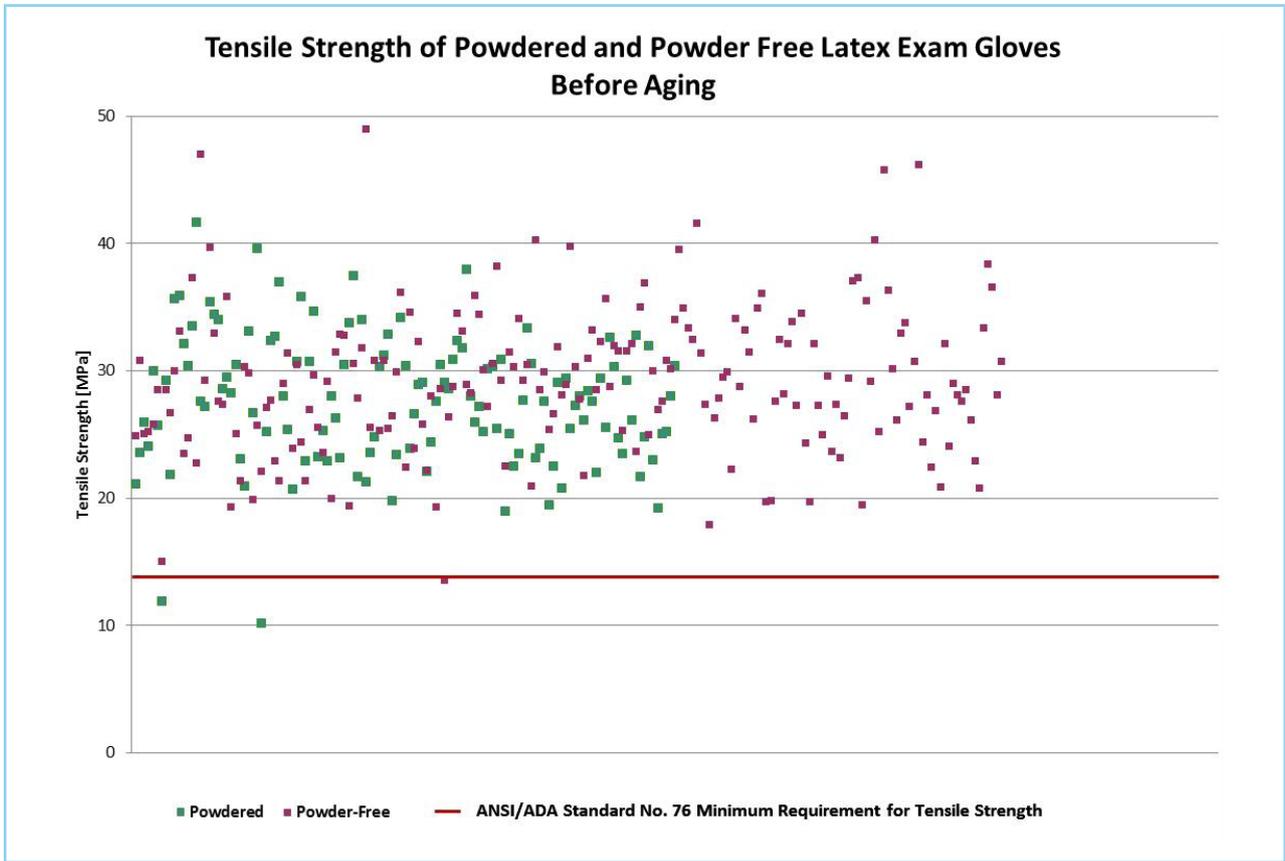
Figure 1. Plot of tensile strength values for powdered and powder-free gloves before aging
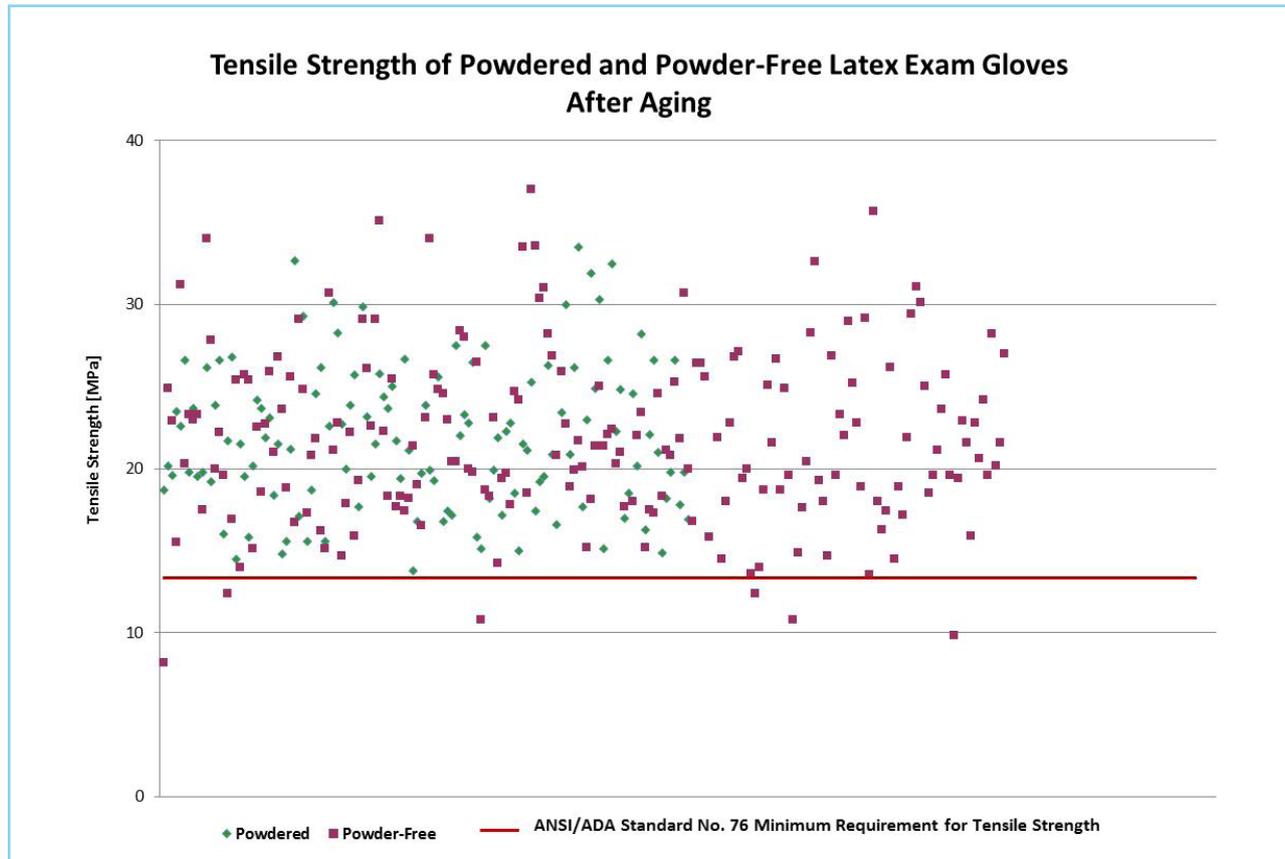

Figure 2. Tensile strength of powdered and powder-free latex exam gloves after aging.

While a glove's ability to protect against the transmission of bloodborne pathogens is paramount, there is some inherent risk in using any product. Hence, safety is a situation of probability that involves presence of the hazard (a glove having a pinhole leak) combined with contributing factors, such as presence of infectious materials, in which each has its own probability of occurrence.

Gloves are manufactured in batches (lots) of thousands, and, if the manufacturing process is under control and there is no assignable cause to a failure, these failures will be randomly distributed throughout the batch. Thus, the chance that a dentist will wear a defective glove and have an exposure incident in which the transferred material is infectious and of sufficient quantity is very low. The glove failure rate observed in the powdered and powder-free glove samples is acceptable. Based on these observations, acceptable risk to the user means that no infection control measure is 100% safe, but the barrier effectiveness of gloves is adequate, and, when combined with other measures one takes, provides a high level of confidence in infection control practices. This should be reassuring to dental healthcare staff, although glove users must be vigilant in checking gloves for discovery for the small number of manufacturing defects that will inevitably occur.

The water tightness test as specified in ANSI/ADA Standard No. 76 does not account for manipulations, or the solubility of glove ingredients when exposed to perspiration or dental materials. Evaluating the water tightness of gloves under these clinical conditions was the purpose of the clinical evaluation, which also appears in this issue.

Tensile Strength

Test Summary
Cross-linkers are chemicals that connect rubber molecules. The combination of cross-linkers, activators, and accelerators determines the rate of cure. Curing, or vulcanization, is the process that promotes cross-linking polymerization of NRL, causing the rubber molecules to change from an unorganized structure to a bound lattice orientation that lends physical strength and elasticity to the material. The curing process is initiated by the application of heat and catalyzing agents.[8] Tensile strength is the stretching or pulling force (stress) required to completely separate these cross-linked rubber polymer chains to the point of failure (glove rupture). Tensile strength serves as a measure of the completeness and number of cross-links, as well as an indicator to monitor the curing procedure. The more organized the lattice structure, the better the elastic "memory", and thus the higher the tensile strength.[8] Tensile strength is measured in megapascals (MPa). ANSI/ADA Standard No. 76 requires that latex gloves have a minimum tensile strength of 14 MPa before aging as well as afterward.[15]

Methods
Random number lists were used to select 125 powdered gloves and 200 powder-free gloves to comprise the test group. Tensile strength was determined by software-driven mechanical testing apparatus by the methods described in ASTM D412 Test for Rubber Properties in Tension, using Method A, Die D for Dumbbell-shaped specimens.[20] The test parameters are as follows:

- The cross head speed was 20.00 in/min.

- The default specimen width was 3.00 mm.

- The default specimen thickness was 0.120 mm. For each specimen, the thickness was measured and the corrected thickness was entered for each specimen.

- The extensometer gauge length was 1.00 inch (approximately 25 mm).

An accelerated aging test was conducted at 70°C for seven days as specified in ASTM D3578, Standard Specification for Rubber Examination Gloves, Section 7.5 to assess the extent to which the gloves' physical properties decrease at the end of their shelf life.[21]

Results
See Figure 1 on page 8.

Observations
Two gloves out of 125 powdered gloves did not have an adequate tensile strength (< 14 MPa). All powder-free gloves passed the requirement for minimum tensile strength

Clinical Significance
Both tensile strength and elongation are important properties. Adequate tensile strength is required to put a glove on without tearing. Nearly all powdered and powder-free gloves tested by the ADA Laboratory exhibited a higher tensile strength than 14 MPa, the minimum tensile strength required by the ANSI/ADA Standard No. 76 for a glove to be considered as having adequate tensile strength. While it is important for a glove to resist tearing, having too high a tensile strength could make it difficult to don or too tight. NRL is known for its comfortable yet close fit allowing good tactile sensitivity when compared to other glove materials such as nitrile and vinyl. The minimum tensile strength and elongation for NRL gloves is higher than that of other glove materials.

Tensile Strength after the Aging Process

Test Summary
Manufacturers utilize an accelerated aging test to establish shelf-life of their product. In the event gloves are not used by the time they reach the end of their shelf life, test values after aging provide an indicator of the strength and durability of the gloves at this later point in time.

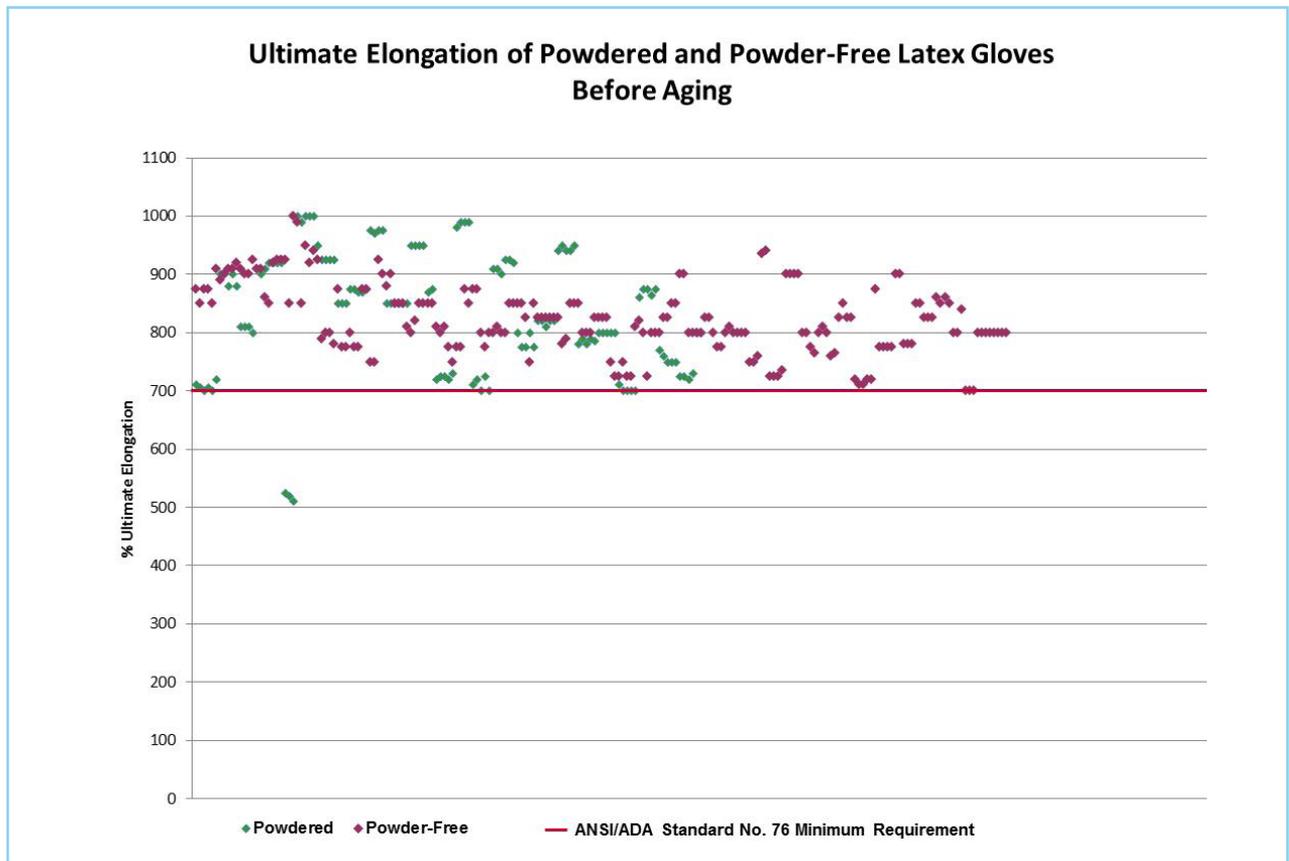**Ultimate Elongation of Powdered and Powder-Free Latex Gloves
Before Aging**

Figure 3. Ultimate elongation of powdered and powder-free latex gloves before aging.

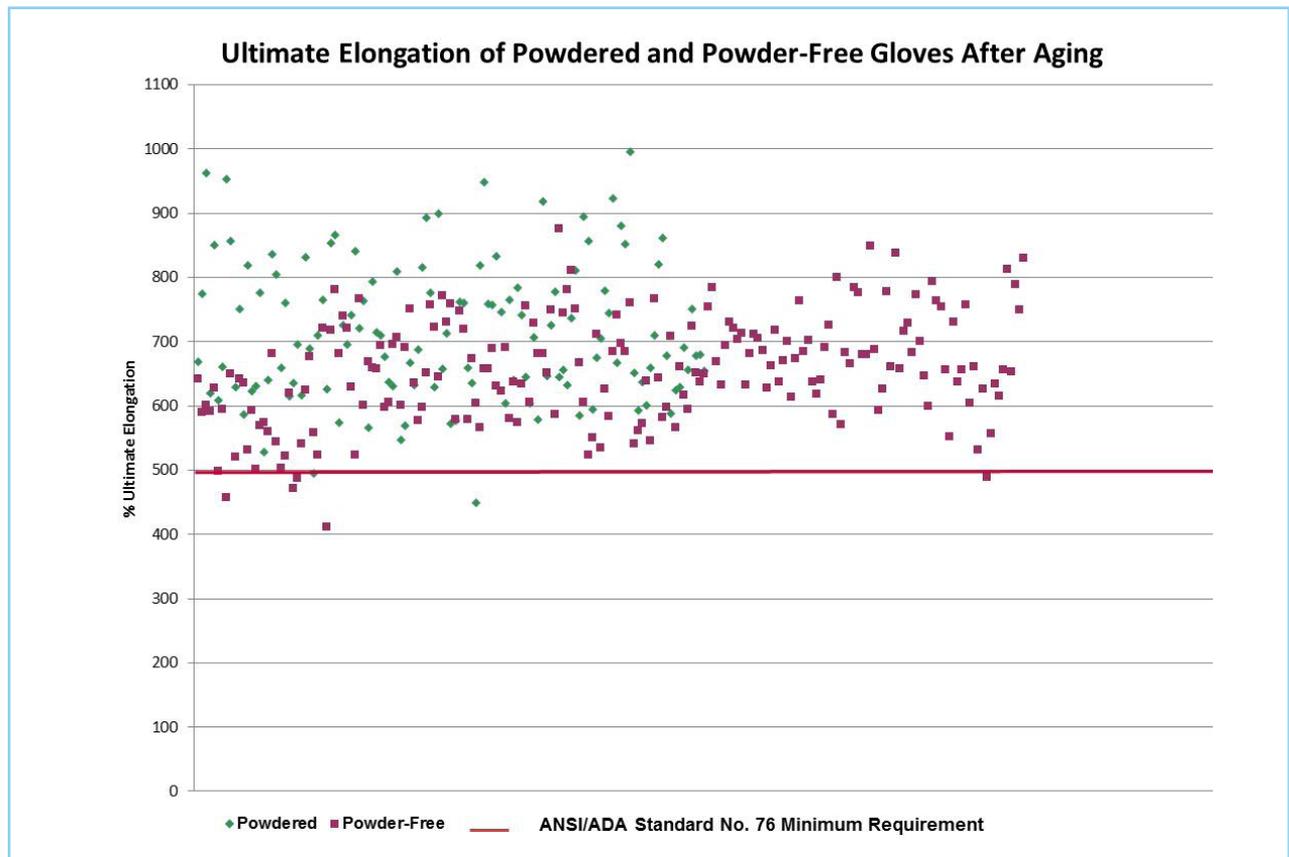**Ultimate Elongation of Powdered and Powder-Free Gloves After Aging**

Figure 4. Ultimate elongation of powdered and powder-free gloves after aging.

The aging procedure is conducted at an elevated temperature for a finite period. Gloves are subjected to this accelerated aging process and tested again for tensile strength and elongation.

Method
The accelerated aging test is conducted at 70°C for seven days as specified in ASTM D3578, Standard Specification for Rubber Examination Gloves, Section 7.5.[21] After aging, the specimens are tested using the same parameters as before aging.

Results
See Figure 2 on page 8.

Observations
Only six of 200 powder-free gloves failed to meet the minimum requirement of 14 MPa after aging. According to ANSI/ADA Std. No 76, up to 14 gloves of a lot (batch) can have less than 14 MPa tensile strength and allow the lot to be considered acceptable. All powdered gloves met this requirement. This means that the gloves are likely to have adequate tensile strength at the end of shelf-life.

Clinical Significance
This data shows that the majority of powdered and powder-free glove brands will likely have acceptable performance at the end of shelf-life. If the tensile strength and elongation have decreased, but are still within acceptable limits, there is a high degree of confidence that the glove will not tear during donning or removal over the course of their shelf-life under proper storage conditions. Accelerated aging tests are designed to represent a worst case scenario, and thus, the product might have better tensile strength at the end of shelf-life than is represented here. As a result of such test values, manufacturers will err on the side of caution and date their product accordingly.

Elongation Before and After Aging

Test Summary
Certain proteins in the raw extract impart elongation properties to the rubber polymer. In addition to specific proteins that impart elongation properties to the latex, cross-linkers are added during the manufacturing process to enhance the elongation properties of the material. Elongation is a strain measurement represented by the percent increase in length until the time of rupture (failure) when a pulling (tensile) force is applied to the material. Elongation is a means of quantifying the elasticity, that is, the degree to which a glove material can be stretched without it rupturing. As the material ages, its elasticity usually decreases. ANSI/ADA Standard No. 76 requires that latex gloves have a minimum ultimate elongation value of 700 % (stretch seven times their original length). After aging, the minimum ultimate elongation shall be at least 500%.[15]

Clinical Significance
Elongation is important in predicting the clinical performance of a glove. When a material has a high elongation, if snagged, the material can stretch or give rather than tear.

Method
Elongation was determined by the methods described in ASTM D412 Test for Rubber Properties in Tension, using Method A, Die D for Dumbbell shaped specimens. Elongation was measured again after accelerated aging, which was conducted as specified in ASTM D3578, Standard Specification for Rubber Examination Gloves, Section 7.5.21

Results
See Figure 3 on page 10.

Observations
Three out of 125 powdered gloves had insufficient ultimate elongation before aging. All powder-free gloves had acceptable elongation properties before aging.

Results
See Figure 4 on page 10.

Observations
One powdered glove out of 125 tested and four powder-free gloves out of 200 tested did not pass the ANSI/ADA minimum requirement for ultimate elongation after aging

Clinical Significance
The fact that only a few brands failed to meet these physical requirements does not suggest that there is an industry-wide problem that presents a significant clinical risk.

Total Aqueous Extractable Protein

Test Summary
When latex particles are concentrated by centrifugation, the portion containing rubber molecules is used in additional manufacturing steps, and many other latex proteins are discarded. These remaining proteins are further removed by the leaching and washing processes. Water-soluble proteins that remain in the glove will readily contact the skin during perspiration. The total aqueous extractable protein assay measures all proteins found in the glove that become soluble in a water-based medium (isotonic buffer, sweat, etc.). ANSI/ADA Standard No. 76 sets a maximum limit of 200 µg/dm2 Total Aqueous Extractable Protein.[15]

Test Method
Surface area was determined according to ASTM D3578, section 7.7.[21] Three gloves of each brand were extracted and pooled into one sample for each glove brand. A portion of each extract was treated with acid to precipitate proteins. Samples were concentrated to detect protein at very low levels.

Figure 5. Antigenic protein in powdered latex exam gloves.

Figure 6. Antigenic protein in powder-free latex exam gloves.

The Total Aqueous Extractable Protein assay was performed according to The Modified Lowry Method by LEAP Testing Service (Guthrie Research Institute), Sayre PA. Background subtraction was used to remove interfering chemicals that will produce a color reaction and inflate absorbance values. The assay's limitation is that it is not specific for any particular type of protein and is subject to chemical interference. Total Aqueous Extractable Protein for each glove brand is reported as µg/dm2.

Results and Observations
Among the 29 brands of powdered gloves and 68 brands of powder-free gloves, all gloves had a total protein content less than 20 µg/dm2; 10 times lower than the maximum level allowed by ANSI/ADA Standard No. 76.[15]

Clinical Significance

These very low protein levels demonstrate that, in general, manufacturers of powdered and powder-free gloves have very efficient means of removing excess protein from their products.

Antigenic Protein

Test Summary

Not all proteins present in latex cause latex allergy. Thirteen proteins have been identified as responsible for causing allergy. Determination of antigenic protein is highly specific for these known 13 proteins, and is not subject to chemical interference or contamination by other proteinaceous substances. The maximum allowable level of antigenic protein set forth by ANSI/ADA Standard No. 76 is 10 µg/dm2 , as determined by ELISA Assay.

Test Method

Surface area was determined by measuring the gloves from the tip of the middle finger to the cuff and the width across at the palm ignoring the thumb. Three gloves of each brand were extracted in 10 mL phosphate buffered saline per gram of glove. The extracts were pooled into one sample for each glove brand. The protein measurement for each pooled glove extract is reported as µg/dm2 antigenic protein for each brand.

Results

See Figures 5 and 6 on page 12.

Observations

Powder-free glove brands had half the maximum amount or less of antigenic protein. These low levels are likely due to the extra chlorination and washing steps powder-free gloves undergo to remove powder and water-solubilized excess proteins. In so doing, antigenic proteins are substantially reduced as well. In contrast, not all powdered glove brands could attain less than 10 mg/dm2.

Seven of 29 brands of powdered gloves, which accounts for almost 10 % of the group tested, had levels above the maximum allowable level, with one brand containing more than twice that allowed by ANSI/ADA Standard No. 76. This is likely because powdered gloves do not have to undergo additional washing steps to remove excess powder, and thus more protein stays in the glove. It is a concern, however, that though all powdered gloves had a low total protein concentration, the antigenic protein concentration was higher than the maximum allowable level for two brands of powdered gloves. While the washing step may remove most of the total protein from a glove, which residual proteins are left intact cannot be controlled.

Clinical Significance

The amount of protein required to induce an anaphylactic reaction is not known. Therefore, as with any other exposure risk, levels should be as low as reasonably achievable. The observation above indicates that for a few powdered glove brands, more residual protein is left intact than is safe for a NRL glove. The fact this occurred in powdered gloves makes it a worse problem than if it occurred in a powder-free glove, as these are the specific proteins known to induce allergic response in individuals. If aerosolized, these proteins are likely to cause latex hypersensitivity in individuals or cause anaphylactic reaction in those who are already allergic. For this reason, ADA and NIOSH promote the use of powder-free gloves because they carry an extra measure of assurance: remove the powder and most of the protein goes with it.[24]

Residual Powder

Test Summary and Clinical Significance

Total residual powder (cornstarch and other particulate matter) is a concern because latex proteins can adsorb to it. When the glove is removed, the powder aerosolizes latex, thus increasing the potential for sensitization through inhalation. Hence, if the amount of powder is reduced, so will the potential for sensitization to latex. The test for residual powder measures the amount of all particulate matter in a glove. ANSI/ADA Standard No. 76 requires that gloves making a claim of "powder-free" contain no more than 0.7 mg of particulate per gram of glove, and powdered gloves not contain more than 10 mg/dm2 powder. A glove's surface area is more relevant than its mass in conveying the amount of powder a glove has present because it takes into account the total area of all faces of a curved surface, in this case, the hand. The amount of powder in powder-free gloves was calculated based on surface area. The maximum powder amount of powdered and powder-free gloves is expressed in terms of surface area (dm2).

Test Method

Determination of total residual powder by calculating mass is conducted according to ASTM D6124-06.22 Two gloves are used in the determination for powdered gloves and five gloves are used in the determination for powder-free gloves.

Results
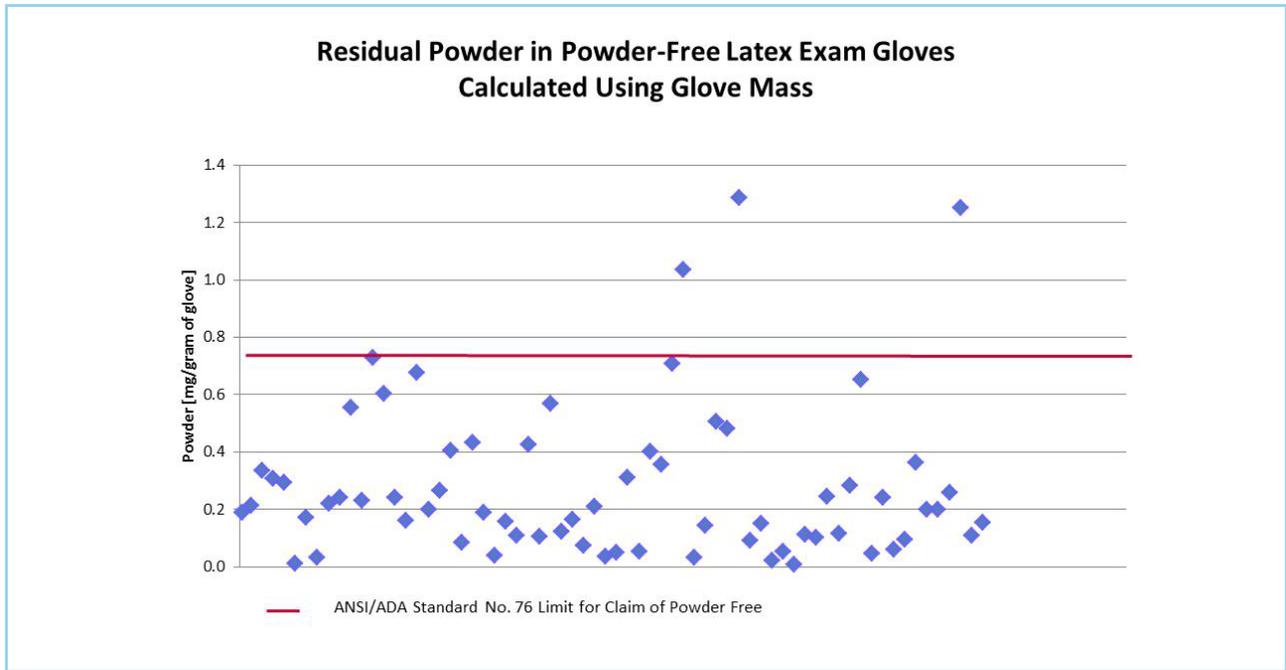
See Figures 7 and 8 on page 14.

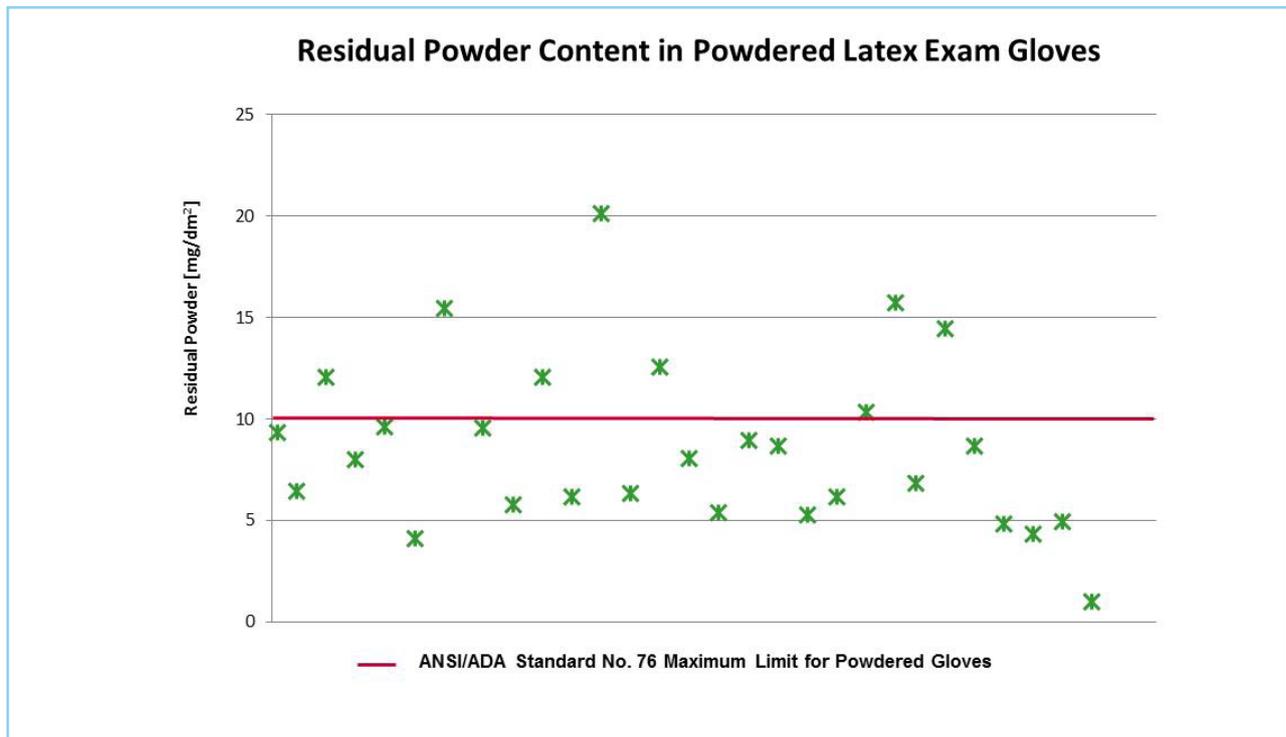Figure 7. Residual powder content in powder-free latex exam gloves.

Figure 8. Residual powder content in powdered latex exam gloves.

Observations

While only three out of 68 powder-free glove brands contained more powder than the maximum limit set forth in ANSI/ADA Standard No. 76, eight out of 29 powdered glove brands exceed the maximum requirement for powdered gloves. Powdered gloves are allowed to have more than 10 times the amount of powder than powder-free gloves. By comparing the residual powder of powdered and powder-free gloves using the same units, it can be seen that there are more brands of powdered gloves that do not adhere to the maximum limit set forth in ANSI/ADA Standard No. 76 than powder-free gloves. This is likely due to steps in the manufacturing process aimed at removing powder from powder-free gloves doing so very efficiently,

but powdered gloves do not benefit from being subjected to a process that will remove excess powder from the product.

Clinical Significance

Excess powder adsorbs proteins readily and is easily aerosolized. This could increase the potential for sensitization to high-protein latex gloves when powder-carrying proteins is inhaled.

Ash Content

Note: In this discussion, "ash" means inorganic filler.

Test Summary

In use, latex articles will be stretched (elongated), often to four or five times their original dimensions. Latex integrity is therefore a very important feature of gloves. Fillers are employed in the manufacturing of latex gloves to impart strength and durability.[8,19] Starch, an organic filler, will readily degrade when exposed to water and is subject to attack by microorganisms. Further, there does not appear to be a test method to quantify starch or other organic fillers in latex products.[20] Inorganic fillers such as calcium carbonate degrade less readily. As with all other ingredients, the quantity and type of filler used must be optimal for the glove formulation. Neither filler amount nor performance-in-use is addressed by the current ANSI/ADA or ASTM Standards. This data will be used to propose new relevant tests for ANSI/ADA Standards. The purpose of measuring ash content was to estimate how much inorganic filler a glove contains to provide a basis for selecting powder-free gloves used in a clinical evaluation. There is a concern that improper use of filler compromises the durability of the glove under wet-use conditions encountered in dentistry, which could contribute to accelerated deterioration during wear. The subsequent clinical evaluation sought to determine whether or not filler amount affected glove integrity after simulated clinical use.

Test Methods

We measured inorganic filler amount in powder-free latex gloves according to ASTM Method D4574-06.[25] Four gloves were combined and four determinations were made instead of performing two determinations each for two gloves. Four gloves were used to quantify the ash in each brand of gloves, as this sampling strategy provides for more consistent numbers between determinations than two gloves. Five grams of glove material were placed into crucibles, ignited until all volatile material and pyrolysis products were removed leaving only the carbon residue, and placed in a furnace, heated at $750 \pm 25\,°C$ for two hours, then cooled. The mass difference indicated the amount of ash present in the sample, which represents the inorganic filler.
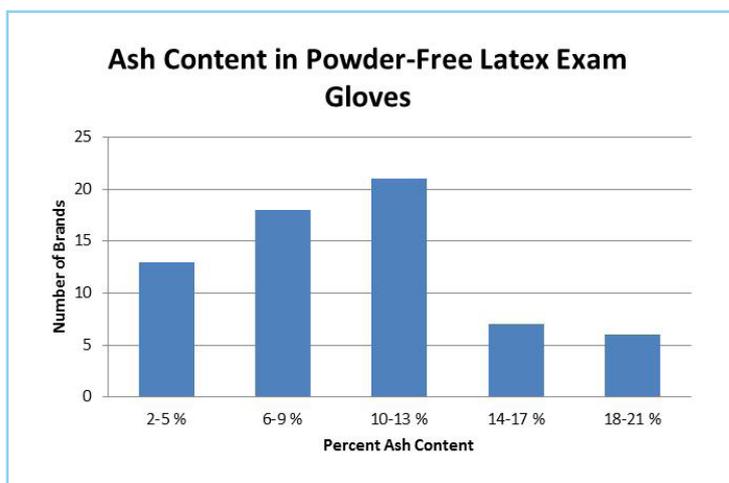

Figure 9. Ash content in powder-free latex exam gloves

Results

See Figure 9 on this page.

Observations

The average inorganic filler amount in the powder-free latex gloves is 10% (standard error of the mean ±0.6%). From 68 different brands of gloves, the minimum filler amount quantified was 2% and the maximum filler amount was 21.5%. According to the frequency table above, the majority of powder-free latex glove brands contain between 10-13% filler.

Manufacturers tend to use less filler rather than more filler. Very few manufacturers appear to use more than 15% inorganic filler in their formulations. This suggests that manufacturers are aware of decreased physical properties with increased filler amount. However, this chart only conveys the amount inorganic filler used. One limitation of the ash content determination is that any organic filler is burned off and cannot be quantified by this method. When organic filler such as starch is used, the total filler amount could be much greater.

Clinical Significance

Fillers are in widespread use in the manufacture of latex gloves. Manufacturers do not state in their safety data sheets the amount or type of filler used, as they are not required to do so and the information may be considered proprietary. Many in the rubber industry state that formulations typically require 4-10% of various additives, among them filler, for gloves to be functional, and that up to about 15% inorganic filler is tolerable.[23] Filler amounts above 15% have not shown promising results.[23,26] One manufacturer of rubber products contends that the tensile strength of a thin latex film is rarely increased by adding fillers like clays, talcs and calcium carbonates, and that their addition to the polymer promotes pinholes and interrupts the continuous nature of the latex film.[8]

Continued from previous page

Cai et al. looked at several physical properties of latex films formulated with different levels of calcium carbonate filler and found that up to 15% filler has a beneficial effect on the strength and durability of latex film, and that properties decrease dramatically when the filler amount increases above 15%.[26] Because there is no information about filler amounts in gloves, we chose15% filler to represent a "moderate" amount of filler used, based on this literature. The article further indicates that filler type and uniform dispersion throughout the film also contribute to performance.[26] Because no criteria for filler type, amount, or dispersion has been established, this determination was used merely as a tool to select products for the clinical evaluation. Filler amount alone cannot be used as a predictor of wear performance. Factors relating to the use of fillers—type, total filler amount, both inorganic and organic, and dispersion pattern—will need to be studied if definitive requirements are to be published in reference standards for critical maximum levels.

The Bottom Line

This laboratory analysis screened several brands of powdered and powder-free latex exam gloves, selected based on surveys and market analysis, which dentists routinely use in practice. Laboratory tests on unworn gloves did not reveal any deficiencies in performance or uncover any possible quality problems of latex gloves overall when the gloves were tested according to currently published tests standards for natural rubber latex gloves. Filler content is not a required test part of ANSI/ADA

Standard No. 76: Non-sterile natural rubber latex gloves for dentistry, although there is an ASTM test standard for the determination of ash content, which is believed to correspond to filler amount. Because there may be distinct differences in glove performance among glove brands when worn, knowing more about a glove's composition with respect to filler type and amount and requiring post-wear test data would be initial steps in elucidating such differences among gloves. A subsequent study, "Evaluating the Water Tightness of Powder-Free Natural Rubber Latex (NRL) Exam Gloves Following Simulated Clinical Use: A Pilot Study," provides very preliminary information about glove quality as a function of filler amount and wear.

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Evaluating the Water Tightness of Powder–Free Natural Rubber Latex (NRL) Exam Gloves Following Simulated Clinical Use: A Pilot Study

Kristy L. Vogt, Diana G. Lin, Cameron G. Estrich, and Nicholas B. Hanson

Background and Significance

Microleaks in examination gloves can develop over the course of wear and a compromised barrier is not always visible to the practitioner.[1] ANSI/ADA Standard No. 76:2002, Non–Sterile Natural Rubber Latex Gloves for Dentistry,[2] does not include a test that examines changes in the barrier effectiveness of gloves post–wear due to mechanical or chemical stresses, such as hand movement and instrument use, degradation due to contact with dental materials, or practitioner perspiration, which may contribute to deterioration during the course of wear. Studies that report on glove failure as a function of wear duration reveal a wide range in failure rate—from less than 5% to 50%. However, the length of time the gloves were worn ranged from 30 minutes up to 3 hours, or the duration was not specified.[1, 3-5]

In addressing the failure of natural rubber latex (NRL) gloves during wear, factors that could exacerbate breakdown of the glove should be considered. Multiple factors regarding glove quality can cause it to fail, including the latex formulation, the manufacturing process and glove thickness. Filler is one of many ingredients added to latex to make gloves more durable, but it may also affect the physical properties of gloves. A study by Cai et al. measured multiple physical properties such as tensile strength and elongation of NRL film specimens containing 5, 10, 15, 20, and 30% calcium carbonate filler.[5] This study found that physical properties of latex film improved as filler amount increased up to 15%, and then decreased beyond 15% filler amount. ANSI/ADA Standard No. 76 does not address filler amount.

Results from a Web-based survey of the ADA Clinical Evaluators Panel revealed that the majority of the 673 responding dentists, most of whom are general practitioners, wear nitrile or latex powder-free gloves to deliver dental care (unpublished data). Slightly more than half the dentists surveyed wear their gloves for 15–30 minutes; only 20% wear a pair of gloves for more than 30 minutes, and just over 25% wear them for less than 15 minutes. Based on this data, 30 minutes is considered a reasonable wear time for clinicians. Shorter wear times may not reveal glove deficiencies, and longer wear times may not reflect typical wear time in clinical practice.

A pilot study was undertaken to see if the barrier effectiveness of powder-free latex exam gloves is associated with filler amount when worn for a consistent length of time. Findings of this preliminary clinical evaluation will define future research efforts to discern the relationship, if any, between filler, and glove integrity during wear as well as identify the effects of other confounding factors. Data from future studies can be used to specify tests such as determination of ash content and wear testing in applicable test standards.

Purpose and Scope

The purpose of this pilot study is to explore the association between high versus low filler amount and glove integrity after 30 minutes of wear.

Methods

Selection of Gloves

For this pilot study, we selected six brands of gloves. Sizes extra-small (XS) through extra-large (XL) for all six brands were assigned an identification number.

Prior to this pilot clinical study, the ash content was measured for each of 68 brands of gloves evaluated in the ADA laboratory according to The American Society for Testing and Materials (ASTM) D4574-06 Standard Test Methods for Rubber Compounding Materials-Determination of Ash Content.[6] Determination of ash content by this method cannot identify the specific type of fillers used in a particular glove brand, but it does tell us the approximate amount of filler. In the study by Cai et al, it was found that physical properties of latex film improved as filler amount increased up to 15%, and then decreased beyond 15% filler amount.[7] For the clinical study described here, three glove brands having greater than 15% filler were pooled together into Group 1, the High Filler group; and three glove brands having less than 15% filler were pooled into Group 2, the Low Filler group.

In addition, before the clinical study began, water tightness results were obtained from a control group of 20 powder-free gloves from every box of gloves used in the clinical evaluation. All gloves were tested according to the Standard's requirements. According to ANSI/ADA Standard No. 76, one failure out of 20 is deemed acceptable.[2] The gloves tested had either zero or one failure out of 20.

Glove thickness at the palm and index finger was measured according to ASTM 3578.[8] All gloves in the study passed the ANSI/ADA standard requirement for minimum thickness, which is 0.08 mm at each locus.

Glove Testing

Informed consent was obtained from first-year dental students at the Arizona School of Dentistry and Oral Health, Mesa, Arizona. Students indicated their glove size (XS, S, M, L, and XL) in a questionnaire before the study began. Various sizes of powder-free NRL gloves were sent for students to try on for fit. First-year dental students wore powder-free latex exam gloves for three 30-minute time segments during one simulation clinic procedure. Over the course of 90 minutes, students prepared and restored complex amalgams that involved three or more tooth surfaces, or replaced one or more cusps. During the first 60 minutes, students were likely using more hand manipulations and cutting, including diamond or carbide bur changes that could abrade the gloves without being apparent. During the last 30 minutes, there was likely very little hand manipulations or contact with rough or sharp objects, as the task would primarily have been placing and condensing the amalgam restorative material.

The null hypothesis is that there is no expected difference in failure rate of NRL gloves having different amounts of filler after 30 minutes of wear. The cut-off value used to distinguish the High and Low Filler groups was 15% ash content. For the High Filler group, three glove brands having the highest ash content (21%, 19%, and 17%) were chosen. The Low Filler group was comprised of three glove brands having 10% filler, as this percentage represents a common ash content of gloves. Students were provided two gloves of the appropriate size of random brands for each time segment.

Since we did not find any evidence in the literature that hand dominance affects glove failure, students wore NRL exam gloves on both hands and each glove counted as a separate sample, the logic being that even if hand dominance was a confounding factor, a high leakage rate is unacceptable regardless of which hand it occurs on. The proctor and students were blinded as to the brand of gloves students wore. Two gloves of appropriate size were randomly assigned to each student for the simulation clinic procedure. The glove number was recorded on the data sheet for each procedure.

Each student wore the two gloves for the same procedure in the simulation clinic for each 30-minute time segment. Glove wear by dental students and collection were both proctored. The proctor was notified immediately if a failure occurred. Gloves that failed during a procedure were recorded as a failure along with the length of time into the procedure that the failure occurred. For example, if a hole was observed 10 minutes into the procedure, failure

at 10 minutes, and location/description of failure (tear at tip of index finger) was recorded. Ripping upon donning or removal was recorded as a failure. However, if tears or holes were caused by overt glove damage—poked with an explorer, snagged on a bur, etc., or other obvious cause— these instances did not count as a failure and a new glove would be selected and worn for 30 minutes.

After wear and collection, all gloves that did not visibly fail during the procedure or upon removal were tested for water-tightness as soon as possible after wear. In the interim, gloves were stored according to manufacturers' instructions; below 40°C (104°F), and shielded from exposure to direct sun or fluorescent lighting, x-rays, moisture and ozone.

Water Tightness Testing Post-Wear and Evaluation of Results

Water leakage is the primary indicator of failed barrier protection. The American Society for Testing and Materials (ASTM) D5151 Standard Test Method for Detection of Holes in Medical Gloves was used for water tightness testing.[9] Taking care to keep the outside surface dry of excess water, gloves were observed for leakage over two minutes. Occurrence of a leak and its location on the glove was noted. Gloves that ripped during the clinic procedure were recorded as failures and not tested for leaks.

According to ANSI/ADA Specification No. 76, water droplet or stream formation indicates a failed glove, while absence of water droplet or stream formation indicates the glove passes the water tightness test.[2] Water-tightness data obtained for the High Filler group was compared to the data for the Low Filler group to determine any difference in failure rate of powder-free NRL exam gloves. Statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC). Pearson's Chi-square tests and Fisher's Exact Test were used, with an alpha level of 0.05 for all tests.

Water tightness failure rates for each glove brand with respect to their filler amount were compared while investigating the possible confounding factors of glove size or clinic time segment in which the gloves were worn. The simulation clinic procedure was divided into three consecutive time segments of 30 minutes each, termed Time Segments 1, 2 and 3. The difference in failure rate between the High Filler group and Low Filler group was not significant; 11.2% of high-filler gloves failed to be water-tight compared to 10.5% of low-filler gloves (Chi-square p-value: 0.86). Although the difference in failure rate between the High Filler and Low Filler groups was not statistically significant, there was significant variation between individual brands (Chi-square p-value: <0.001) within their respective filler groups. Upon statistical analysis, one glove brand (Blossom Powder-Free) from the high-filler group and one glove brand (Beesure Powder-Free) from the low-filler group had statistically higher failure rates than the other brands in their respective groups (Fisher's Exact Test p-values: <0.01 for each group).

Table 1. Statistical comparison of water tightness failure rates post-wear, by filler amount

Statistical Comparison of Failure Rates by Filler Amount			
Filler Group	Filler Amount	Brand	Proportion Failed (n)
High	19 %	AccuTouch Powder Free	5.3% (2 out of 36)
	21 %	Blossom Powder Free	27.9% (12 out of 31)
	17 %	Vibrant Powder Free	4.2% (3 out of 68)
Low	10 %	Beesure Powder Free	18.9% (7 out of 30)
	10 %	Diamond Grip Plus Powder Free	10.0% (3 out of 27)
	10 %	Diamond Grip Powder Free	4.3% (2 out of 45)

Fisher's Exact Test p-value: <0.001

Observations

Within each group, there was one glove brand that failed more than the other two brands. Therefore, 20 gloves of each size of brands Beesure Powder-Free and Blossom Powder-Free were tested unworn for water tightness. ANSI/ADA Standard No. 76 allows up to one glove to fail out of 20 gloves when the batch size is 100 gloves.[2] No more than one glove failed in each glove size of Beesure and Blossom brands.

Table 2. Proportion of failures by each 30-minute segment of clinic simulation

Proportion of Failures by Time Segment	
Time Segment	Proportion Failed (n)
First Thirty Minutes	18.2% (16 out of 88)
Next Thirty Minutes	8.9% (8 out of 90)
Last Thirty Minutes	5.7% (5 out of 88)
Pearson's Chi-Square	0.02

Observations

None of the gloves tested in the clinic simulation ripped during donning or removal, or developed visible holes during the 90-minute procedure.

The first 30 minutes of the clinic simulation had twice the number of failures than the last sixty minutes, even though the entire evaluation took place on the same clinic day. The proportion of gloves that failed the water tightness test varied significantly by what time period the gloves were initially used (Pearson's Chi-square, p-value: 0.02).

The last 30 minutes of the simulation had significantly lower proportion of water tightness failures compared to the first 39 minutes (post hoc Marascuillo procedure, $\alpha=0.05$). Failure rates were not significantly different between the first and second 30-minute segments or the second and third 39-minute segments.

Additionally, there was a borderline significant difference

(Chi-square, p-value: 0.076) in the number of gloves of each brand that were used during each 30-minute segment of testing. Although 33.3% of each brand should have been tested in each 30-minute segment, as much as 51.4% of all the gloves tested for a single brand were used in a single 30-minute segment. Gloves were randomized within the low and high filler groups. As such, the goal was to keep the number of gloves representing the high filler group approximately equal to the number of gloves representing the low filler group. Because we did not expect a particular glove brand from within each group to have a significantly different failure rate than the other two brands representing that group, random numbers of different brands within each respective group were tested. Initially, it was expected that 134 gloves would be distributed per time segment. In fact, only 88 gloves per time segment were tested due to lower than expected attendance in clinic on the day of the evaluation.

Limitations of the Study

A limitation of this pilot study is that water tightness failure rates were lower than expected, and additionally, due to lower than expected clinic attendance, fewer gloves were tested than originally planned. However, the similarly low failure rates in the two filler groups mean that 1,143,888 gloves would need to be tested to detect a significant difference between the low and high filler groups (post-hoc power analysis for 95% confidence). Hence, although the sample size was inadequate, the actual difference in water tightness failure rate between filler groups may be too small to be clinically meaningful. Several glove factors that could affect the results are the filler type (organic fillers such as starch versus inorganic fillers such as calcium carbonate or magnesium carbonate), filler particle diameter, dispersion of filler particles throughout the latex and glove thickness. Other factors present in the study design are procedure type, student proficiency/skill level, and hand dominance. Further, when gloves were evaluated for tensile strength and elongation under laboratory conditions, the six glove brands tested in this clinic evaluation had statistically significantly different means of these two physical properties (ANOVA F test p-values:

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<0.0001) (unpublished data). However, none of these variables were addressed in this clinical evaluation.

Discussion

There are several factors that might affect the association between water tightness and filler amount. Testing round, or time segment, is among them. Students were likely to be doing more hand manipulations and cutting during the first 60 minutes whereas during the last 30 minutes, there was likely very little hand manipulations or contact with rough or sharp objects. It is possible that there was a technique learning curve during the first time segment, as it was the students' first day doing complex amalgam preparations. Because there was variation in how many gloves of each brand were used in each round, testing round could have confounded the association between water tightness test failure and filler amount.

While it was originally believed that the amount of filler used in glove manufacturing could cause gloves to fail during wear, there was no statistically significant difference in gloves' water tightness when grouped by filler amount. However, there were statistically significant differences in water tightness failure rates when grouped

by brand. Hence, brand, not filler amount, was the significant predictor of water tightness failure after use. This investigation shows that filler amount alone is likely not an independent cause of failure and other factors may be associated. Future research studies will be necessary to determine what other factors might affect glove integrity under in-use conditions, such as filler type or size, as well as to expand the number of brands evaluated and to test tensile strength and elongation after simulated wear. The number of students as well as time allotment in simulation clinic may be too limited to address all possible aspects of this problem at once, requiring a series of small scale studies that look at one factor at a time.

This pilot study shows that performance according to a standard is not indicative of glove properties during clinical use. Currently, test standards of NRL gloves are not designed to detect the causes that jeopardize barrier effectiveness with wear but only provide a minimum level of assurance and aim to establish some consistency among manufacturers. Clinically-relevant tests must be developed. This evaluation is a first step in that direction. After in-use studies have been developed, it would be within the FDA's purview to insist on test data of simulated wear studies from manufacturers.

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Dental Therapeutics: Palliative Over-the-Counter (OTC) Treatments for Oral Dryness and Associated Inflammation

Oral dryness and its associated inflammation can seriously affect a patient's quality of life, and may be caused by orofacial conditions, systemic diseases, and/or medical drug therapy. Regardless of the underlying cause, most patients who suffer from oral dryness seek advice on its management from the dental healthcare team, who must be well-informed about management options. This article provides an overview of clinical approaches to the management of oral dryness based upon over-the-counter products, and provides examples of the various types of products available to U.S. dental patients.

Dr. Arthur Jeske is Professor, Department of General Practice and Dental Public Health and Associate Dean for Strategic Planning at the University of Texas School of Dentistry at Houston, TX. He received his Ph.D. and D.M.D. from the Medical College of Georgia, Augusta, GA. He is Editor-in-Chief of Mosby's Dental Drug Reference, Pharmacology Section Editor for Cranio—The Journal of Craniomandibular Practice, and Coordinating Editor for Oakstone's Practical Reviews in General Dentistry. Dr. Jeske teaches local anesthesia, dental pharmacology and restorative dentistry, has co-authored a textbook in dental pharmacology and two textbook chapters, and has contributed more than 70 scientific articles to the dental literature. A Fellow of the American College of Dentists and the International College of Dentists, Dr. Jeske served on the ADA's Council on Scientific Affairs from 2000-2004, which he chaired in 2004.

Introduction

The goal of any dental therapy is to not only relieve the patient's symptoms, but also to eliminate the etiologic factors associated with oral disease. Unfortunately, the factors underlying many oral conditions, both chronic and acute, cannot be eliminated or are poorly understood, or even unknown. In other cases, the causative factor(s) result from the therapy of a systemic disease, the management of which cannot be suspended or discontinued because of serious, even life-threatening outcomes. In such cases, the dentist and dental healthcare team may be able to provide palliative therapies. The term palliative may be defined as: 1) reducing the severity of, and 2) denoting the alleviation of symptoms without curing the underlying disease.[1]

In fact, although palliative dental therapies do not prevent or cure oral disorders, they may significantly improve the patient's quality of life and facilitate improved health in a variety of ways. However, it must be emphasized that a careful diagnosis of the underlying disorder must be done so that the use of a palliative therapy does not mask its signs and symptoms or indications that the disease is worsening.

The purpose of this article is to summarize palliative therapies for mouth dryness (hyposalivation and/or xerostomia) and its associated discomfort, and provide an overview of currently available over-the-counter (OTC) products.

Xerostomia, Hyposalivation

There are many causative factors for hyposalivation and xerostomia, including drug therapy, e.g., drugs for depression/anxiety and anti-allergy agents, both of which possess anticholinergic actions at the parasympathetic innervations of the salivary glands, as well as diabetes, anemia, head-and-neck irradiation and systemic cancer chemotherapy and systemic disorders, such as Sjogrens syndrome.[2,3] Changes in the quantity of saliva may severely impact food chewing and swallowing, wearing of partial and complete removable dentures, and may result in candidiasis, burning mouth and an elevated risk for dental caries. Behavioral issues that arise can impact the patient's quality of life, such as awakening from sleep at night because of oral dryness.

Products for Relief

Saliva substitutes constitute the largest and most frequently utilized palliative agents for the relief of hyposalivation.[4,5] While water is commonly employed for this purpose, its effects are transient and it does not replace the lubricating components of natural saliva. Another strategy is to dissolve small pieces of ice in the mouth. Patients with dry mouth may benefit from restricting caffeine intake, avoiding the use of alcohol-containing mouthrinses, humidifying room air in dry climates, and coating the lips with petrolatum.[1,3] A lanolin-based lip-care product is most likely better than petrolatum, which can be drying.

Saliva substitutes address the lack of lubricating components by incorporating salts and cellulose derivatives or mucins to increase their viscosity and oral retention, as well as flavoring agents and preservatives. Unfortunately, saliva substitutes lack many of the anti-microbial properties of natural saliva, such as immunoglobulin A. A representative list of some currently available agents, including solutions, gels and mouthrines, with their physical forms, follows:

Table 1. A representative sample of over-the-counter products for the management of xerostomia/hyposalivation[3]

Product/Trade Name*	Physical Form	Ingredients	Packaging
GC Dry Mouth Gel	Gel	Sodium carboxymethylcellulose, carrageenan, polyglycerol, (diglycerol), ethyl-p-hydroxybenzoate, sodium citrate, flavor, water	35-ml tubes
Entertainer's Secret	Solution	Sodium carboxymethylcellulose, dibasic sodium phosphate, potassium chloride, parabens, aloe vera gel, glycerin, flavor, water	60-ml pump spray
Moi-Stir	Solution	Sodium carboxymethylcellulose, dibasic sodium phosphate, calcium, magnesium, potassium and sodium chloride salts, parabens, sorbitol, water	120-ml pump spray
MouthKote	Solution	Yerba santa, citric acid, ascorbic acid, sodium benzoate, flavor, sodium saccharin, sorbitol, xylitol, water	60- and 240-ml pump spray
Moist Plus Mouth Moisturizer	Gel	Carboxymethylcellulose, xylitol, water	15-ml tube
Oasis Moisturizing Mouth Spray	Solution	Glycerin, sodium benzoate, xanthum gum, PEG-60, hydrogenated castor oil, copovidone, cetylpyridinium chloride, methlparaben, propylparaben, sodium saccharin, xylitol, flavor, water	30-ml pump spray
Optimoist	Solution	Hydroxyethylcellulose, electrolytes, sodium monofluorophosphate, xylitol, citric acid, water	60-ml pump spray
Oral Balance	Gel	Hydoxyethylcellulose, hydrongenated starch, glycerate polyhydrate, potassium thiocyanate, glucose oxidase, lactoperoxidase, lysozyme, lactoferrin, aloe vera, xylitol	45-ml tube
Orajel Dry Mouth Moisturing Gel	Gel	Polyglycitol, glycerin, xanthan gum, calcium disodium EDTA, citric acid, disodium phosphate, methylparaben, propylparaben, sucralose, thione antioxidant complex, flavor, water	45-ml tube
Oral Balance Dry Mouth Mouthwash	Solution	Water, propylene glycol, xylitol, polyglycitol, Poloxamer 407, hydroxyethyl cellulose, sodium benzoate, benzoic acid, natural peppermint, sodium phosphate, zinc gluconate, lactoferrin, calcium lactate, aloe vera, potassium thiocyanate, enzyme system (lysozyme, lactoperoxidase, glucose oxidase)	
Oralube	Solution	Potassium, sodium, magnesium, calcium, chlorides, phosphate, fluoride, methyl hydroxybenzoate, sorbitol, flavor, water	125-ml pump spray
Oramoist	Patch	Xylitol, enzymes	16 patches per package
Rain Dry Mouth Spray	Solution	Glycerin, aloe vera concentrate, cellulose gum, calcium glycerophosphate, grapefruit seed extract, xylitol, flavor, water	30- and 105-ml pump spray
Salivart Oral Moisturizer	Solution	Sodium carboxymethylcellulose, dibasic potassium phosphate, calcium, magnesium, potassium, sodium chlorides, sorbitol, water, nitrogen propellant	30- and 75-ml pressurized spray cans
Saliveze	Solution	Water, calcium, potassium and magnesium chlorides, mint, flavor	50-ml pump spray
Thayers Dry Mouth Spray	Solution	Glycerin, Tris Amino buffers, citric acid, potassium chloride, calcium gluconate, flavor, water	120-ml pump spray
Theraspray	Solution	Glycerin, Microdent 2%, xylitol, xanthan gum, sodium saccharin, mint flavor, EDTA	50-ml pump
Zylimelts	Mucoadhesive disk	Xylitol, cellulose gum, natural peppermint flavor, calcium/magnesium stearate	Disk

*Note: This list is a representative sample of products available in the U.S. at the time of publication, and is not intended as a comprehensive listing of all products, nor is it intended as an endorsement of a specific product.

Practical Considerations

Obvious considerations in selection of a product for relief of dry mouth include efficacy, availability and price. Additional factors include patient preference, potential allergy to product components of the saliva substitute (e.g., presence of paraben preservatives), taste, viscosity, and retention in the mouth. Another important consideration is the ability of the patient to appropriately apply the product. While it may seem a rather simple task of opening the mouth and spraying the product on the oral tissue, it may be a challenge for patients with disabilities, such as severe arthritis, making a disk dose form or a propelled spray a more practical alternative. In patients at risk for caries, selection of dry mouth products containing anti-caries ingredients (fluoride, xylitol) may offer additional benefit, but would not be expected to replace oral hygiene measures along with more effective delivery forms for topical fluoride prescription strength (fluoridated gels/dentifrices, in-office fluoride applications). The practitioner should also consider the possibility that dry mouth is often accompanied by an altered sense of taste (dysgeusia), so that some products may be intolerable based on taste alone.

Scientific Evidence

A limited number of scientific studies with a variation in scientific evidence have confirmed the efficacy of saliva substitutes. Oh et al. reported that a carboxymethylcellulose-based artificial saliva provided the greatest beneficial effects in patients with severely deficient whole stimulated and unstimulated salivary flow rates, based on quality-of-life outcomes, such as oral dryness during eating, sleep disruption and oral dryness during waking hours.[7] Femiano and others reported outcomes of a randomized clinical trial in which patients with self-reported xerostomia received artificial saliva, a salivary stimulant (3% citric acid) or distilled water 4 times a day for 30 days.[8] Fifteen minutes following administration, 67% of the subjects in the artificial saliva group reported subjective relief of symptoms improvement, while 50% in the stimulant group and only 10% of subjects who used distilled water reported subjective benefit, respectively. However, one hour following use, the greatest benefit was seen in the salivary stimulant group (56% of subjects with significant improvement) with a lower number of subjects with symptom improvement in the artificial saliva group (39%), and none of the subjects in the distilled-water group had improvement. These investigators suggested that the persistent effect of the citric acid stimulant was due to protracted activity on salivary gland function, whereas the other agents were likely cleared by swallowing from the oral cavity much more rapidly.

Shirodaria et al. assessed Oasis Mouth Moisturizing Spray in two randomized, single-blind, four-arm, crossover studies. In the first study of a small number of subjects (N=24), the Oasis product was compared with two experimental mouth spray formulations and another commercially available spray (Salivez).[9] Based on usage rates of two to three times daily for three days, Oasis performed better than the other commercial product based on the subjects' perceptions of a demulcent (coating) effect and longer duration. In the second, larger-scale study of 120 subjects in a home-use consumer test of Oasis alone, a comprehensive survey instrument confirmed positive ratings of the product based on subjectively evaluated quality-of-life parameters.

Beneficial outcomes have recently been reported with the use of mucoadhesive disks (e.g., Xylimelt and placebo) in dry mouth patients. In a randomized, crossover study of 27 subjects with dry mouth, both disks that were tested resulted in a statistically significant improvement in a subjective evaluation of dryness after two weeks compared to pre-treatment baseline scores. Both active and placebo disks also produced a significant increase in salivary flow 60 minutes following application compared with baseline flow rates after one and two weeks of use.[10] In this study, the disks were not associated with adverse events, such as irritation of the oral mucosa or allergic reactions. A systematic review revealed considerable variation among studies of various interventions for xerostomia, with only one intervention (prescription pilocarpine, Salagen) supported by relatively strong scientific evidence.[11] Systematic reviews of various interventions for dry mouth have determined that there is no strong evidence to support the use of lubricants or protectants, and recommend that both patient preference and the dental professional's clinical judgment, along with potential adverse effects of the various products, be considered when selecting a specific product.[12,13] However, a review of 52 studies reported by Hahnel et al. indicated that there are significant differences in the performance of various saliva substitutes in patients with radiation-induced xerostomia, and that both in vitro and in vivo studies are needed to further define the physical and chemical properties of saliva substitutes.[14]

Management of Oral Irritation/Inflammation Associated with Mouth Dryness

Dry mouth may be associated with painful irritation, dental caries, fungal infections, and difficulty swallowing, primarily due to the lack of the lubricating action of saliva.[15] While the use of saliva substitutes and oral moisturizers/lubricants described above provide the main line of defense, over-the-counter products offer temporary pain relief including topical anesthetics and topical antihistamines. Children's Benadryl Allergy Liquid (12.5% diphenhydramine solution) can be used as a rinse for two minutes approximately every two to four hours. The product should be expectorated as the cumulative effects of swallowing diphenhydramine includes sedation and ataxia, and may actually contribute to mouth dryness through its well-documented anticholinergic actions.[3]

There are numerous over-the-counter products containing local anesthetics for topical administration, most containing benzocaine as the active ingredient. A list of examples of these products and their dose forms can be found in Table 2:

Table 2. Over-the-counter products with local anesthetics for topical administration[6]

Product Name*	Ingredients	Dose Form
Anbesol Regular Strength	Benzocaine	Gel/liquid
Baby Anbesol	Benzocaine	Gel
Baby Orajel Teething Pain Medicine	Benzocaine	Liquid
Banadyne	Benzocaine	Cream
Benzodent	Benzocaine	Cream
Chloraseptic Sore Throat	Benzocaine	Lozenge
Orajel PM Maximum Strength	Benzocaine	Cream
Rid-A-Pain Dental Drops	Benzocaine	Liquid
HDA Toothache	Benzocaine	Gel
Sucrets Children's	Dyclonine	Lozenge
Sucrets Regular and Maximum Strength	Dyclonine	Lozenge
Zilactin-B	Benzocaine	Gel

*Note: This list is a representative sample of products available in the U.S. at the time of publication, and is not intended as a comprehensive listing of all products, nor is it intended as an endorsement of a specific product.

With the exception of relatively rare, localized allergic reactions, there are few adverse effects of these agents, and they are widely available for the short-term relief of oral pain. Benzocaine has been associated with methemoglobinemia, particularly after relatively large amounts are absorbed. Patients who use these products should be warned that prolonged pain of unknown origin should be diagnosed by the dentist and treated appropriately. For example, burning mouth is frequently associated with oral candidal infections requiring antifungal treatment.

Summary

There is a wide array of OTC products to manage dry mouth (xerostomia, hyposalivation) and its associated complications. The choice of a specific agent should be based upon availability, patient preference for specific characteristics (e.g., dose form, flavor, viscosity), as well as specific therapeutic needs, such as inclusion of an anticaries or antibacterial component. If pain accompanies oral dryness, there are numerous topical agents available in OTC forms, which also vary in physical form and will generally be selected based on availability, cost and patient preference. Ideally, the clinician should question the patient regarding use of these products during regular review of the health and medication history so that potentially serious conditions, e.g., sialadenitis and autoimmune disorders, can be identified and appropriately addressed.

(Editor's note: These articles are intended to be a resource and the views expressed are those of the author and do not necessarily reflect the opinion or official policy of the ADA or its subsidiaries. The article's contents are not a substitute for the dentist's own judgment and dentists are encouraged to consult with patients' physicians concerning drugs mentioned herein.)

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