



## Effect on Mechanical Properties of Orthodontic Elastomeric Ligatures on Immersion in Disinfecting Solutions - an *in vitro* Study

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### Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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### ABSTRACT

**Background and Objectives:** Cold water disinfection can damage the elastomeric material, cross contamination in handling elastomeric ligatures is a serious concern in the orthodontic office. In addition, elastomeric strips with enough ligatures for both arches of a single patient are produced by most manufacturers. Thus, cross -contamination can occur in remaining ligatures if an entire strip is not used at once.

In this investigation effect on tensile strength on short to medium exposure of elastomeric ligatures to disinfection solution and in turn its effect on force delivery is studied.

**Aims and Objectives:** Effect of extended exposure to disinfection solutions on tensile load at failure of different orthodontic elastomeric ligatures is assessed.

**Materials and Methods:** Orthodontic elastomeric ligatures were obtained from 5 manufacturers; 3M Unitek, Ormco, Ortho organizer, GAC, T P Orthodontics.

3 Disinfectant solutions used were

Glutarex-3M Unitek, Cidex-Johnson and Johnson and Cidex OPA- Johnson and Johnson.

From each manufacturer, ten orthodontic elastomeric ligatures will be exposed to each disinfectant solution with exposure times of 30 minutes, 1 hour, 12 hour and 24 hours. Ten unexposed

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elastomeric ligatures from each manufacturer will also be tested which will act as control group. Ligatures were stretched in custom made jig of a universal testing machine (INSTRON) until they fractured to determine the tensile load failure. Maximum tensile load were recorded. The tensile load at failure was used as an analog to the clinical situation of the ligature breakage during tie-in.

Results and Conclusions: Three-way ANOVA showed significant differences ( $P < .0001$ ) not only within manufacturer and time of exposure but also between disinfectants ( $P < .001$ ). Significant interactions ( $P < .0001$ ) were observed between manufacturer and time and between disinfectant and time. Greater significant changes were seen in tensile load at failure for all 5 manufactures ligatures in Cidex solution whereas changes were less significant in Glutarex and Cidex OPA solution. The ligatures from all companies showed significantly different failure loads from each other, with the ligatures from 3M exhibiting the greatest tensile load at failure and those from Ortho Organizer, the least.

**Elastomeric Ligatures Tensile Load at Failure Followed the Pattern:** 3M Unitek \_ GAC \_ Ormco \_ T P Orthodontics \_ Ortho organizer. Tensile load to failure of elastomeric ligatures, compared to unexposed specimens changed when exposed to disinfectant solution for as little as 30 minutes.

*Keywords: Elastomeric ligatures; disinfection; disinfectants; tensile load at failure.*

## 1. INTRODUCTION

The increase in blood-originated microbial diseases caused by bacteria or viruses such as hepatitis B and C and HIV require enhanced safety measurements to control clinical, nosocomial or cross infections in dentistry. There has been a great rise in sterilization and disinfection techniques since the 1990s. As a result, problems regarding the deterioration of instruments and alteration of the physical and chemical properties of materials used in dentistry have emerged [1].

According to Association for Professionals in Infection Control and Epidemiology, Inc. dental instruments that are not intended to penetrate oral soft tissue or bone but may come into contact with oral tissues are classified as semi-critical and should be sterilized. If the semi-critical instrument could be damaged by the sterilization process, the instrument should be high-level disinfected. The exact time for disinfecting semi-critical items is somewhat elusive at present because of conflicting label claims and lack of agreement in published literature. The longer the exposure of an item to a disinfectant, the more likely it is that all contaminating microorganisms will be inactivated. Unfortunately, with extended exposure to a disinfectant it is also more likely that delicate and intricate instruments materials may be damaged. Medical equipment or materials, which are difficult to clean and disinfect because of narrow channels or other areas that can harbor organisms should be exposed to a high level disinfectant for at least

20 minutes at room temperature after cleaning [2].

One type of dental material that is very sensitive to different processes of sterilization is the elastomer. Elastomer is a general term which encompasses materials that after substantial deformation rapidly returns to their original dimensions. Natural rubber, probably used by the ancient Incan and Mayan civilizations, was the first known elastomer. It had limited use because of its unfavorable temperature behavior and water absorption properties. With the advent of vulcanization by Charles Goodyear in 1839, uses for natural rubber greatly increased. Early pioneer practitioners advocated use of natural latex rubber elastics in orthodontics [3].

Other elastomeric materials used in orthodontics frequently are synthetic elastomers made from polyurethanes. These polymers are also not ideal elastic material because their mechanical and physical properties change with different environmental conditions. Environmental factors such as temperature changes, tooth movement, pH variations, oral fluoride rinses, salivary enzymes, and masticatory forces have all been associated with the deformation, force degradation, and relaxation behavior of these elastomers [4].

These polymers have been widely used by orthodontists since the 1960s in the form of ligatures and chains or modules, the exact composition of elastomers is an industry secret.

In orthodontic treatment, forces needed for tooth movement is generated by elastomeric ligatures,

because they tie the arch wire to the bracket. The cost efficiency and ease in application make them more commonly used than other forms of ligation. e. g, wire ligatures, self-ligating brackets [5].

Studies published on elastomeric products have evaluated threads and chains of two or more links for the effects of time, temperature, salivary pH, and water sorption on force loss, permanent deformation, and strength. Although elastomeric ligatures are made of the same material as elastomeric chains, the clinical applications are different. Consequently, the clinical response may be different [6].

Elastomeric materials are altered in the presence of moisture by water sorption that facilitates slippage of molecules or polymer chains past one another accelerating the force decay process of these materials [7]. Many authors have reported permanent deformation and rapid force loss of these products. These products lose 50% to 70% of their force in the first 24 hours.

The consequences of changing the environment with regard to initial force delivery and force decay of elastomeric materials have been attempted by several investigators. These attempts have looked at conditions that could exist within the oral cavity or might be used in disinfection of the elastomeric materials before placement in the mouth [8].

Contamination during processing, packaging, and manipulation by the dental assistant or orthodontist prior to reaching its final destination in the oral cavity of elastomeric ligatures can be present.

Some studies have shown higher number of microorganisms can be verified on tooth surfaces than the elastomeric ligatures because of its rough surface and the absorption properties of this material. However, studies to evaluate the presence of microbial contamination of elastomeric materials after unpacking or prior to its insertion into the oral cavity, are scant.

The orthodontist may use from 1 to 30 modules of the elastomeric ligatures sold in strips in any one appointment. Accordingly, the remaining modules have to be disinfected before they can be used for another patient [9].

Communications on infection control recommend that heat sterilization be used for heat resistant instruments and materials while heat-sensitive

articles be immersed in a glutaraldehyde solution for at least 30 minutes for disinfection and 10 hours for sterilization [10].

Glutaraldehyde solution has been used since the 1940s for disinfecting surgical instruments in situations where heat sterilization was not feasible, such as in battlefield settings. Its effectiveness in killing all forms of bacteria, viruses and spores has been documented extensively [11].

More recently, ortho-phthalaldehyde (OPA) has been proposed as a possible alternative to glutaraldehyde for high-level disinfection [12]. OPA has demonstrated excellent microbicidal activity. It has shown superior myco-bactericidal activity compared with glutaraldehyde. OPA has excellent material compatibility. Limited clinical studies of OPA are available.

Orthodontic elastomeric ligatures or modules are polyurethane elastomers. Industrial polyurethanes are not inert materials. They decompose under prolonged contact with enzymes, water and moist heat. Moreover, in the dental context, the clinical behavior of synthetic elastic polymers is highly problematic [13].

For orthodontic ligatures, maintenance of force delivery is needed to sustain full engagement of arch wires in the bracket slot. Chemical factors such as water, saliva and compounds such as peroxide, which generate free radicals, can accelerate the breakage of the molecular cross-links and it is possible that sterilization or disinfection may elicit similar effects. Since there are indications that acidic solutions are more likely to produce a breakdown of the elastomeric chain, neutral and alkaline solutions were investigated [14].

A limited number of studies testing the effect of antibacterial solutions on orthodontic elastomers appear in the literature. Early measures of forces required to stretch three brands of elastomeric chains a prescribed distance after 20 cyclic exposures of 10 minutes to a 0.5% glutaraldehyde solution, in addition to testing after other disinfection procedures. These results reflect a slight weakening of the modules. Others examined the tensile force to fail of six elastomeric chains exposed to two brands of 2% alkaline glutaraldehyde solution for 30 minutes, 10 hours, and 144 hours. Compared to as-received material, they found a significant decrease in failure load in four of the chains after exposure to one brand for 10 hours. At 144

hours, all materials were significantly decreased in strength. Curiously, the other solution did not affect the failure load of the chains. Generally, these studies show exposure to disinfectant solutions, may result in a decrease in tensile strength and force delivery [9].

Manufacturers of disinfectant solutions have minimum contact time and temperature requirements to ensure the effectiveness of antibacterial action, but they have not expressed any maximum contact time of exposure to the solutions. It is not unusual for an orthodontic clinic to be operating less than five days a week. Often, due to clinic operating schedules, these ligatures are immersed for longer, continuous hours, even days, before being removed and stored for future clinical use. Temperature maintenance according to disinfectant specifications requires either specific device like incubator or constant temperature monitoring if device like water bath is used. Also it is not unusual for an orthodontic clinics' armamentarium to not include temperature maintaining device.

In this investigation, simulating the clinical practice, at room temperature short to medium exposure of elastomeric ligatures to disinfectant solutions and its effects on tensile load at failure were studied.

### 1.1 Aims and Objectives

The aim and objectives of the study were to assess the effect of extended exposure to disinfection solutions 1) GLUTAREX 2) CIDEX and 3) CIDEX OPA, on tensile load inducing failure-of-function for different orthodontic elastomeric ligatures.

## 2. MATERIALS AND METHODS

### 2.1 Collection of Materials

Clear Orthodontic elastomeric ligatures for twin brackets were obtained from 5 manufacturers;

- A. 3M UNITEK,
- B. ORMCO
- C. ORTHO ORGANIZER
- D. GAC
- E. T P ORTHODONTICS

3 disinfectant solutions used were

- A. GLUTAREX (3M)
- B. CIDEX® (Johnson and Johnson Ltd)

### C. CIDEX® OPA (Johnson and Johnson Ltd)

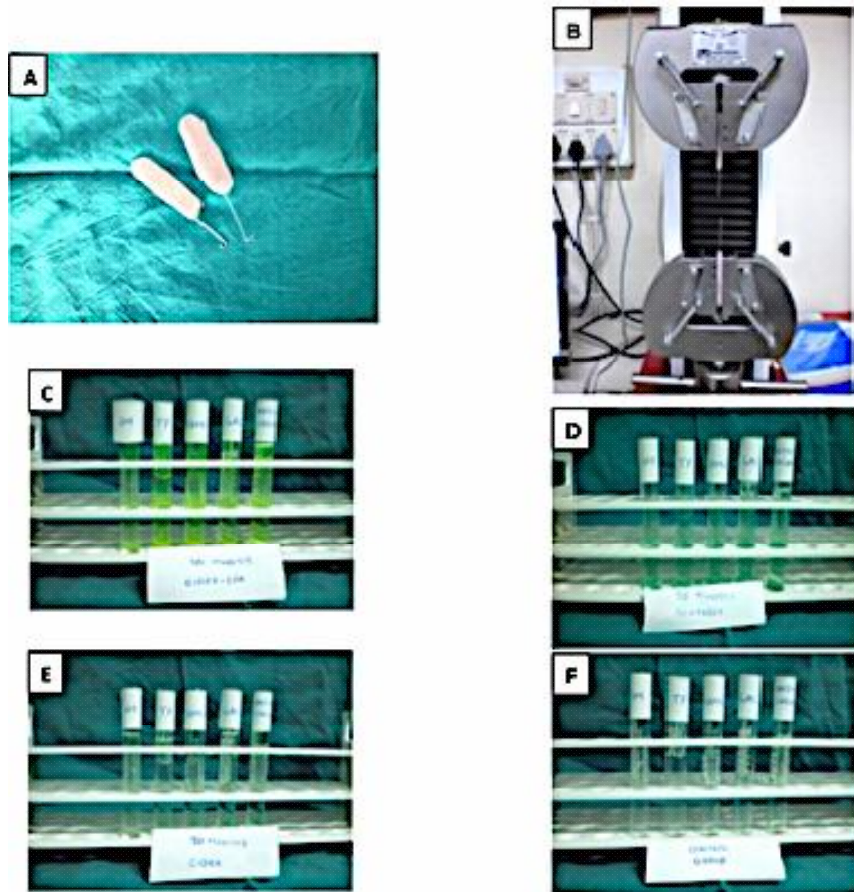
Glutarex (3M) is 2% glutaraldehyde solution with pH value of 6.5. It is indicated for use as disinfectant when used or reused for a minimum of 10 hours at room temperature. It is indicated for use as a disinfectant when used or reused with a minimum immersion time of 10 minutes (a high level disinfectant for minimum of 45 minutes) at room temperature.

Cidex® (Johnson and Johnson Ltd) is an activated glutaraldehyde solution. with the minimum effective concentration of above 1.5% glutaraldehyde with pH value between 8.2-9.2. It is a disinfectant when used or reused for up to a maximum of 14 days at 25°C with an immersion time of at least 10 hours. It is indicated for use as a high level disinfectant when used or reused for up to a maximum of 14 days at 20°C with an immersion time of at least 20 minutes. The disinfection time for polyurethane recommended is 8 hours of continuous contact with Cidex® solution.

Cidex® OPA (Johnson and Johnson) is ortho-phthalaldehyde solution with the minimum effective concentration (MEC) of the active ingredient of .55% with pH value of 7.5. It is indicated for use as a high level disinfectant when used or reused for up to a maximum of 14 days at 20°C with an immersion time of at least 5 minutes.

### 2.2 Methods

Ten Elastomeric ligatures from each manufacturer were exposed to each disinfectant solution with exposure times of 30 minutes, 1 hour, 12 hours and 24 hours. Ten unexposed elastomeric ligatures from each manufacturer were also tested for which acted as control group. This represent the common clinical situation of using the ligatures as received from the manufacturer. All control ligatures were stored dry at room temperature, unexposed to light. Mechanical testing was performed by placing a specimen in a custom made jig comprised of two metal pins attached respectively to the fixed and movable crossheads of a universal testing machine (LLOYD Instruments, LR 50K). Each ligature was loaded in tension at a crosshead speed of 100 mm/min until fracture occurred. Maximum tensile load was recorded in Newton's. The tensile load at failure was used as an analog to the clinical situation of ligature breakage during tie in.



**Fig. 1. A. Mounting Jig, B. Instron machine with mounted elastomeric ligature (C,D,E.) Elastomeric ligatures in disinfecting solutions, F. control group**

### 3. RESULTS

Three-way ANOVA showed significant differences ( $P < .0001$ ) not only within manufacturer and time of exposure but also between disinfectants ( $P < .001$ ). Significant interactions ( $P < .0001$ ) were observed between manufacturer and time and between disinfectant and time. Greater significant changes were seen in tensile load at failure for all 5 manufactures ligatures in Cidex solution whereas changes were less significant in Cidex OPA solution and least in Glutarex solution. The failure loads were significantly different from each other of all five companies, with the ligatures from 3M exhibiting the greatest tensile load at failure and those from Ortho Organizer, the least.

A Student t test showed that T P Orthodontics, Ormco and Ortho Organizer ligatures showed significant change in tensile load at failure with 30 minutes' exposure time in different solutions

whereas 3M and GAC did not show significant differences. At 1 hour, there was significant change in tensile load at failure for 3M, Ormco and Ortho Organizer ligatures. At 12 hours, changes in 2 brands i.e. 3M and T P Orthodontics were not significant whereas GAC showed changes which were moderately suggestive of significance and Ormco, Ortho Organizer showed changes which were strongly significant. Again at 24 hours, changes were significant for 3M, Ormco and Ortho Organizer but not for GAC and T P Orthodontics.

In comparison to unexposed specimens, Post-Hoc Turkey test values showed that significantly ( $P < .001$ ) lower tensile failure loads were found in 3M, Ormco, GAC, T P Orthodontics ligatures when exposed to disinfectants for all exposure times in all disinfectants. Ortho Organizer ligatures showed increase in tensile failure loads when exposed to Cidex and Cidex OPA

disinfectants for 30 minutes and 1 hour whereas to Glutarex at 24 hours.

### 3.1 Study Design: A Comparative Study

A comparative study was done to study tensile load at failure of unexposed orthodontic elastomeric ligatures from each manufacturer, stored dry at room temperature unexposed to light.

## 4. DISCUSSION

The unexposed ligatures showed tensile load failure, which were significantly different with each manufacturer. This may be attributed to small differences in production despite the fact that most of the orthodontic elastomers currently available share similar fabrication methods. Some factors identified previously include [15]:

- a. Processing variations in manufacturing techniques involving injection-molding or cutting of the raw material, the injection molded ligature is made by injection of liquefied elastomeric material into a mold and curing, whereas the cut ligature is sliced from previously processed elastomeric tubing.
- b. Effects induced from various additives incorporated in the final product, and different morphologic or dimensional characteristics.
- c. Strictness of quality control procedures followed
- d. Modular diameters.

Tensile load at failure followed the order:

3M \_ Ormco \_ GAC\_T P Orthodontics\_Ortho organizer.

Synthetic rubber elastomers have a weak molecular attraction consisting of primary and secondary bonds. At rest, a random geometric pattern of folded linear molecular chains exists. On extension or distortion, these molecular chains unfold in an ordered linear fashion at the expense of the secondary bonds. Cross links of primary bonds are maintained at a few locations along the molecular chains. The release of the extension will allow for return to a passive configuration provided the distraction of the chains is not sufficient to cause rupture of these primary bonds. If the primary bonds are broken, the elastic limit has been exceeded and permanent deformation occurs [3].

A study was done to measure the production and decay of forces produced by elastic modules

under conditions simulating clinical usage over a time period of 2 hrs. to 4 weeks. Force decay was moderate and all modules tested produced approximately 1 lb. of force at the end of the 4-week test period. Therefore, from a clinical stand point, modules need not be changed more frequently than once every 4 weeks [16].

A study was done to investigate the effects of pre-stretching on force degradation characteristics of plastic modules. A specially designed apparatus employing a Carpo gauge provided reproducible force measurements. Results showed that pre-stretching provides a technique for the orthodontist to obtain plastic modules with nearly constant forces, but these appliances must be used immediately after pre-stretching to avoid substantial relaxation effects [17].

Synthetic elastomers (polymers) are very sensitive to the effects of free radical generating systems, notably, ozone and ultraviolet light. The exposure to free radicals results in a decrease in the flexibility and tensile strength of the polymer. Manufacturers have added antioxidants and antiozonates to retard these effects and extend the shelf life of elastomeric.

In an in-vitro study, stability of different formulations of urethane elastomers in water, dry air and moist air environments were examined. The practical implication of this study is that, for most applications, polycaprolactone and polyether based urethane elastomers can be formulated to provide continuous service in moisture- containing environments [18].

Polyurethane is a generic term given to elastic polymers that contain the urethane linkage. Elastomeric orthodontic ligatures are polyurethanes, whose exact composition is a commercial secret, are polyurethanes [5].

A study investigated the change in the physical properties of conventional and Super Slick elastomeric ligatures after they had been in the mouth and found that there were statistically significant differences in the failure loads of elastomeric that had not be placed in the mouth and those that had been in the mouth for 6 weeks. There were no differences in the static frictional forces produced by conventional and Super Slick ligatures either before or after they had been placed in the mouth. There appears to be a direct proportional relationship between failure load and static friction of elastomeric ligatures [19].

**Table 1. Comparison of orthodontic elastomeric ligatures in different exposure with ANOVA and student t test**

	<b>Control</b>	<b>30 min</b>	<b>1 hour</b>	<b>12 hour</b>	<b>24 hour</b>	<b>P value</b>
3M-Glutarex	18.16±0.93	15.26±1.52	13.16±1.14	14.44±1.17	14.17±0.92	F=27.175; P<0.001**
3M-Cidex	18.16±0.93	15.59±0.41	16.10±1.34	14.12±0.87	12.96±0.48	F=51.373; P<0.001**
3M-OPA	18.16±0.93	15.33±0.81	15.06±1.29	13.57±0.61	13.40±0.63	F=46.2.99; P<0.001**
P value	-	0.747	<0.001**	0.115	0.002**	-
Ormco-Glutarex	17.28±1.13	13.86±0.81	13.86±0.81	12.93±1.09	14.52±1.69	F=20.787; P<0.001**
Ormco-Cidex	17.28±1.13	15.02±0.54	15.89±0.79	13.23±1.01	12.96±0.93	F=40.580; P<0.001**
Ormco-OPA	17.28±1.13	15.41±0.75	14.72±0.56	11.88±0.71	14.45±0.58	F=63.115; P<0.001**
P value	-	<0.001**	<0.001**	0.009**	0.008**	-
Ortho-Organizer Cidex	13.54±1.04	18.14±1.45	16.52±0.74	11.66±1.19	13.04±1.01	F=57.751; P<0.001**
Ortho-Organizer OPA	13.54±1.04	14.41±0.56	15.20±0.78	13.18±0.91	13.63±1.09	F=9.168; P<0.001**
P value	-	<0.001**	<0.001**	0.003**	<0.001**	-
GAC-Glutarex	16.85±0.70	15.57±0.63	15.27±0.82	14.24±0.49	14.04±0.79	F=26.082; P<0.001**
GAC-Cidex	16.85±0.70	15.84±0.54	16.25±0.92	14.76±0.38	14.28±0.46	F=30.861; P<0.001**
GAC-OPA	16.85±0.70	15.65±0.53	15.61±1.18	14.32±0.45	13.65±0.44	F=30.089; P<0.001**
P value	-	0.583	0.100	0.030*	0.180	-
TP ORTHODONTICS- Glutarex	15.06±0.59	13.37±0.68	12.71±1.14	12.72±0.99	11.43±1.18	F=19.255; P<0.001**
TP ORTHODONTICS- Cidex	15.06±0.59	13.73±0.36	13.25±0.61	13.29±0.82	11.27±1.18	F=31.351; P<0.001**
TP ORTHODONTICS- OPA	15.06±0.59	12.77±0.76	12.92±0.65	13.01±0.77	11.09±0.89	F=36.262; P<0.001**
P value	-	0.008**	0.318	0.351	0.786	-

Elastomeric orthodontic modules, in general, are polyurethanes; thermosetting polymer products of a step-reaction polymerization process, possessing a  $-(NH)-(C=O)-O-$  unit. Polyurethane elastomers are produced by the rearrangement polymerization of diisocyanates and polyols [6].

A recent study investigated the force decay in orthodontic elastomeric chains after immersion in disinfection solutions including chlorhexidine and per-acetic acid concluded that there were no significant differences among the investigated groups, in most interval times, indicating that both chemical solutions can be used for previous disinfection of orthodontic elastomeric chains [20].

## 5. CONCLUSION

This study evaluated the effects of extended exposure to disinfection solutions on tensile load at failure of different orthodontic elastomeric ligatures.

The study evaluated tensile load at failure of different elastomeric ligatures from the unexposed elastomeric ligatures.

Elastomeric Ligatures tensile load at failure followed the pattern:

3M \_ GAC \_ Ormco \_ T P Orthodontics \_ Ortho organizer.

The study evaluated the tensile load at failure of different elastomeric ligatures exposed to different disinfectants with exposure time of 30 minutes, 1 hour, 12 hours and 24 hours.

- a. Compared to unexposed specimens, tensile load at failure of elastomeric ligatures of 3M, Ormco, GAC and TP Orthodontics decreased when exposed to all three disinfectant solutions for as less as even 30 minutes.
- b. Compared to unexposed specimens, tensile load at failure of elastomeric ligatures of Ortho Organizer increased in two disinfectants and decreased in one disinfectant for as less as even 30 minutes.
- c. Behavior of all different brands of elastomeric ligatures in terms of tensile load at failure was different in different disinfectant solutions.

## CONSENT

It is not applicable.

## ETHICAL APPROVAL

It is not applicable.

## COMPETING INTERESTS

Author has declared that no competing interests exist.

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