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ABSTRACT

AN ASSESSMENT OF THREE DIFFERENT FORMS OF STERILIZATION AND CLINICAL USAGE ON VARIOUS ORTHODONTIC PIN AND LIGATURE CUTTERS, A PILOT STUDY

by

Warren L. Creed

With an awareness of cross infection in dentistry and of AIDS (acquired immune deficiency syndrome), sterilization in the dental office has been brought to the public's attention by the news media. Much work has been done on which sterilization methods are acceptable but little has been written about the effects of sterilization procedures on the instruments themselves. In this study, 36 pin and ligature cutters were sterilized 250 cycles using three different methods of sterilization following the guidelines given by the Center for Disease Control (CDC). The cutters were examined for changes in lateral hinge movement, visual appearance and ordinal ranking by preference.

The results of this study showed that the lateral side movement of the cutters was not clinically significant except for the AEZ inserted cutters. Visually, the cutters showed

various amounts of discoloration due to the sterilization
type and manufacturer of the cutters.

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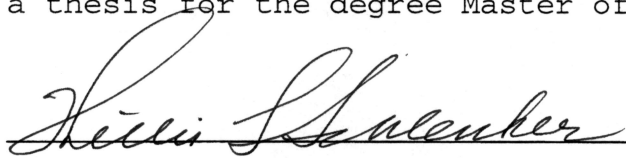
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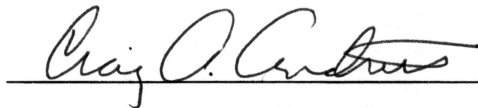
A Thesis in Partial Fulfillment
of the Requirements for the Degree Master of
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June 1994

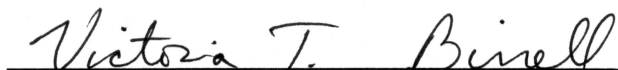
Each person whose signature appears below certifies that this thesis in their opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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- 9) Unitek Corporation for their pin and ligature cutters.

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INTRODUCTION

With the publicity of cross infection and the increased awareness of AIDS, sterilization techniques in the orthodontic office have been brought to the attention of the public by the media. "Even though the recognized infection risks of Mycobacterium tuberculosis, herpes simplex virus and other microorganisms have been historically documented, the impact of HBV and HIV infections changed the way dentistry is practiced as a clinical discipline."¹ It is no longer acceptable that instruments be clean and disinfected, it is now expected that they be cleaned and sterilized between each patient. Regardless of their classification of use. All instruments must be sterilized.

"The epidemic of HIV infection and AIDS has also become an epidemic of fear. Not since the polio epidemic in the 1950's has the public reacted so emotionally to a medical situation. The public concern has intensified as each new observation has been announced".²

Sterilization is the process by which all forms of microorganisms are destroyed; including viruses, bacteria, fungi, and spores. Disinfection is generally less lethal to pathogenic organisms than sterilization. The disinfection process leads to a reduction in the level of microbial

contamination and covers, depending on the disinfectant used and treatment time, a broad range of activity that may extend from sterility at one extreme to a minimal reduction in the microbial contamination at the other.³

Instruments that penetrate soft tissue and or bone must be sterilized after each use. Instruments that do not penetrate oral soft tissues or bone but may come into contact with oral tissues should be sterilized after each use. If the instruments cannot be sterilized then they should receive high level disinfection.^{4,5,6,7,8}

The American Dental Association makes the following recommendations for the sterilization of orthodontic instruments: 1) Orthodontic cutters constructed of high-quality stainless steel can be sterilized by any of the following methods: steam autoclave, dry heat, or chemical vapor sterilization. 2) Instruments containing carbon steel should be protected, when using the steam autoclave, with a 2% sodium nitrite rinse.³ 3) Any instruments that have plastic parts should be sterilized with ethylene oxide (a 24 hour process).

Orthodontic cutters and instruments, particularly those composed of stainless steel and carbide steel, are subject to damage from sterilization. The steam autoclave can cause corrosion, dulling, loss of temper and staining of the instruments. Staining of instruments may not be caused by

imperfections in the instruments but by the steam itself or by the ultrasonic solution used first. If normal tap water is used it can contain rust particles, scale from the pipes and chemical additives that can cause discoloration of the instruments.^{9,10} The dry heat sterilizer can cause loss of temper and corrosion in these instruments. The Chemiclave dulls the instruments and produces fumes.^{11,12}

Corrosion is the destructive attack of a metal by an electrochemical reaction with its environment.¹³ Orthodontic instruments are typically subjected to two types of corrosion: 1) solution corrosion and 2) debris corrosion. Heat, of itself, will not cause corrosion but it will accelerate the process. In solution corrosion, blood, saliva, soaps and other chemical cleaners react with metal as either an acid or a base. With debris corrosion, dry blood, saliva, cement, lubricants, soaps and other chemical cleaners may set up a potential difference that results in rust formation.⁹

Orthodontic cutters and instruments that are to be sterilized should be prepared properly so that the sterilization can be effective. Immediately after use, the instruments should be rinsed under warm running water to remove blood, body fluids and tissue. Then, instruments should either be scrubbed with hot water and soap or detergent or placed in an ultrasonic cleaner with the proper

cleaning solution. Time in the ultrasonic cleaner depends on the size of the load and degree of contamination. After cleaning with the ultrasonic cleaner, instruments should be drained and dried to prevent spotting or staining. Instruments should be packaged or wrapped to maintain their sterility. This is so they will not be touched with bare hands or contaminated when restocking.³

The purpose of this study was to examine the deterioration of pin and ligature cutters when subjected to multiple sterilization and clinical cycles over an extended period of time. The null hypothesis is that there is no significant difference between the sterilization methods on the deterioration of the cutters.

METHODS AND MATERIALS

Typically, orthodontic pin and ligature cutters are constructed by one of two designs. The first design is known as the one piece construction. This implies that the beaks and handle are constructed from a single piece of raw stock. High carbon chromium molybdenum (HCCM) stainless steel is used in the construction of the one piece instruments.

The second design consists of a handle, tip insert and brazing alloy to join the tip and handle. Most orthodontic cutters are constructed by this second method. The handles are typically fabricated from three different metals: 1) 17-4 Ph stainless steel, 2) 420 series stainless steel or 3) chrome plated tool steel. The tip inserts are typically fabricated from two different metals: 1) carbide and 2) T-15 (5% cobalt) tool steel. The brazing assembly of the tips and the handles is done with silver-based copper containing braze alloys.

The hinge joint of the cutters are typically of either the box joint construction or overlapping joint design. Both designs have a screw running through the middle to hold the handles of the cutters together. In the box design one handle is surrounded on both sides by a plate that is part of the other handle. The box joint is not adjustable once fabricated. The overlapping joint consists of the two

handles over lapping each other and held together with a screw. The head of the screw is generally flattened off. The screw may be tightened if the cutter is returned to the manufacturer.

New pin and ligature cutters were obtained from various manufacturers of orthodontic cutters. The cutters were visually examined for any sign of defects before they were included in the study. The cutters, by manufacturer, were randomly assigned to one of three groups and numbered. The instruments were placed in Thompson stainless steel cassettes by group.

The instruments were then used to cut a .014" twisted stainless steel ligature wire. The wire was held in a jig so that the cuts were 2 mm. from the tip of the cutters. (See Fig. 1)

Each cutter was used to make ten cuts between sterilization cycles. The instruments were then placed in an ultrasonic cleaner containing a 2% solution of sodium nitrite and ultrasonically cleaned for 10 minutes. The cutters were then removed and toweled dry. The joint was dried with a blast of compressed air and placed back in their respective cassettes.

The cassettes were then sterilized according to their group. The first group was sterilized in a Castle steam autoclave, model GLS 10, at 135°C (275°F) for 3 minutes at

30 pounds per square inch (psi). The second group was sterilized in a rapid transfer dry heat sterilizer, Dentronix DDS 5000 at 184°C (375°F) for 6 minutes. The third group was sterilized in a chemical vapor sterilizer, the Harvey Chemiclave 5000, at 132°C (270°F) at 20 psi for 20 minutes. The Vapo Sterile solution used in the chemical vapor sterilizer consists of 72% ethanol and .23% formaldehyde with rest being other inert ingredients.

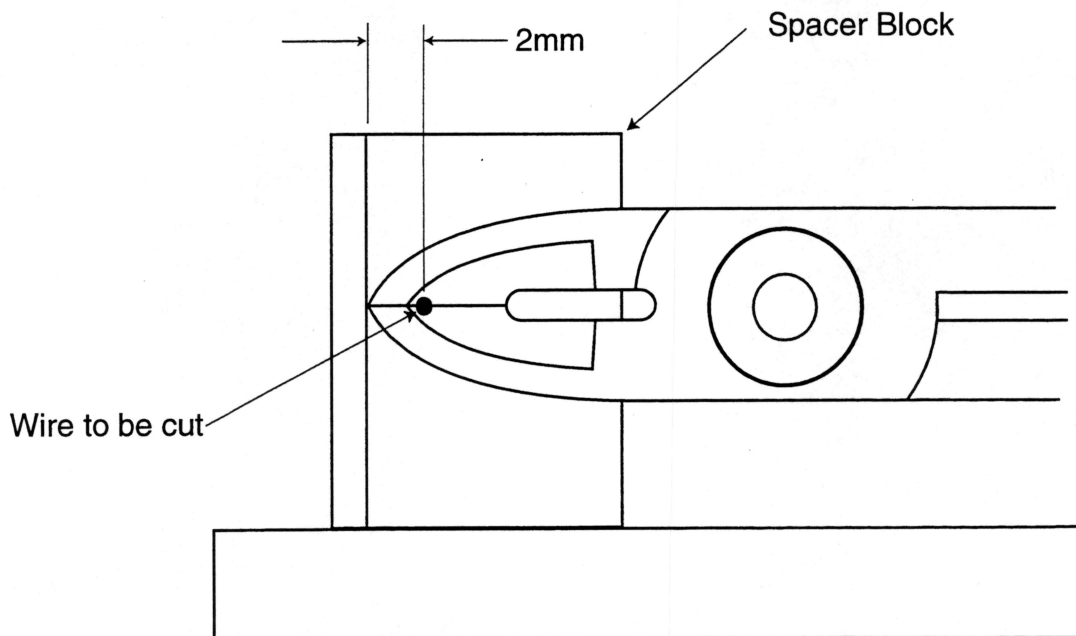


Figure 1. Diagram depicting fixture used in repetitive cuts.

Each group was sterilized for 250 cycles. Before sterilization and at every 50 cycles the lateral hinge movement of the joint was evaluated. One half of the handle

was held tightly in position while a force of 454 grams was applied to the other half of the handle (See Fig. 2). The movement was recorded to the nearest .001".

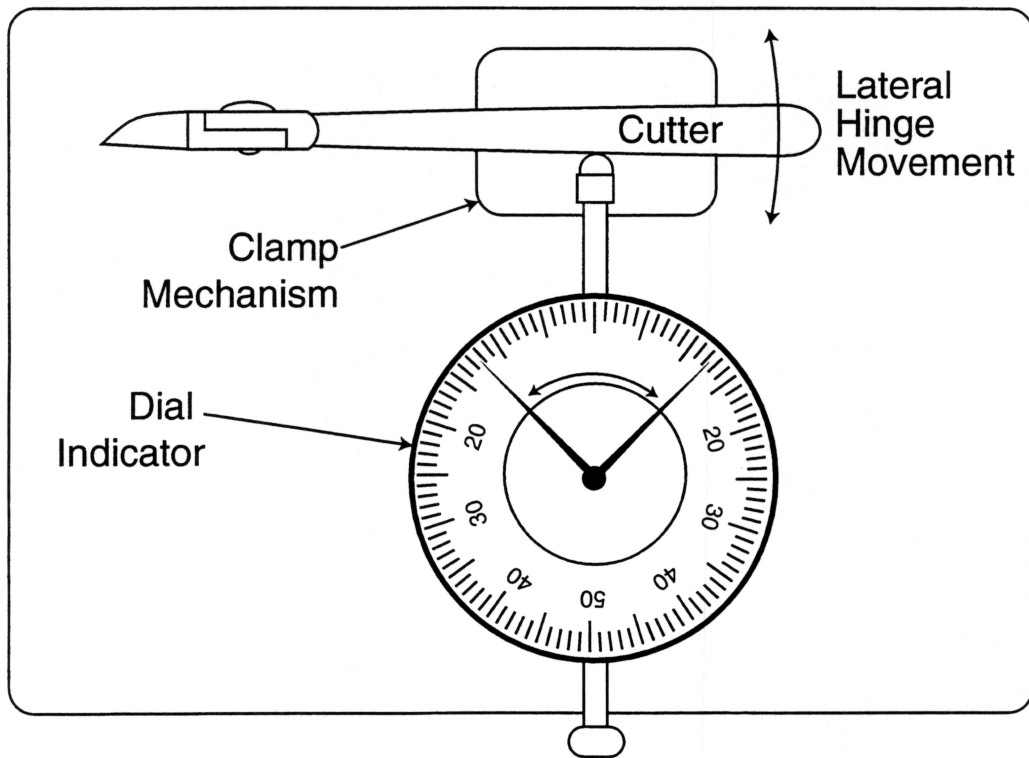


Figure 2. Diagram of lateral side movement test fixture.

A motion ratio was determined for each cutter (See Table 1). The motion ratio is the ratio of the length of cutter arm to the length of the handle. Length of the cutter arm is measured from the tip of the cutter to the middle of the joint. The length of the handle was measured from the middle of the joint to where the force was applied to the handle (See Fig. 3).

The inserted cutting edges of the cutters were examined under a scanning electron microscope, Zeiss model DSM 940, at a magnification of 100 X. At the same time an EDAX (energy dispersive x-ray analysis) was performed on the insert material, using a Link model eXL EDAX, thus allowing any changes in the surface composition to be noted.

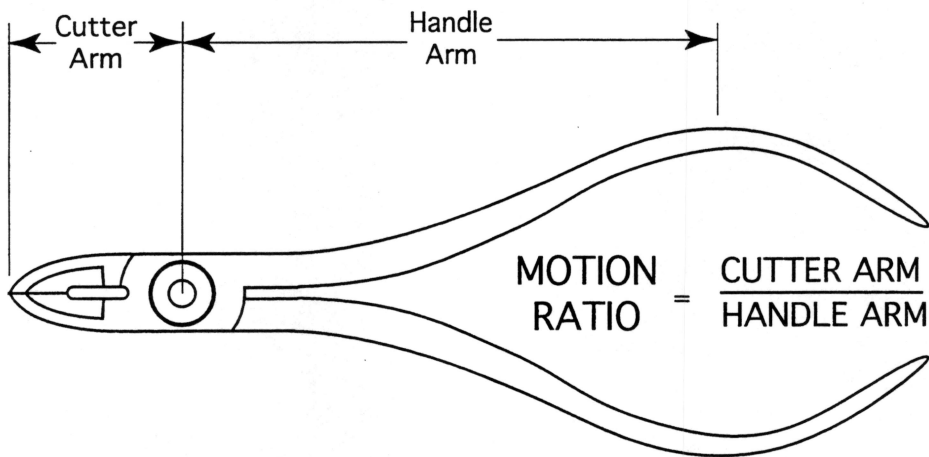


Figure 3. Motion ratio diagram

Cutter	Handle Arm	Cutting Arm	Motion Ratio
AEZ inserted	2.90"	0.80"	.28
AEZ one piece	3.10"	0.96"	.31
Dentronix	2.80"	0.90"	.32
ETM	2.80"	0.90"	.32
Orthopli	2.65"	1.10"	.41
Unitek	2.85"	0.90"	.32

Table 1. Motion Ratio

Sharpness of the cutters was determined by comparing the radius of the cutting edge before and after sterilization. The radius of the cutting edge was measured by cutting partially through a .020" brass wire and measuring the radius of the impression left in the wire (See Fig. 4). The before and after measurements were then compared.

The sharpness measurements were made with the OMIS II optical measurement inspection system. The image clarity and detail allow an operator to realize .000050" resolutions.

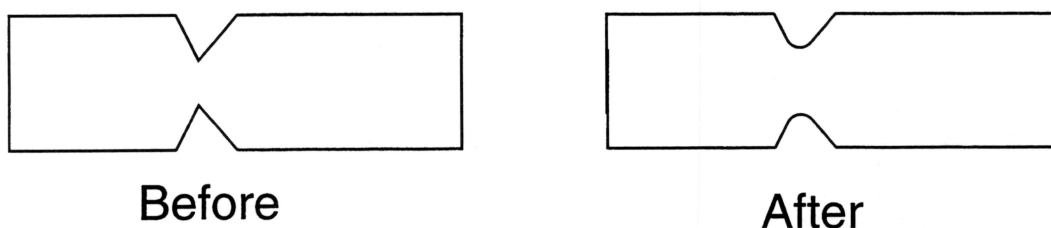


Figure 4. Before and after impression of cutting edges. Notice change in cutting groove from beginning to end.

The cutters were subjectively measured for sharpness and ranked from sharpest to dullest after the 250 sterilization cycles. These measurements were made independently by three dental students (See Tables 3, 4, & 5).

RESULTS

In this study 36 new pin and ligature cutters from six different companies were sterilized using chemical vapor, steam autoclave and dry heat sterilization. Comparisons were made of the lateral hinge movement, sharpness of the instruments, changes in the elemental composition on the surface of the cutting edge, and ordinal ranking.

Each sterilizer was tested weekly to assure that each device was working properly and that the instruments were being subjected to sterilizing conditions. The test strips that were subjected to the three types of sterilization showed no signs of growth after culturing. The control strips were all positive after culturing.

The change in the lateral tip movement of the cutters when compared by manufacturer for the three types of sterilization was least for the autoclave, 2.4 ± 1.2 mils. The change was greater for the dry heat and chemical vapor sterilization, 3.6 ± 1.7 and 4.5 ± 3.0 mils, respectively (See Table 2 and Fig. 5).

The change in lateral tip movement when compared by form of sterilization for each of the manufacturer's varied greatly (See Fig. 6, 7, & 8).

To correct for errors in the lateral hinge movement the standard measurement of error was calculated by measuring

Sterilizing method	AEZ inserted	AEZ one piece	Dentronix	ETM screw joint	Orthopli	Unitek	Mean	Std Dev
Autoclave	0	3.1	0	1.6	3.3	2.6	2.4	1.3
	2.7	4.0	1.9	2.2	3.3	3.8		
Chemiclave	8.4	--	1.9	1.9	2.9	1.9	4.5	3.0
	10.6	1.9	3.8	2.9	5.7	8.0		
Dry Heat	--	3.1	3.8	3.8	4.5	1.9	3.9	1.7
	8.3	3.7	2.6	2.6	5.3	2.9		
Mean	6.0	3.2	2.3	2.5	4.2	3.5		
Std Dev	4.0	0.7	1.3	0.7	1.1	2.1		

Table 2. Tip Movement After 250 Cycles in Mils

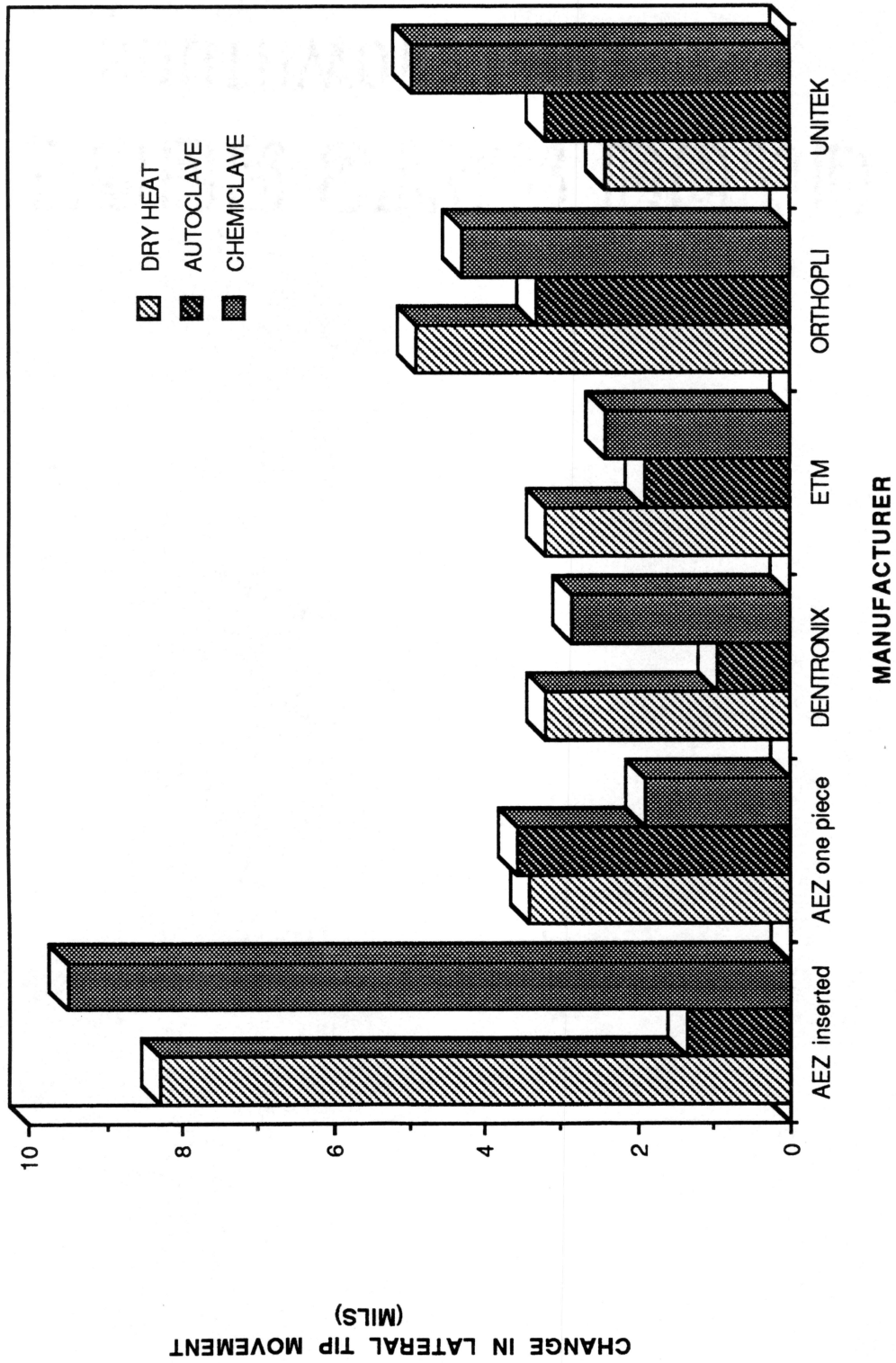


Figure 5. Change in lateral tip movement vs. manufacturer. For three different types of sterilization.

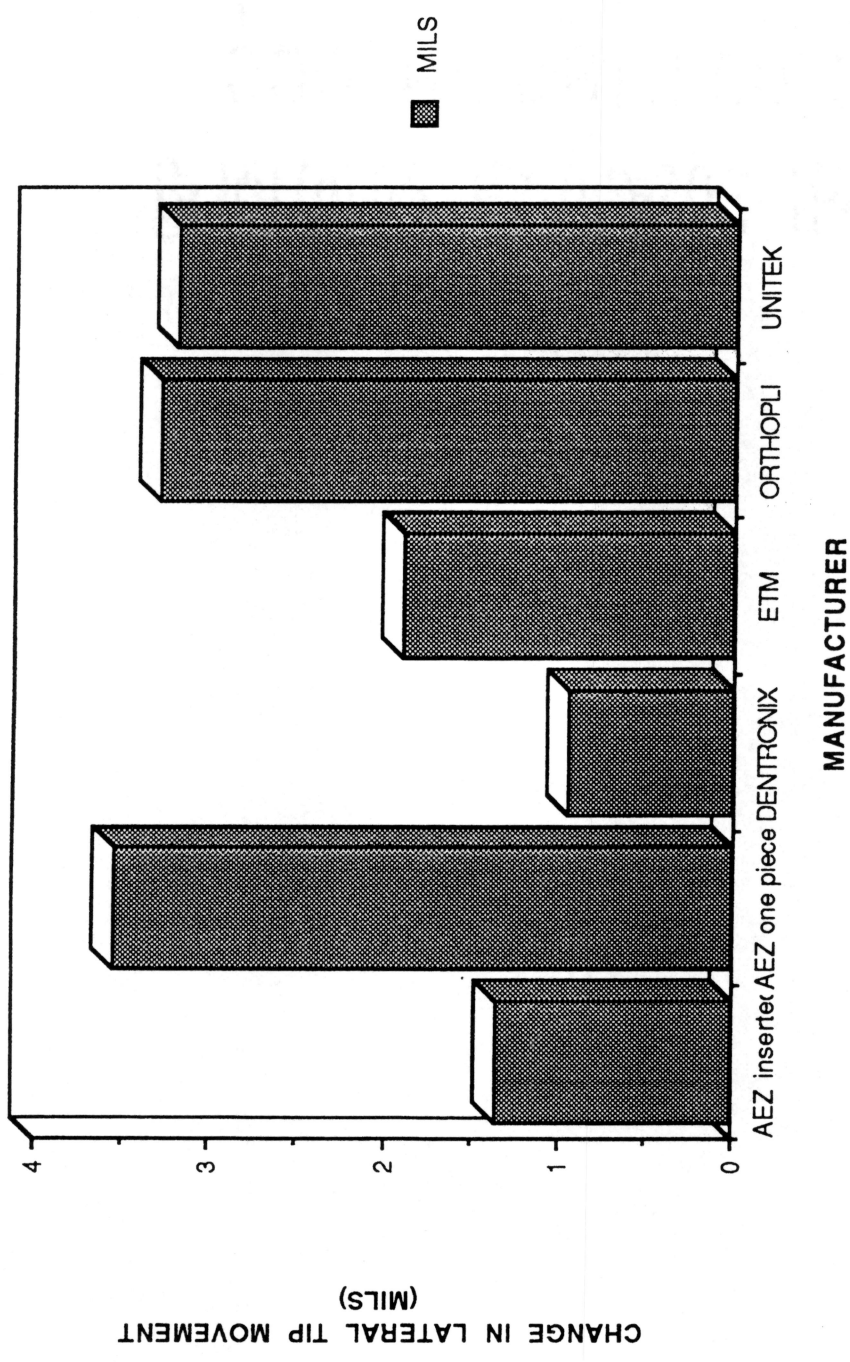


Figure 6. Change in lateral tip movement vs. manufacturer. Autoclave sterilization.

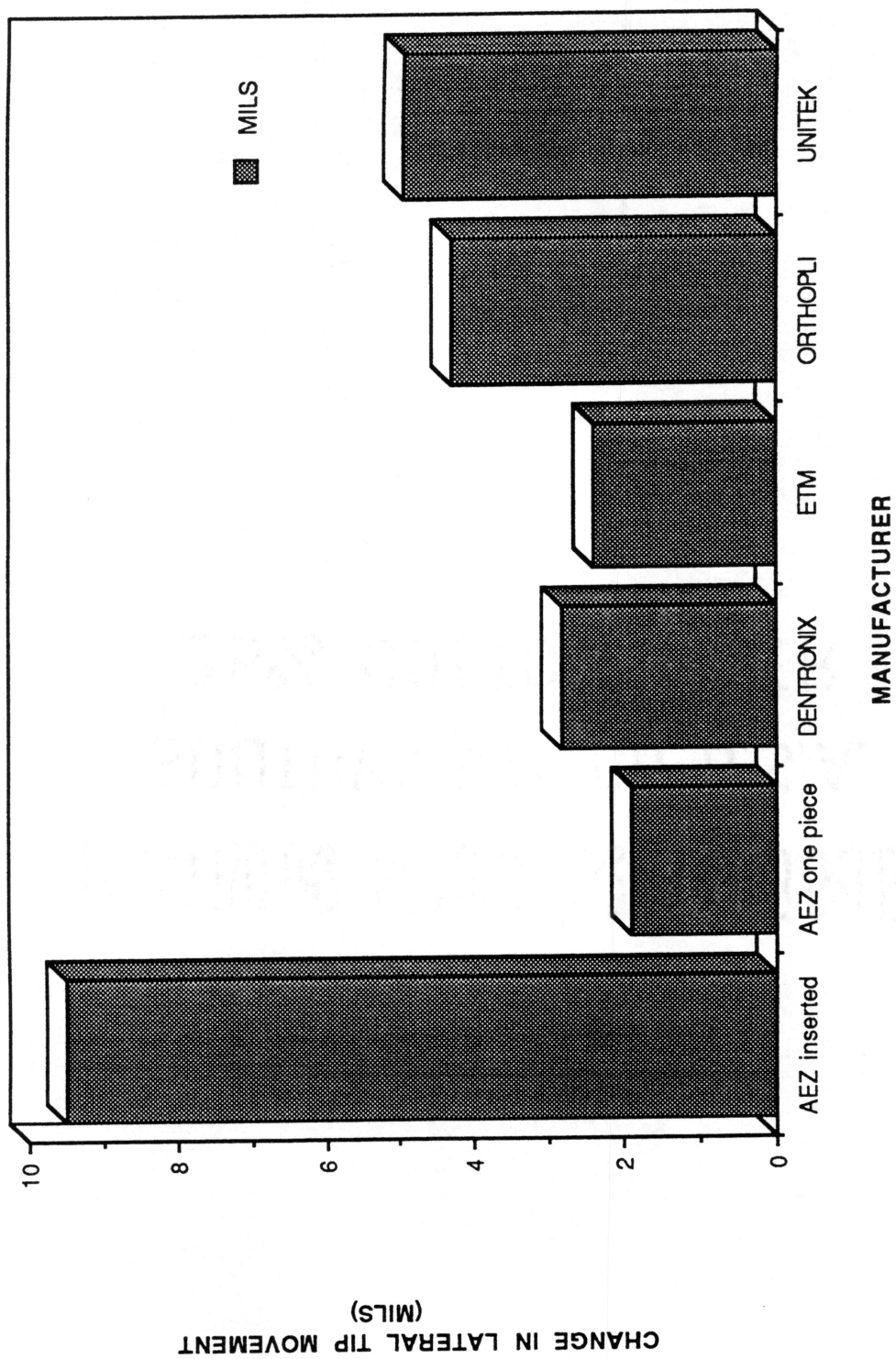


Figure 7. Change in lateral tip movement vs. manufacturer. Chemiclave sterilization.

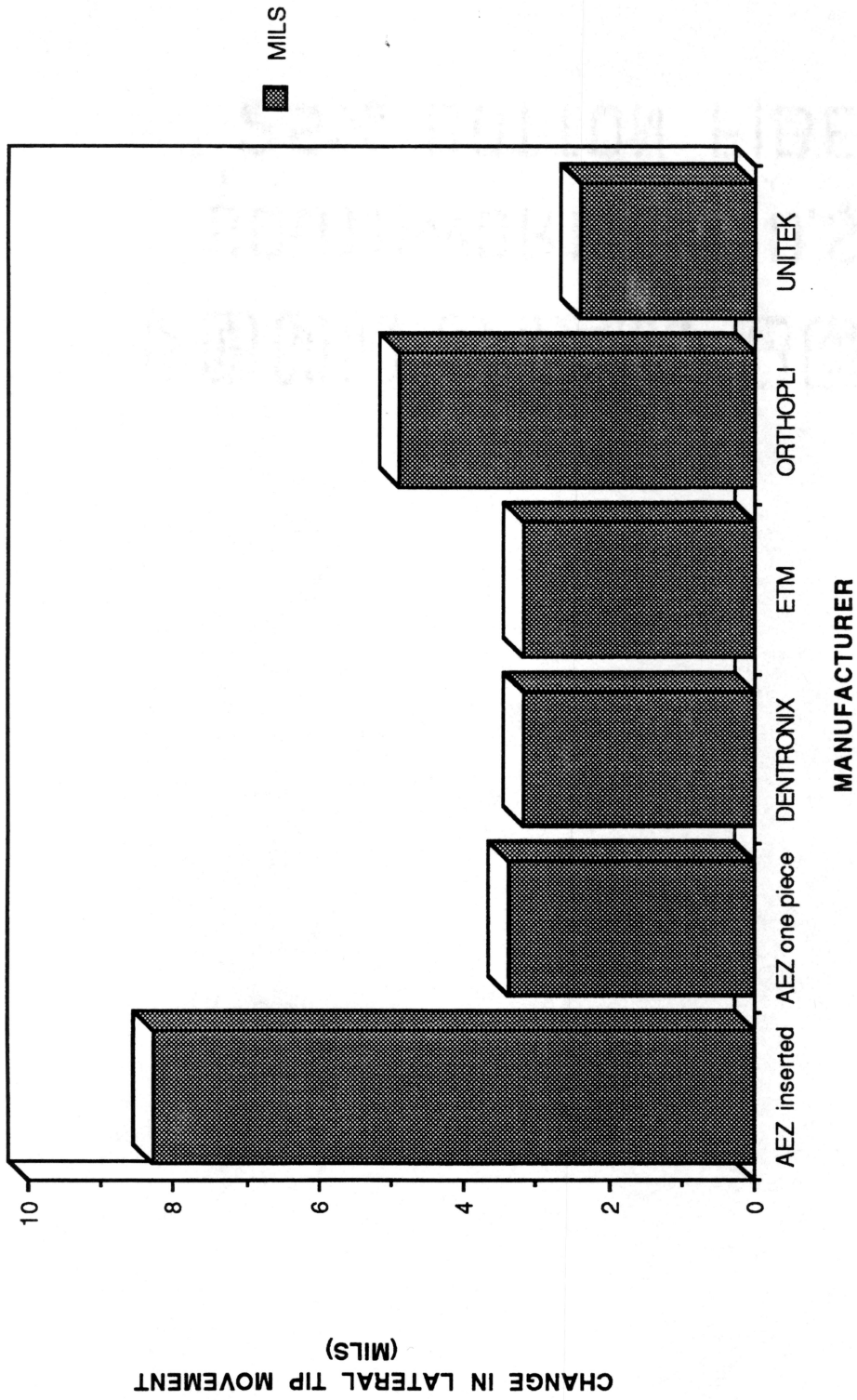


Figure 8. Change in lateral tip movement vs. manufacturer. Dry heat sterilization.

consecutively the hinge movement 10 times with a force of 454 gms. on one cutter. All 10 readings gave a lateral hinge movement of .019". Therefore the standard error of measurement for this study is +/- .0005".

The cutting edges were analyzed using the OMIS II optical measurement system. The cutter had an initial radius that was not measurable except for the AEZ one piece pin and ligature cutter that was measured at .0007". The radius measured after 250 cycles of sterilization and 2500 cuts ranged from .0005", for the Orthopli and Unitek cutters, to .0039" for the AEZ inserted cutter.

The cutters when rank ordinally by the students showed varying results (See Tables 3, 4, and 5). The results of the composite of their ranking had the ETM and Unitek cutters tied followed by the Dentronix, Orthopli, AEZ one piece and the AEZ inserted cutters (See Table 6).

The visual examination of the cutters showed no visible signs of rust. All the cutters showed some degree of discoloration of the inserted tips except for the ETM cutter which were chrome plated.

An EDAX evaluation was conducted on the cutters obtaining a beginning and ending composition of the inserted cutter tips. This data was determined to be inconclusive.

Cutter Rank	AEZ inserted	AEZ one piece	Dentronix	ETM screw joint	Orthopli	Unitek	Best Ranked
1	6	6	1	1	2	3	Unitek
2	2	1	6	3	1	6	ETM
3	4	5	2	4	6	2	Dentronix
4	5	3	4	2	5	1	Orthopli
5	1	4	3	5	4	4	AEZ insert
6	3	2	5	6	3	5	AEZ one piece

Table 3. Ranking of Cutters by Student A

Cutter Rank	AEZ inserted	AEZ one piece	Dentronix	ETM screw joint	Orthopli	Unitek	Best Ranked
1	4	5	6	1	1	3	Unitek
2	6	1	3	5	3	2	Dentronix
3	5	6	1	3	6	6	ETM
4	3	4	2	4	2	1	Orthopli
5	1	3	5	2	5	4	AEZ inserted
6	2	2	4	6	4	5	AEZ one piece

Table 4. Ranking of Cutters by Student B

Cutter Rank	AEZ inserted	AEZ one piece	Dentronix	ETM screw joint	Orthopli	Unitek	Best Ranked
1	4	5	2	1	4	1	ETM
2	5	1	4	6	1	2	Orthopli
3	1	6	5	5	3	3	Dentronix
4	3	3	6	3	2	6	Unitek
5	6	4	3	4	5	4	AEZ one piece
6	2	2	1	2	6	5	AEZ inserted

Table 5. Ranking of Cutters by Student C

Manufacturer	ETM	Unitek	Dentronix	Orthopli	AEZ one piece	AEZ inserted
Composite Ranking	1	1	2	3	4	5

Table 6. Composite Ranking of Cutting Efficiency

DISCUSSION

This study was undertaken to determine whether or not one form of sterilization produced greater damage to the cutter than other methods. The intent was to determine the least destructive form of sterilization and recommend to the orthodontic office the sterilization procedure best suited to preserve the cutters and minimize the cost of operation. The size of this study was limited by the cost of the orthodontic cutters.

With the use of tray set-ups in the orthodontic office, instruments are now sterilized on a per patient basis and not only when used. Some instruments are not needed regularly and are individually packaged and used only when needed. Assuming that an office sterilizes their instruments four times a day, these pin and ligature cutters have been exposed to three months of sterilization in the orthodontic office.

There are two significant factors in the cutting efficiency of the pin and ligature cutters measured in this study. The lateral hinge movement and the sharpness of the cutting edge. These will be discussed separately.

The lateral hinge movement is significant, if the beaks of the cutters do not meet together, but deviate upon closing into the wire, the cutting efficiency of the cutters is greatly reduced. This leads to a cutter that will not cut if

the lateral hinge play is excessive. An assumption was made that a mismatch of the cutter tips of 1/2 the diameter of the wire will reduce the cutting efficiency enough to make cutting difficult or impossible. The estimated life expectancy of the cutters is calculated to range from 305 cycles for the dry heat, 345 cycles for Chemiclave and 670 cycles for the steam autoclave (See Table 7).

Sterilizing method	AEZ inserted	AEZ one piece	Dentronix	ETM screw joint	Orthopli	Unitek	Mean	Std. Dev.
Autoclave	925	352	1315	658	379	391	670	352
Chemiclave	132	658	219	521	291	253	345	183
Dry Heat	150	367	391	391	255	278	305	87
Mean	402	459	641	523	308	307		
Std. Dev.	370	141	481	109	52	60		

Table 7. Anticipated Life Time Cycles at One Half Ligature Wire Diameter of .005" Tip Mismatch.

The cutters in this study exhibited a wide range of tip and handle movement (See Tables 2 and 8). The AEZ inserted cutters showed the greatest changes. Four of these instruments were no longer cutting the ligature wire at the end of this study.

The greatest change was in the dry heat group, followed by the Chemiclave and the steam autoclave showed the least amount of change.

Subjectively, the cutting ability of the cutters decreased with sterilization as the lateral hinge play

increased. Generally, all the cutters showed an initial tightening of the joint that reached a maximum between 35 and 40 cycles. This was determined by the increase of force required to cut the ligature wire. After this all, the joints loosened. Dentronix recommends that all new cutters be cleansed ultrasonically for 1 to 1 1/2 hours so that all lubricants from the manufacturing process are removed. This was not done and could account for the tightening of the joints early in the study. They suggest that these residual lubricants turn gummy with sterilization and cause the joint to become stiff and that once in this state they are not removed with ordinary ultrasonic cleaners.

Sample#	AEZ inserted	AEZ one piece	Dentronix	ETM screw	Orthopli	Unitek
1	.000	.010	.000	.005	.008	.008
2	.030	---	.006	.006	.007	.006
3	---	.010	.010	.012	.011	.006
4	.026	.012	.008	.008	.013	.009
5	.033	.006	.012	.009	.014	.024
6	.008	.013	.006	.007	.008	.012
Mean	.019	.010	.007	.008	.010	.011
Std Dev	.013	.002	.004	.002	.003	.006

Table 8. Changes in Handle Play After 250 Cycles

The cutters as they were subjectively ranked by the students showed varying results. They all ranked a different manufacturer's cutter best and no student ranked the AEZ as

best. This could be due to differences in the shape and feel of the cutters in their hands.

The cutter edge as it is sterilized and used dulls. The cutters were used to make 2500 cuts in .014" twisted ligature wire. This is about 2 years of use in a private practice situation. The .014" ligature wire is heavier than is used generally in practice and would probably cause greater dulling of the cutting edges and increased joint play. Since no control was used there is no way to determine the amount of dulling of the cutting edge due to cutter use versus the dulling caused by the sterilization methods.

The results of the EDAX study were inconclusive. There were differences in the percentage composition of the materials from the beginning to the end and some elements showing up in some of the cutters and not in others from the same group. These scattered results may be due to several factors. The size of the area that is measured under the EDAX is very small. This makes it hard to repeatedly measure the same area on the cutting edge. Also, the tolerance of composition allowed by the manufacturers in the material may account for the differences seen in the composition of the material from cutter to cutter. Differences may also be attributed to machining and brazing processes in the manufacture of the cutters. Materials may be rubbed into the surface of the instrument during the manufacturing process by

the various machines used in processing the materials from the raw stock into the finished cutters. Furthermore, while brazing the insert onto the handle, material from the flux or the braze itself may contaminate the cutting tip. The erratic numbers that we achieved in our data may be also due to the fact that the EDAX was not calibrated before the initial testing was done.

The scanning electron microscope showed very little change from the beginning photomicrographs to the final photomicrographs. Observations that were noted in the initial photomicrographs include a range in the spacing of the cutting edges of the cutters. This range is between cutters from the same company and between companies. One cutter appeared to be sharpened only on one side. The surface smoothness varied from company to company depending upon their finishing procedures. All cutters showed debris present from the manufacturing process on the surface.

The final photomicrographs showed the same features as the beginning with the exception of the debris being initially present on the cutters. By the time the cutters had been through the sterilization process 250 times, all the debris from the manufacturing processes had been removed. Additionally, one cutter showed a scalloping of one of its cutting surfaces. Several of the cutters showed dark lines on the surface. This may have been caused by residue from the

sodium nitrite used to prevent rust from forming on the cutters.

On visual inspection of the cutters it was noted that the inserts of the AEZ cutters showed a darkening of the metal, which was greatest with the cutters that had been steam autoclaved. No visible signs of rust were evident on any of the cutters. The AEZ one piece cutters showed no visible signs of corrosion except for the one cutter that failed after 120 cycles. It was noted that there was some rust in the joint area that would not have been visible from the outside. The Dentronix and Orthopli cutters showed dark reddish brown staining of the inserted cutter tips when sterilized with the steam autoclave. The other cutters showed a very slight discoloration of the inserted cutter tips. One of the Orthopli cutters that was sterilized in the dry heat sterilizer showed some black spotting on the inserts. The ETM and Unitek cutters showed no changes visually. This would be expected with the ETM cutters since the cutters are chrome plated to prevent any corrosion from occurring. There were no signs of discoloration of the handles of any of the cutters examined.

In this study, joints were not lubricated as recommended by the manufacturers. This was done because the variety of lubricants and schedules was felt to increase the variables in this study.

The manufacturers recommend various lubrication schedules and different lubricants. The manufacturers' suggested lubrication schedules vary from weekly to everytime the cutter is sterilized. The manufacturers recommend various lubricants for the joint including mineral oil and silicone. With regular lubrication it would be expected that friction would be reduced in the joint, thereby reducing the wear in the joint and decreasing the lateral side shift.

CONCLUSION

This project was undertaken to examine the deterioration of pin and ligature cutter when subjected to multiple sterilization and clinical cycles over an extended period of time.

In this study it was determined that the EDAX was not an appropriate method of analyzing the sample for corrosion due to the small area sampled, the difficulty in detecting the presence of oxygen, the difficulty in repeatedly testing the same area, and instrument calibration.

The change in the lateral side movement of the cutters was not clinically significant except for the AEZ inserted pin and ligature cutters. Further study to determine the effect of different lubricants and lubrication schedules on the lateral side movement of the joints should be done. A study to determine the amount of lateral tip movement a cutter can possess and still function effectively should be done.

It would be useful if the manufacturers would make the hinge joint so that it could be adjusted and not merely tightened. This would make the cutter more useful over time and reduce expenses in the orthodontic office.

The change in the radius of the cutting edge showed that the cutters dulled over time with use and sterilization.

Whether or not this was from use, the ultrasonic cleaning or the sterilization process could not be determined and needs further study. The amount of change in the radius of the cutter before a significant clinical decrease in cutting efficiency should be studied.

Hardness testing of the cutters would give information about metallurgical changes in the instruments due to the sterilization process and should be included in future studies.

It is important to stress that the cutters were placed in the sterilizers dry and free of all debris. It should also be recognized that de-ionized or distilled water was used for the ultrasonic cleaning and sterilizing procedures. These are practices that should be emphasized in the orthodontic office.

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