Force/Deflection Properties of New and Retrieved .014" and .016" Nickel-Titanium Orthodontic Arch Wires from Different Manufacturers

by

Robert Park D.M.D.

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Thesis Advisor: John Lewandowski, Ph.D.

Case Western Reserve University

School of Dental Medicine

Department of Orthodontics

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LITERATURE REVIEW

In 1959, William Buehler, a metallurgist at the Naval Ordnance Laboratory (NOL) was charged with creating a new material to be used for the cone end of naval ballistic missiles and in the process, he discovered a new nickel-titanium alloy that possessed different structures at different temperatures and named it Nitinol. The discovery was made by intentionally dropping bars of varying temperatures of the alloy and realizing that they created a different sound upon hitting the floor and that this process was reversible by applying heat or cooling. In 1961, when shown a folded sample sheet of this alloy at a laboratory meeting, a co-worker applied heat from a smoking pipe to the alloy and the sheet unfolded to the amazement of others at the meeting. This temperature reversible phase transition became an important discovery for the material. In 1962, a crystal physicist, Dr. Frederick Wang, joined the NOL group and helped discover many of the structural reasons behind Nitinol's mechanical properties.[1,2]

Nickel-titanium alloys are composed of roughly equal atomic proportions of nickel and titanium (or 55% nickel and 45% titanium by weight). Nitinol has two phases, austenite and martensite, and can transition between those two phases by applying heat or stress. The transition of martensite to

and from austenite is reversible by changing the temperature (the martensitic-active form). In the austenitic-active form of Nitinol, the transition from austenite to martensite is caused by deformation of the wire. The austenite phase typically exists at higher temperatures and forms a body-centered cubic structure while the martensite exists at lower temperatures and forms a more complicated monoclinic structure. While these properties were early discovered early, the practical use of these wires was delayed.

Manufacturing consistent batches of Nitinol proved to be challenging. By the 1970s, manufacturing techniques had improved and nitinol was gaining popularity, particularly with Dr. Andreasen from the University of Iowa who was the first person documented to have used nitinol for orthodontic purposes. Interestingly, Buehler provided Dr. Andreasen with nitinol samples which were used to treat Buehler's wife. Dr. Andreasen would later go on to develop and patent orthodontic nitinol archwires.

Since Andreasen's application of Nitinol, many orthodontists have come to rely on placing nickel-titanium (NiTi) arch wires in the initial stages of treatment for extended periods of time as teeth are becoming aligned. NiTi wires have been shown to possess many properties that are useful for the initial stages of orthodontic treatment such as shape memory, biologically favorable force/deflection properties and in some cases, thermal activation , when compared to stainless steel.[3-14] Recent research has elucidated

differences in tension between 3M and GAC brand nitinol arch wires, particularly when variable rates of tension are applied in air (Figures 1-3).[15] According to Proffitt's textbook, the ideal arch wire for the initial leveling and aligning stage of orthodontic treatment would be one that delivers an "almost flat load-deflection curve, and delivers about 50gm at almost any degree of deflection" and is typically an .014" or .016" NiTi arch wire.[16] Research has also suggested that optimal and consistent force levels produce direct resorption of the socket wall by histological evaluation.[17] Unfavorable orthodontic tooth movement has also been implicated in root resorption and pulpal necrosis.[18] While some studies have shown that the histology of tooth movement is similar across species, Ren's systematic literature review could not find any evidence for optimal force levels in orthodontics.[19,20]

Because misalignment of the teeth can often last several months, clinicians often use the same NiTi arch wires for several months, assuming that the wire's properties will not change. Indeed, some studies have shown that permanent deformation after long periods of deflection occurs less with superelastic NiTi than it does with other orthodontic wire materials such as stainless steel and B-titanium.[21] The decision to leave NiTi wires intraorally for several months has also become popular with practitioners due to self-ligating brackets and longer treatment intervals. Research has also shown that ligation type affects the superelasticity of NiTi wires,[22-23] suggesting that

elastic ligation mutes the superelastic properties of NiTi wires more than stainless steel ligatures. However, much of the research pertaining to intraoral aging of NiTi arch wires has involved using in vitro models. Alternatively, some investigations have studied "retrieved wires," wires that have been used in the mouth, but in a manner that introduces extraneous variables.

Schwaninger et al performed mechanical tests on the older Nitinol wires after varying months (1, 3, 5, 7, 9 and 11 months) of immersion in a 1% sodium chloride solution.[24] They found no differences in the force/deflection properties of the arch wires when using the Young's modulus of elasticity. However, they did not mention the deflection distance or rate. In addition, the authors did not mention if the solutions containing the wires were agitated.

Kuhta performed an experiment that examined metal ion release when wires were placed in various levels of acidic artificial saliva. The research suggests that ions are relased in enough quantity to cause allergic reactions.[25] Huang also performed a similar experiment on only NiTi wires and found that ion release of nickel and titanium were well below levels to cause an allergic reaction or dietary intake levels. Huang suggests that the titanium oxide film that coats these wires is protective from acidic attack. However, Huang suggests that surface defects might be a preferred location for corrosion. Since these studies were done in vitro using straight lengths of wire, the effects of wire engagement with the bracket or bending of the wire

from forces of mastication were not considered.[26] Pun and Berzins examined corrosion behavior of various nickel-titanium based orthodontic wires and found that corrosion rate increases with increased temperature.[27]

Walker performed a study in which NiTi wires were immersed in an acidulated fluoride solution and tested their mechanical properties. The results suggest that fluoride treatment decreases functional loads.[28] Kaneko performed a similar experiment and found that tensile strengths were greatly reduced. In addition, NiTi wires fractured before they yielded and the type of fracture was brittle compared to the ductile fracture type seen in non-fluoridated wires.[29] The authors proposed hydrogen embrittlement as the cause of these mechanical property changes. However, Zinelis examined wires that were fractured intraorally and found similar brittle fractures without plastic deformation but did not find an increase in hardness, suggesting that hydrogen embrittlement was not the likely method for the brittle fractures. They found that most fracture sites were in the posterior region between the 1st molar and premolar of the arch and concluded that fractures were most likely due to forces of mastication and intraoral aging.[30]

Lee performed an in vitro experiment testing the mechanical properties of NiTi arch wires after being bathed in artificial saliva.[31] They used 3 different manufacturers of .016x.022 arch wires (Ni-Ti by Ormco, Sentalloy by Tomy Japan, Optimalloy by Jinsung Korea), 60 arch wires for each

manufacturer, divided into 3 groups of 20 arch wires each. There was 1 control group of new arch wires that was untreated, 1 treatment group that was subjected to artificial saliva and incubated at 37°C for 4 weeks, and 1 treatment group treated the same (with saliva and incubation) and autoclaved at 121°C at 15-20 psi for 20 minutes. Lee found no differences in ultimate tensile strength, elongation rate, or modulus of elasticity between any of the 3 groups. They also found no difference in frictional coefficients or bending fatigue test. It was noted that the authors tested the wires at 37°C. However, there were limitations to this study. First, they did not perform a sample size calculation. Second, they were not entirely clear in their methods, such as the direction in which they bent the rectangular wire during the fatigue test, and if they segmented the arch wires to test for ultimate tensile strength and fatigue test, both of which require the wire to break. Third, they used modulus of elasticity to describe a wire that is superelastic which is not an adequate measure, since NiTi wires do not follow Hooke's law in the clinically important plateau region of the force/deflection curve. Finally, they did not describe the nature of the artificial saliva solution and did not agitate the arch wires as they sat for 4 weeks. The authors use an in vitro model to mimic recycling of arch wires. However, their model does not recreate the numerous realistic conditions that are present in the mouth, such as forces of mastication, constant circulation of oral fluids, or fluctuations in oral temperature.

Some research has shown that retrieved wires exhibit significant changes.[32-34] Eliades in 2000, examined NiTi arch wires using light microscopy, infrared spectroscopy, scanning electron microscopy and wavelength dispersive electron probe micro-analysis on 60 retrieved wires of .016" and .016x.025" sizes which had stayed intraorally over a period of 1-6 months. Their results "imply adsorbed proteinaceous matter," smoother striations, increased surface porosity. Prolonged exposure was associated with calcified solids. No differences were noted between the molar and incisor regions of the arch wires. While these results are interesting, their analysis was mainly descriptive. Data for all 60 arch wires was not published and only "representative examples" were shown. In addition, those representative examples were subjected to polishing with a diamond paste and etched using concentrated acid. Polishing and acid etching may have altered the surface that they later examined under light microscopy.

Grimsdottir also examined surfaces of retrieved NiTi arch wires. They examined Ormco and GAC arch wires in 0.44mm round (0.17") and 0.4x0.55mm (0.16x22") sizes which had stayed intraorally over a period of 3 weeks to 4 months.[35] They compared intraoral with specimens to unused posterior segments that were cut for patient comfort. They used scanning electron microscopy. Their results showed no systematic differences in scratches from intraoral use. However, they did find scratches and crevices

from manufacturing. Like Eliades, Grimsdottir found that retrieved specimens had smoother surfaces than new wires. However, that finding was highly variable with the authors noting that "the opposite was also found." They did find a difference in the metal composition in the crevices, a change in the Ni/Ti ratio from 54/46 to 58/42 but no statistical testing was done to determine significance.

Kapila published one study testing the mechanical properties of retrieved arch wires after one cycle (T1), and two cycles (T2) in the mouth (AJODO 1991).[36] One cycle was defined as 8 weeks +/- 1 week with elastic re-ligation after 4 week intervals. Their first test used cold sterilization (2% acidic gluteraldehyde). They used Nitinol classic (3M) wires and superelastic Sentalloy (GAC) which they called "NiTi." 10 wires of each type were tested at T0 (unused and unsterilized), T1 and T2. They used a modified 3-point bending test using twin brackets and elastomeric ligation, as described by Miura et al (AJODO 1986). They found statistically significant differences in Nitinol's loading forces and in NiTi's loading and unloading. Their results were inconsistent in that the differences between all three time intervals, T0/T1, T1/T2 and T0/T2 were not all significant. In general, their significant findings did show an increase in force levels during loading and unloading. There were some flaws in this study. First, they used two brackets to bind the distal ends of the wire but did not specify how they were aligned in the beginning

which could introduce friction. Second, they used elastic ties but did not mention if they were systematically placed. In addition, they did not mention the length of the wire segment. They did not mention at what temperature this test was conducted, but it is implied to be at room temperature. Sentalloy is known to have different mechanical properties at body temperatures than at room temperature. They also did not perform a sample size calculation and only used 10 arch wires for each treatment group. In addition, their control group was not cold sterilized. Therefore, readers are unable to evaluate the differences that just the cold sterilization may have played. Finally, the authors performed an F-test and ANOVA without doing a test for normality on their data.

Kapila's second study in 1992 looked at new and retrieved arch wires after dry heat sterilization (DHS).[37] Their experimental set-up was very similar to their previous study in 1990 using cold sterilization. 10 wires each of Nitinol and NiTi were tested without sterilization (T0), after one cycle of DHS (T1), or two cycles of DHS (T2). In addition, 10 wires of each were subjected to one clinical use cycle (T1), as defined above, or two clinical use cycles (T2). Due to the design of this study, because the control group was also DHS, the authors are able to compare directly the effects of clinical recycling on the properties of arch wires. Their results show statistically significant results in the unloading and loading characteristics of both Nitinol and NiTi wires for

both wires that were in the mouth and DHS as well as for wires were only DHS. However, the magnitude of the difference in the wires that were DHS only was minimal. The larger effect was seen in wires that had been retrieved, particularly at the largest deflections, 1.8mm. Many of the same issues raised in their previous study (Kapila et al AJODO 1991) study apply to this newer study. Contrary to Kapila's findings, Mayhew and Kusy did not find any differences in mechanical properties or surface topography of Nitinol and Titinol wires after sterilization.[38]

During the initial leveling and alignment stage, NiTi is often the arch wire of choice.[39] Kapila showed that the properties do change over time. However, these tests were done at room temperature with Sentalloy wire which has been shown to have different properties at oral temperature.[40-42] In addition, Kapila's studies used a relatively modest 2.0mm deflection of 0.16" round wire. It was at the largest deflection value measured, 1.8mm, where Kapila found the largest differences after clinical recycling. Often times, malocclusions require larger deflections or lighter wire. Therefore, it is clinically relevant to test lighter NiTi wires, such as 0.14", for larger deflections. The results of this study have implications for orthodontic mechanotherapy, cost of treatment, and time management in a practice setting.

In 2006, the ADA and ANSI revised their specifications for testing mechanical properties of wires. These specifications were changed to accommodate superelastic wires. To date, no studies have been published that test mechanical properties of superelastic wires using these revised specifications. Therefore, this study's purpose was to address the dearth of published research in changes of mechanical properties of new and retrieved archwires using the revised ADA/ANSI specifications.

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STATEMENT OF THESIS

This study's objective is to measure force/deflection values and slope of the force/deflection curve of 3M and GAC .014" and .016" new and retrieved wires using the revised ANSI Specification No. 32. Comparisons will be made between new and retrieved conditions and between 3M and GAC wires of the same diameter. The null hypothesis is that there is no difference between new and retrieved wires and no difference between 3M and GAC wires of the same diameter.

FORCE/DEFLECTION PROPERTIES OF NEW AND RETRIEVED .014" and .016" NICKEL-TITANIUM ORTHODONTIC ARCH WIRES FROM DIFFERENT MANUFACTURERS

Authors: Robert Park D.M.D.[1]

John J. Lewandowski Ph.D.[2]

J. Martin Palomo D.M.D., M.S.D.[3]

Richard J. Griffith D.M.D., M.S.D.[4]

1. Resident, Department of Orthodontics at Case Western Reserve University School of Dental Medicine in Cleveland, OH
2. Professor, Department of Engineering at Case Western Reserve University Cleveland, OH
3. Program Director, Department of Orthodontics at Case Western Reserve University School of Dental Medicine in Cleveland, OH
4. Associate Professor, Department of Orthodontics at Case School of Dental Medicine in Cleveland, OH

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Objectives: 1. To compare differences in force/deflection properties of new vs. retrieved 3M and GAC .014" and .016" nickel-titanium arch wires. 2. To compare 3M Nitinol SE and GAC Sentalloy wires of the same diameter and condition (new vs. used). **Methods:** The sample consisted of 224 wires tested, 28 wires for each of 8 groups (3M/GAC, .014"/.016" and new/retrieved). The revised ANSI Specification No. 32 was used for testing conditions. Wilcoxon rank-sum tests and Spearman's correlations were performed on the data. **Results:** When comparing new vs. retrieved, statistically significant results were found in 11 of 16 force measurements and 1 of 4 slope measurements, indicating higher force levels in the retrieved wires. When comparing 3M vs. GAC measurements, statistically significant results were found in 15 of 16 force measurements and 4 of 4 slope measurements, indicating higher force levels for the 3M wires. Correlations were also found in new arch wires when comparing upper vs. lower arch forms in 10 of 16 measurements, indicating higher force levels with lower arch wires. **Conclusions:** Small statistically significant differences were found in many of the force measurements taken in new vs. retrieved arch wires but the magnitude of these differences may not be clinically significant. When comparing 3M Nitinol SE and GAC Sentalloy, the GAC wires behaved more ideally for an initial arch wire than 3M Nitinol SE under these conditions.

INTRODUCTION

Since Buehler at the Naval Ordnance Laboratory invented nickel-titanium and named it Nitinol in 1959 and Dr. Andreason first started using it to treat orthodontic patients at the University of Iowa in the 1970s[1,2], many modern orthodontists have come to rely on placing nickel-titanium (NiTi) arch wires in the initial stages of treatment for extended periods of time as teeth become aligned. NiTi wires have been shown to possess manhy properties that are useful for the initial stages of orthodontic treatment such as shape memory, biologically favorable force/deflection properties and in some cases, thermal activation, when compared to stainless steel.[3-14] Nickel-titanium alloys are composed of roughly equal atomic proportions of nickel and titanium and has two phases, a stiffer austenite and a less stiff martensite, and can reversibly transition between these two phases by applying heat or stress. According to Proffitt's textbook, the ideal orthodontic arch wire for the initial leveling and aligning stage of orthodontic treatment would be one that delivers an "almost flat load-deflection curve, and delivers about 50gm at almost any degree of deflection."[15] However, Ren's systematic literature review could not find any evidence for optimal force levels in orthodontics.[16] Because misalignment of the teeth can often last several months clinicians often use the same NiTi arch wires for several months, assuming that the

wire's properties will not change. This practice has been further advocated with the recent increased use in self-ligation brackets and longer appointment intervals. Interestingly, little research has been published using standardized testing methods of true "retrieved wires," wires that have been used in the mouth.

Many in vitro studies have been performed using artificial saliva and found little differences in mechanical properties.[17,18] However, some have called into question the methodology of current in vitro studies because intraoral environments provide many other challenges to orthodontic appliances such as temperature cycling, food and forces of mastication.[19]

When retrieved wires have been studied under various microscopic methods, the wires did exhibit changes including surface porosity, smoother striations and protein accumulation on the surface.[20] While these results are interesting, the analysis was mainly descriptive and the authors showed representative examples. Other authors have examined surfaces of retrieved wires and showed no differences in striations from intraoral use but did find striations and crevices from manufacturing.[21]

Two studies have been published that studied mechanical properties of new wires and retrieved nitinol wires after 8 weeks in 1 patient (T1) and 16 weeks in 2 patients (T2) with a round of sterilization between the two patients.

In one study, Kapila used cold-sterilization between and tested Nitinol classic and GAC Sentalloy.[22] For unloading values, the results did show significant results in the GAC Sentalloy between T0 and T1 and T0 and T2. In another study, Kapila the authors tested the effects of dry heat sterilization and clinical recycling on Nitinol classic and GAC Sentalloy wires.[23] T0 wires were untreated while T1 wires had 8 weeks of intraoral use with 1 cycle of DHS and T2 had 8 weeks of intraoral use with 1 cycle of DHS followed by another cycle of DHS prior to testing. Significant differences were found in unloading foce values for the Nitinol and Sentalloy between T0 and T1 wires and between T0 and T2 wires. While these differences are interesting, most modern orthodontists do not re-use retrieved orthodontic wires since their prices have decreased in recent years. Instead, the clinically relevant question is whether orthodontic wire properties change from intraoral aging without cold or heat sterilization.

In 2006, the ADA and ANSI revised specification no. 32 for testing mechanical properties of orthodontic arch wires. These specifications were changed to accommodate superelastic wires. One of the significant changes has been to require heat-sensitive wires to be tested at 36°C. To date, no studies have been published that test the mechanical properties of superelastic wires using these revised specifications. The purpose of this study is to determine if any significant differences exist between new and

retrieved .014" and .016" 3M and GAC wires using the new ADA/ANSI revised specification no. 32. The null hypothesis is that there are no differences between new and retrieved .014" and .016" 3M and GAC wires.

METHODS AND MATERIALS

An analytical study was undertaken using the ANSI/ADA Specification no. 32 that was updated in 2006. New and retrieved wires were collected for mechanical testing. GAC and 3M Unitek wires were collected in .014" and .016" diameters. Using a standard deviation of 5.1g (0.05N) from previous similar studies,[13,21] a sample size calculation was performed for a two-tailed alpha of .05, Beta of .10, and effect size of 20g (0.196N). Our minimum sample size was 21 wires per group.

28 wires were collected for each of the eight groups, amounting to a total of 224 wires:

GAC .014" new

GAC .014" retrieved

GAC .016" new

GAC .016" retrieved

3M Unitek .014" new

3M Unitek .014" retrieved

3M Unitek .016" new

3M Unitek . 016" retrieved

New wires were obtained from the CWRU Orthodontic clinic. The batch numbers for the new wires tested were as follows:

3M .014 Upper (#1-14): BJ4ZX, BK7CX

3M .014 Lower (#15-28): BO4BW, BI5TK

3M .016 Upper (#1-14): BN9MH

3M .016 Lower (#15-28): BI6MD, BB8UW

GAC .014 Upper (#1-14): H248, H239

GAC .014 Lower (#15-28): H219, H139

GAC .016 Upper (#15-28): H3Y9

GAC .016 Lower (#1-14): H3Z9

The retrieved wires were from patients treated in the CWRU core clinic, and their ages ranged from 10-17. The batch numbers for the retrieved wires were unable to be collected because the researchers were not involved in distributing the wires to be used in the patients. Retrieved wires had to remain in the patient's mouth for a minimum of 4 weeks (28 days) up to a maximum of 8 weeks (56 days). Emails and phone calls were made to GAC and 3M Unitek to elicit more information regarding the wire manufacturing

process for their wires. However, attempted emails and phone calls were not returned.

Selection criteria for the wires were as follows:

1) Arch wires must be either .014" or .016" round as measured by a micrometer with .0001" precision

2) Archwires must be 3M Nitinol SE or GAC Sentalloy as described in the chart or determined by practicing orthodontist.

3) No obvious signs of fractures in the arch wire

4) No obvious signs of permanent deformation

Measurements were taken using a MTS 20 Kip machine using a 20lb load cell. Testing specifications were adopted from the ADA/ANSI Specifications no. 32. The distance between supports of the wire was 10mm.The radius of the supports and the indenter was 0.1mm. The deflection rate was 7.5mm/minute. The wires were deflected to 3.1mm, and the force levels were measured upon unloading at levels of 3.0mm, 2.0mm, 1.0mm, and 0.5mm of deflection. Forces were recorded in Newtons. Force levels were measured at 25Hz. According to the specification, the wire length should be at least 30mm. Due to wire trimming during placement, often times the straight portion of the retrieved wires were 25-30mm in length. When

possible, 30mm lengths were used. Each wire was inspected after testing to ensure that no permanent deformation occurred during testing. Wires were tested at 36 ± 1°C in a temperature controlled cabinet with a thermometer probe verifying the temperature.

Force and displacement data was imported to a PC computer using TestWorks 4.0 into Microsoft Excel 2010. Measurements were taken from Microsoft Excel and imported into SPSS v. 17 for data analysis. Other related data such as the patient's name, sex, date or wire placement and retrieval, upper or lower archwire, supervising orthodontist, bracket slot size, bracket prescription, and bracket manufacturer were obtained using the CWRU clinical practice management software, Ortho2.

The data were subjected to Shapiro-Wilks and Kolmogorov-Smirnov tests for normality and the data set was determined not to have a normal distribution. Therefore, non-parametric statistical tests were performed: Wilcoxon Rank-Sum test and Spearman's Correlation. Significance was set at $\alpha \leq 0.05$

A reliability test was conducted to determine the consistency of the method. Nine wires from each of the eight groups were randomly selected and tested two or three weeks after the original data collection. A total of 72 wires were tested. An intraclass correlation test was conducted and the

results show the method to be reliable. The intraclass correlation coefficients were as follows:

3mm measurements: 0.928

2mm measurements: 0.968

1mm measurements: 0.974

0.5mm measurements: 0.886

The average reliability of these measurements is 0.939.

Wilcoxon Rank sum tests were performed to determine if any significant differences exist between the force/deflection values of new and retrieved wires in 3M .014", 3M .016", GAC .014", and GAC .016" sizes at 3mm, 2mm, 1mm and 0.5mm of deflection. In addition, testing was done to determine if any differences exist between the force/deflection values of 3M vs. GAC wires of new or retrieved conditions.

Overall slope of the force/deflection curve were calculated for each wire by calculating the slope between of the curve 3mm-2mm, 2mm-1mm, and 1mm-0.5mm, and then taking the mean of these three slopes. The slopes of the new and retrieved wires were then subjected to statistical testing. In addition, statistical testing was done to determine if any differences exist between the slopes of 3M vs. GAC wires of new or retrieved conditions.

Spearman's correlational coefficients were calculated using the new arch wire data to determine if upper or lower arch wire status was correlated with force/deflection values and/or slope values. Spearman's correlational coefficients were also calculated using the retrieved wire data to determine if intraoral duration, storage duration, upper or lower archwire, sex of patient, or slot size were correlated with force/deflection values and/or average slope values.

RESULTS

Descriptive Statistics

The mean force levels for new and retrieved wires as well as the average slopes and their statistical significances are discussed below.

Twenty-eight .014" round 3M new wires were used in total, 14 upper arch forms and 14 lower arch forms. Because the new wires did not spend any time intraorally, there is no intraoral duration or storage duration. For .014" 3M retrieved wires, the mean intraoral duration was 36.64 days. The mean days in storage prior to testing was 159.14 days. Fourteen upper wires and 14 lower wires tested. Nine wires came from males, and 19 came from females. Nine different supervising orthodontists were represented. Thirteen wires were placed in an .018" slot, and 15 wires were placed in an .022" slot. One wire was used with an Alexander prescription bracket, 14 in an MBT prescription bracket, 12 in a Roth prescription bracket, and 1 in a Tip-Edge prescription bracket. Twenty-four wires were used in 3M brackets, 3 in GAC brackets, and 1 in a Tip-Edge bracket.

Twenty-eight .016" round 3M new wires were used in total, 14 upper arch forms and 14 lower arch forms. For the .016" 3M retrieved wires the mean intraoral duration was 37.00 days. The mean days in storage prior to

testing was 200.46 days. Thirteen wires were upper arch forms and 15 wires were lower arch forms. Sixteen wires came from males and 12 came from females. Eight different supervising orthodontists were represented. 14 wires were used in an .018" slot, and 14 wires were used in an .022" slot. Thirteen wires were used in an MBT prescription bracket, 14 in a Roth prescription bracket, and 1 in a Tip-Edge bracket. Twenty-three wires were used in 3M brackets, 3 in American Orthodontic brackets, 1 in GAC brackets, and 1 in Tip-Edge brackets.

Twenty-eight .014" round GAC new wires were used in total, 14 upper arch forms and 14 lower arch forms. For the .014" GAC retrieved wires, the mean intraoral duration was 41.11 days. The mean duration in storage was 93.18 days. Fifteen wires were upper arch wires, and 13 wires were lower arch wires. 7 wires came from males, and 21 wires came from females. Nine different supervising orthodontists were represented. Eight wires placed in an .018" slot, and 20 wires were placed in an .022" slot. Twelve wires were placed in MBT prescription brackets, and 16 wires were placed in Roth prescription brackets. Twenty wires were used in 3M brackets, 1 in Dentauram brackets, and 7 in GAC brackets.

Twenty-eight .016" round GAC new wires were used in total, 14 upper arch forms and 14 lower arch forms. For the .014" GAC retrieved wires, the mean intraoral duration was 42.71 days. The mean duration in storage prior

to testing was 121.00 days. Twenty wires were upper arch wires, and 8 were lower. Seventeen wires came from males, and 11 came from females. Eight orthodontists were represented. Two wires were used in an .018" slot, and 26 were used in an .022" slot. Twenty-five arch wires were used in MBT prescription bracket, and 3 were used in a Roth prescription bracket. Eleven wires came used in 3M brackets, 1 in Dentaurum brackets, and 16 wires were used in GAC brackets.

Comparing 3M vs. GAC Within Same Diameter and Condition (New vs. Retrieved)

When comparing the 3M vs. GAC wires for differences in force/deflection values, statistically significant results were found.

When comparing the force levels at the deflections of 3mm, 2mm, 1mm, and 0.5mm, statistically significant results were found in all measures, except the .014" retrieved wires at 0.5mm of deflection. Therefore, statistically significant results were found for the .014" new wires at 3mm, 2mm, 1mm, and 0.5mm of deflection, for the .014" retrieved wires at 3mm, 2mm, 1mm of deflection, for the .016" new wires at 3mm, 2mm, 1mm and 0.5mm of deflection, and for the .016" retrieved wires at 3mm, 2mm, 1mm and 0.5mm deflection. These differences indicate that the GAC wires produce lower force

levels than the 3M wires at a given level of deflection and condition (new vs. used)

When comparing the average slopes of the 3M vs. GAC archwires, statistically significant results were also found. For both .014" and .016" sizes and new and used conditions, the GAC wires had statistically significant smaller slopes, indicating a flatter portion of the force/deflection curve.

The results show that compared to 3M Nitinol SE, GAC archwires produce lower force magnitude and have a more constant level of force application over the deflection range of 3mm-0.5mm for the .014" and .016" sizes.

Comparing New vs. Retrieved of the Same Archwire Diameter and Manufacturer

When comparing new vs. retrieved wires of the same diameter and manufacturer, statistically significant results were found in the force/deflection values.

For the 3M .014" wires, the force at 3mm, 2mm, and 0.5mm of deflection were not significant, but the forces at 1mm was statistically significant. At 3mm of deflection, the mean for new wires is 1.1437 ± 0.06449 N (mean±SD), and used wires is 1.1588 ± 0.08524 N. At 2mm of deflection, the mean for new wires is 1.1491 ± 0.0391 N, and used wires is 1.1755 ±

0.0953 N. At 1mm of deflection, the mean for new wires is 0.9874 ± 0.0422 N, and used wires is 1.0324 ± 0.1077 N. At 0.5mm of deflection, the mean for new wires is 0.6938 ± 0.0357 N, and used wires is 0.7205 ± 0.0845 N.

For the 3M .016" wires, the forces at all the levels of deflections were significant. At 3mm of deflection, the mean for new wires is 1.8073 ± 0.1284 N (mean±SD), and used wires is 1.9015 ± 0.1032 N. At 2mm of deflection, the mean for new wires is 1.7274 ± 0.0726 N, and used wires is 1.9698 ± 0.1153 N. At 1mm of deflection, the mean for new wires is 1.4230 ± 0.0580 N, and used wires is 1.7588 ± 0.1145 N. At 0.5mm of deflection, the mean for new wires is 1.0386 ± 0.0531 N, and used wires is 1.3039 ± 0.1539 N.

For the GAC .014" wires, the force values at 3mm of deflection was not significant, but the forces at 2mm, 1mm, and 0.5mm of deflection were significant. At 3mm of deflection, the mean for new wires is 0.9362 ± 0.0525 N (mean±SD), and used wires is 0.9424 ± 0.0627 N. At 2mm of deflection, the mean for new wires is 0.7334 ± 0.0403 N, and used wires is 0.7617 ± 0.04934 N. At 1mm of deflection, the mean for new wires is 0.6845 ± 0.0432 N, and used wires is 0.7249 ± 0.0481 N. At 0.5mm of deflection, the mean for new wires is 0.6582 ± 0.0402 N, and used wires is 0.6997 ± 0.0491 N.

For the GAC .016" wires, the force value at 3mm was not significant, but the values at 2mm, 1mm, and 0.5mm were significant. At 3mm of

deflection, the mean for new wires is 1.4998 ± 0.0625 N (mean±SD), and used wires is 1.5564 ± 0.1371 N. At 2mm of deflection, the mean for new wires is 1.2174 ± 0.03695 N, and used wires is 1.3055 ± 0.1462 N. At 1mm of deflection, the mean for new wires is 1.1267 ± 0.0505 N, and used wires is 1.2046 ± 0.1325 N. At 0.5mm of deflection, the mean for new wires is 1.0681 ± 0.0499 N, and used wires is 1.1134 ± 0.09460 N.

When comparing the average slope values of new vs. retrieved wires, statistically significant results were found for the GAC .014" wire only. All other wires did not have statistically significant differences [Table 2]. For the 3M 014 wires, the average slope of the new wires was 0.2478 ± 0.02468 N/mm, and retrieved wires was 0.2500 ± 0.0284. For the 3M 016 wires, the average slope of the new wires was 0.3843 ± 0.05498 N/mm, and retrieved wires was 0.3509 ± 0.0833. For the GAC 014 wires, the average slope of the new wires was 0.1015 ± 0.01927 N/mm, and retrieved wires was 0.08933 ± 0.0215. For the GAC 016 wires, the average slope of the new wires was 0.1634 ± 0.02636 N/mm, and retrieved wires was 0.1780 ± 0.0684.

Correlational Studies

For the .014" 3M new wires, correlational studies show that there are associations between upper or lower arch wire status and force/deflection

values at 1.0mm and 0.5mm, indicating that lower arch wires have higher force values than upper arch wires.

For the .014" 3M retrieved wires, correlational studies show a significant association between patient sex and slope average, indicating that females have smaller slopes than males. No other associations between force/deflection and slope averages and intraoral duration, storage duration, upper or lower archwires, sex of patient or bracket slot size.

For the .016" 3M new wires, no associations were found between upper or lower arch wire status and force/deflection or slope values.

For the .016" retrieved arch wires, significant correlations were found between bracket slot size and force of deflection at 2.0mm, indicating that wires placed in .022" slots had lower force levels. A significant correlation was also found between days in storage and force of deflection at 1.0mm, indicating that more days in storage are correlated with higher levels of force. A significant correlation was also found between slope average and intraoral duration, indicating that more days in the mouth lead to higher slopes.

For the .014" GAC new wires, significant associations were found between upper and lower arch wire status and force/deflection values at 3.0mm, 2.0mm, 1.0mm, and 0.5mm, indicating that lower arch forms have higher force values than upper arch wires.

For the .014" GAC retrieved wires, a significant association was found between intraoral duration and force/deflection value at 2.0mm, indicating that more days in the mouth leads to higher force values.

For the .016" GAC new wires, correlational studies show that there are associations between upper or lower arch wire status and force/deflection values at 2.0, 1.0mm and 0.5mm, and slope average, indicating that lower arch wires have higher force values than upper arch wires and that the slope of the force/deflection curve of lower arch wires is lower than the upper arch wires.

DISCUSSION

While significant differences were found in the majority of measurements taken between new and retrieved wires, the magnitude of the differences was quite small. The largest difference was 0.33 N (for the 3M .016 @ 1mm) or about 20%. In clinical practice, these differences would not convince many clinicians to change an old nitinol wire with a new wire of the same diameter. However, while the mean force levels were insignificant, there were several individual retrieved wires that had very different mechanical properties than their original counterparts.

It is curious why some retrieved wires of the same manufacturer and diameter behaved differently. Previous authors have demonstrated pitting or residue accumulation on the wires, and this could have affected how the wire behaves mechanically.[24,25]

Our study used wire samples from the most distal end of the wire because of its relative straightness. For new wires, obtaining a 30mm sample was not difficult. However, for retrieved wires, since they are cut to the patient's arch form prior to placement, it was often times difficult to obtain a straight sample that was 30mm long. Testing of wires that were not straight

proved to be problematic so a compromise was reached of using wires that were between 25-30mm in length.

To date, no previous published studies have been performed of the mechanical properties of nitinol archwires using the revised ANSI Specification No. 32. One significant change made in revising the specification was to ensure that superelastic wires are tested at oral temperature. The only previously published studies to use the specification tested multistranded stainless steel wires.[26] Because the GAC Sentalloy is heat-sensitive, the authors considered this to be an important part of the study. While Sentalloy is a commonly used arch wire, the authors could not find a previously published study measuring the wires properties at oral temperatures.

Numerous previous studies have tested new and retrieved nitinol wires using brackets and various forms of ligation, such as stainless steel ligatures and elastomeric ligation in air.[22] However, the goal of this study was to test the properties of primarily the arch wires. Placing a wire in a bracket and using ligatures introduces extraneous variables that can influence the amount of force that is measured. For example, steel ligation can be changeable in its tightness and, therefore, introduce variability to the measurements. The same can be said regarding elastomeric ligatures. In addition, elastomeric ligatures have been shown to lose their elasticity by 50% in 24 hours in clinical

situations; therefore, force measurements taken on new elastomeric ligatures may not be relevant.[27] Since our study did not rely on any ligation or brackets, it was a true test of just the mechanical properties of the wire. On the downside, this test does not simulate the magnitude of forces that might be placed on a misaligned tooth since these wires were not ligated.

It was observed that in the new arch wires tested, 3M .014", GAC .014", and GAC .016" wires showed significant correlations indicating that the lower arch wires tended to give higher force values. The authors are unable to provide a reason for this finding. In addition, our study was not designed to explicitly test this. Within each group of new arch wires, 14 upper and 14 lower arch wires were tested. It is possible that because the lower and upper arch forms have slightly different curvatures even in the relatively posterior straight segment, it could influence the force/deflection and slope values. Therefore, future study of this topic is encouraged, since the 3M company data does not seem to make distinctions in force levels and whether the material is an upper or lower arch wire.

The wires have also been shown to behave differently depending on how fast they are deformed in air.[28] This data shows that under fast deformation, the stress is increased. If similar findings exist in bending as they do in tension, the findings could have implications for patients based on their chewing behavior, although the oral cavity may not stress/strain the

material into the superelastic regime. Also, fluid in the oral cavity may modify such effects depending on the fluid temperature.

In addition, other correlations were found for retrieved arch wires with no clear trends. For 3M .014" retrieved wires, female patient sex was associated with decreased slope values. For 3M 016" retrieved wires, longer storage duration and longer intraoral duration were associated with increased force values. For 3M .016" retrieved wires, .022" slot brackets were associated with decreased force values. For GAC .014" retrieved wires, longer intraoral duration was associated with increased force values. These five correlations were found after 100 correlations were tested in all. Because there were no observable trends, it could be that these correlations are from Type I error that is to be expected from performing so many correlation tests.

CONCLUSIONS

When comparing new vs. retrieved conditions, significantly increased levels of force were detected in retrieved wires when compared with their new counterparts in 11 of 16 measurements taken. Relatively small differences were found for the majority of the significant findings. Significantly decreased slope of the force/deflection curve was detected in .014" GAC retrieved wires while the other wires demonstrated no significant change in slope.

When comparing 3M vs. GAC conditions, significantly increased levels of force were detected in the 3M wires in 15 of 16 measurements taken. Significantly increased slope values were detected in the 3M wires when compared with the GAC wires of the same diameter and new vs. retrieved status.

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APPENDICES

APPENDIX A: IRB APPROVAL

Notice of Exemption for IRB Protocol Number: 20100112

1 message

cwru-irb@case.edu <cwru-irb@case.edu> **Thu, Jan 28, 2010 at 2:41 PM**
To: jmp5@cwru.edu, robert.park@case.edu
Cc: cxa3@cwru.edu, mgh4@cwru.edu, patricia.mehosky@case.edu

Case Western Reserve University
Institutional Review Board

NOTICE OF EXEMPTION(#4)

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

This protocol is exempt under the #4 category because this involves existing retrospective de-identified data.

Please note that this only applies to existing data.

Prospective data is NOT included in this exemption – De-identified pre-existing data to be collected on

01/29/2010 and after are NOT covered by this exemption.

Responsible Investigator: **J. Martin Palomo**
Department: **Dental Orthodontics**
IRB Protocol Number: **20100112**
Title: ***Mechanical Properties of Retrieved Nitinol Wires***
Co-Investigator: **Robert Park**

Exemption Date: January 28, 2010

The Institutional Review Board (IRB) has deemed the above protocol EXEMPT under 45 Code of Federal Regulations (CFR) part 46.101(b)(4). The IRB will not conduct subsequent reviews of this protocol.

Any changes to the protocol that put it under the purview of the IRB would require a formal application to, and approval of, the IRB prior to implementation of the change IRB applications are available at the CWRU IRB Pages, or from the Office of Research Compliance (ORC) at Sears Library Building, #657.

Questions? Please visit our website: http://ora.ra.cwru.edu/orc_humansubjects_CWRU_IRB.asp
OR

APPENDIX B: FIGURES AND TABLES

Table #1: Force ± SD values (N)

	Force @ 0.5mm	Force @ 1.0mm	Force @ 2.0mm	Force @ 3.0mm
3M 014 New	0.6938 ± .0358	0.9874 ± .0422	1.1491 ± .0391	1.1437 ± .0645
3M 014 Retrieved	0.7205 ± .0846	1.0324 ± .1077*	1.1755 ± .0953	1.1589 ± .0852
GAC 014 New	0.6581 ± .0402!	0.6845 ± .0432!	0.7334 ± .0403!	0.9362 ± .0525!
GAC 014 Retrieved	0.6997 ± .0491*!	0.7249 ± .0481*!	0.7617 ± .0493*!	0.9424 ± .0627!
3M 016 New	1.0386 ± .0531	1.4230 ± .0580	1.7274 ± .0726	1.8073 ± .1284
3M 016 Retrieved	1.3039 ± .1539*	1.7588 ± .11456*	1.9698 ± .1154*	1.9016 ± .1033*
GAC 016 New	1.0680 ± .0499!	1.1267 ± .05047!	1.2174 ± .0370!	1.4998 ± .0625!
GAC 016 Retrieved	1.1135 ± .0946*!	1.2046 ± .1325*!	1.3054 ± .1462*!	1.5563 ± .1371!

*statistically significant when compared to its new archwire ($\alpha \leq 0.05$)

!statistically significant when compared to the 3M wire of the same size and condition ($\alpha \leq 0.05$)

Table #2: Slope± SD values (N/mm)

	Slope (New)	Slope (Retrieved)
3M 014	0.1800 ± .0253	0.1753 ± .0262
GAC 014	0.1112 ± .0214!	0.0971 ± .0234*!
3M 016	0.3075 ± .0535	0.2390 ± .0584
GAC 016	0.1727 ± .0304!	0.1771 ± .0644!

*statistically significant when compared to the new archwire of same size and manufacturer ($\alpha \leq 0.05$)

!statistically significant when compared to the 3M wire of the same size and condition ($\alpha \leq 0.05$)

Table #3: Descriptive Statistics

Upper arch wire vs. Lower arch wire

	Upper AW	Lower AW
3M 014 New	14	14
3M 014 Retrieved	14	14
GAC 014 New	14	14
GAC 014 Retrieved	15	13
3M 016 New	14	14
3M 016 Retrieved	13	15
GAC 016 New	14	14
GAC 016 Retrieved	20	8

Male vs. Female (for retrieved wires only)

	Male	Female
3M 014 New	N/A	N/A
3M 014 Retrieved	9	19
GAC 014 New	N/A	N/A
GAC 014 Retrieved	7	21
3M 016 New	N/A	N/A
3M 016 Retrieved	16	12
GAC 016 New	N/A	N/A
GAC 016 Retrieved	17	11

Size of brackets in which retrieved wires were placed (.018" or .022" brackets)

	.018"	.022"	# orthodontists
3M 014 New	N/A	N/A	N/A
3M 014 Retrieved	13	15	9
GAC 014 New	N/A	N/A	N/A
GAC 014 Retrieved	8	20	9
3M 016 New	N/A	N/A	N/A
3M 016 Retrieved	14	14	8
GAC 016 New	N/A	N/A	N/A
GAC 016 Retrieved	2	26	8

Bracket prescriptions in which retrieved wires were placed

	Bracket Rx	Bracket Company
3M 014 New	N/A	N/A
3M 014 Retrieved	14-MBT, 12-Roth, 1-Alexander, 1-Tip Edge	24-3M, 3-GAC, 1-Tip Edge
GAC 014 New	N/A	N/A
GAC 014 Retrieved	12-MBT, 16-Roth	20-3M, 1-Dentaurum, 7-GAC
3M 016 New	N/A	N/A
3M 016 Retrieved	13-MBT, 14-Roth, 1-Tip-Edge	23-3M, 3-American, 1-GAC, 1-Tip-Edge
GAC 016 New	N/A	N/A
GAC 016 Retrieved	25-MBT, 3-Roth	11-3M, 1-Dentaurum, 16-GAC

Table #4: Correlation Studies

Associations between Upper/Lower arch wire and force/deflection values and average slope

	Force @ 0.5mm	Force @ 1.0mm	Force @ 2.0mm	Force @ 3.0mm	Average Slope
3M 014 New	*	*	NS	NS	NS
GAC 014 New	NS	NS	NS	NS	NS
3M 016 New	*	*	*	*	NS
GAC 016 New	*	*	*	*	NS

Table #5: Correlation Studies

Associations between retrieved wire variables and force/deflection values and average slope

	Force @ 0.5mm	Force @ 1.0mm	Force @ 2.0mm	Force @ 3.0mm	Average Slope
Intraoral Duration			GAC .014 R.		3M .016 R.
Storage Duration		3M .016 R.			
Upper/Lower AW					
Patient Sex					3M .014 R.
Slot Size of Bracket			3M .016 R.		

Tables #6-9: Tests for Normality

Table #6: 3M .014"

Tests of Normality

	NeworUsed	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
FD3	New	.193	28	.009	.916	28	.027
	Used	.110	28	.200*	.970	28	.585
FD2	New	.198	28	.006	.898	28	.010
	Used	.085	28	.200*	.966	28	.479
FD1	New	.120	28	.200*	.941	28	.120
	Used	.066	28	.200*	.976	28	.752
FD0.5	New	.192	28	.010	.943	28	.133
	Used	.109	28	.200*	.960	28	.357
SlopeAverage	New	.089	28	.200*	.980	28	.841
	Used	.119	28	.200*	.972	28	.622

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Table: #7: 3M .016"

Tests of Normality

	NeworUsed	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
FD3	New	.124	28	.200*	.963	28	.415
	Used	.091	28	.200*	.989	28	.985
FD2	New	.113	28	.200*	.979	28	.822
	Used	.096	28	.200*	.972	28	.633
FD1	New	.108	28	.200*	.955	28	.259
	Used	.110	28	.200*	.968	28	.521
FD0.5	New	.149	28	.114	.915	28	.026
	Used	.248	28	.000	.774	28	.000

SlopeAverage	New	.102	28	.200*	.974	28	.687
	Used	.206	28	.004	.761	28	.000

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Table: #8: GAC .014"

Tests of Normality

	NeworUsed	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
FD3	New	.139	28	.175	.948	28	.176
	Used	.093	28	.200*	.968	28	.540
FD2	New	.146	28	.132	.940	28	.109
	Used	.140	28	.170	.955	28	.268
FD1	New	.160	28	.065	.920	28	.034
	Used	.124	28	.200*	.937	28	.095
FD0.5	New	.172	28	.033	.933	28	.074
	Used	.152	28	.094	.882	28	.004
SlopeAverage	New	.181	28	.019	.871	28	.003
	Used	.098	28	.200*	.974	28	.704

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Table: #9: GAC .016"

Tests of Normality

	NeworUsed	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
FD3	New	.179	28	.023	.918	28	.031
	Used	.150	28	.106	.913	28	.023

FD2	New	.124	28	.200*	.968	28	.521
	Used	.227	28	.001	.810	28	.000
FD1	New	.116	28	.200*	.953	28	.233
	Used	.267	28	.000	.779	28	.000
FD0.5	New	.160	28	.063	.954	28	.255
	Used	.207	28	.003	.712	28	.000
SlopeAverage	New	.154	28	.087	.947	28	.169
	Used	.268	28	.000	.888	28	.006

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Tables #10-13: Error Study (Intraclass Correlation)

Table #10: 3mm Measurements

Intraclass Correlation Coefficient

	Intraclass Correlation[a]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.928[b]	.865	.959	31.080	71	71	.000
Average Measures	.962[c]	.928	.979	31.080	71	71	.000

Table #11: 2mm Measurements

Intraclass Correlation Coefficient

	Intraclass Correlation[a]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.968[b]	.903	.986	88.099	71	71	.000

Average Measures	.984[c]	.949	.993	88.099	71	71	.000

Table #12: 1mm Measurements

Intraclass Correlation Coefficient

	Intraclass Correlation[a]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.974[b]	.958	.983	73.809	71	71	.000
Average Measures	.987[c]	.979	.992	73.809	71	71	.000

Table #13: 0.5mm Measurements

Intraclass Correlation Coefficient

	Intraclass Correlation[a]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.974[b]	.958	.983	73.809	71	71	.000
Average Measures	.987[c]	.979	.992	73.809	71	71	.000

Figure 1: Stress/Strain Plots Showing Differences Between 3M Nitinol SE and GAC Sentalloy In Air

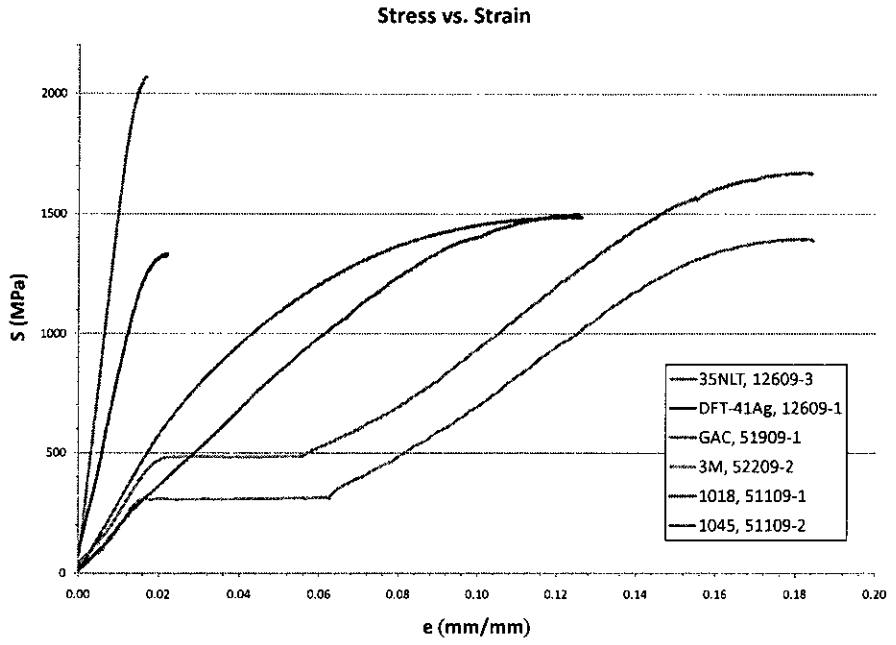


Figure 2: Stress/Strain Plots Showing Differences within GAC Sentalloy .014" (.03556mm) Dependent on Rates of Tension In Air

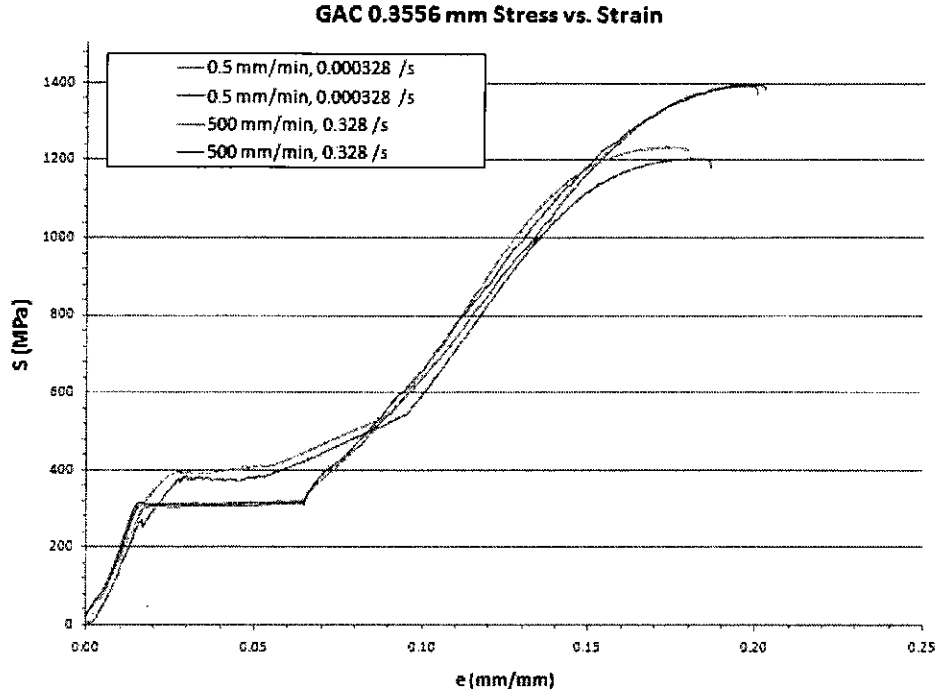


Figure 3: Stress/Strain Plots Showing Differences within 3M Nitinol SE .014" (.03556mm) Dependent on Rates of Tension In Air

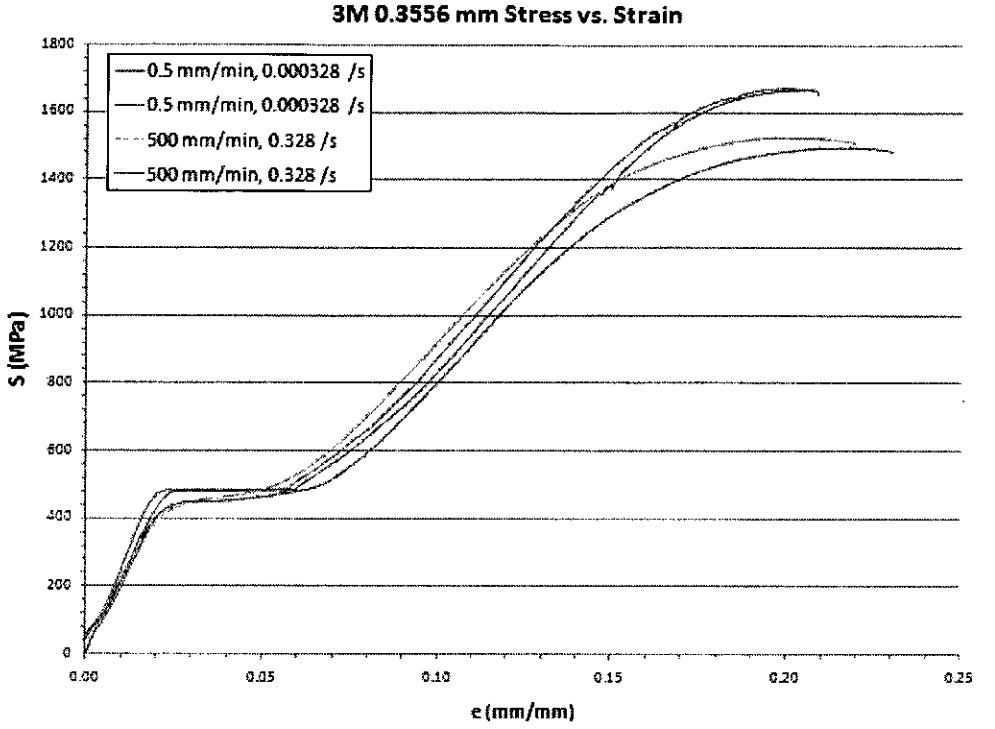


Figure 4: Wire Bending Apparatus with Console and Computer at the Center for Mechanical Characterization of Materials at CWRU

(http://dmseg5.case.edu/groups/Lewandowski/facilities.html)

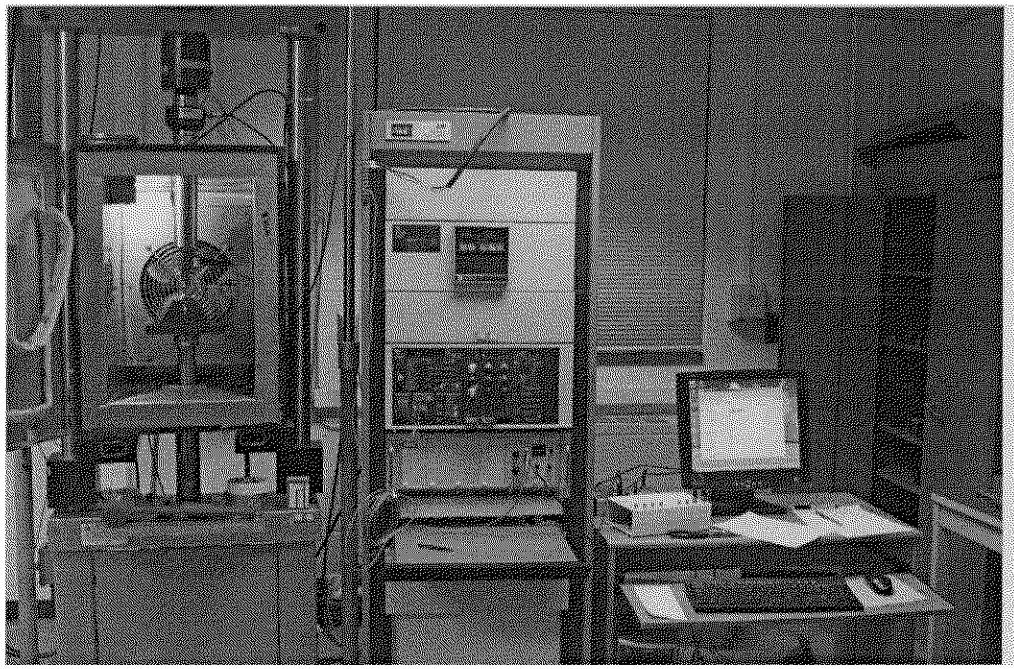


Figure 5: Wire Bending Apparatus at the Center for Mechanical Characterization of Materials at CWRU

(http://dmseg5.case.edu/groups/Lewandowski/facilities.html)

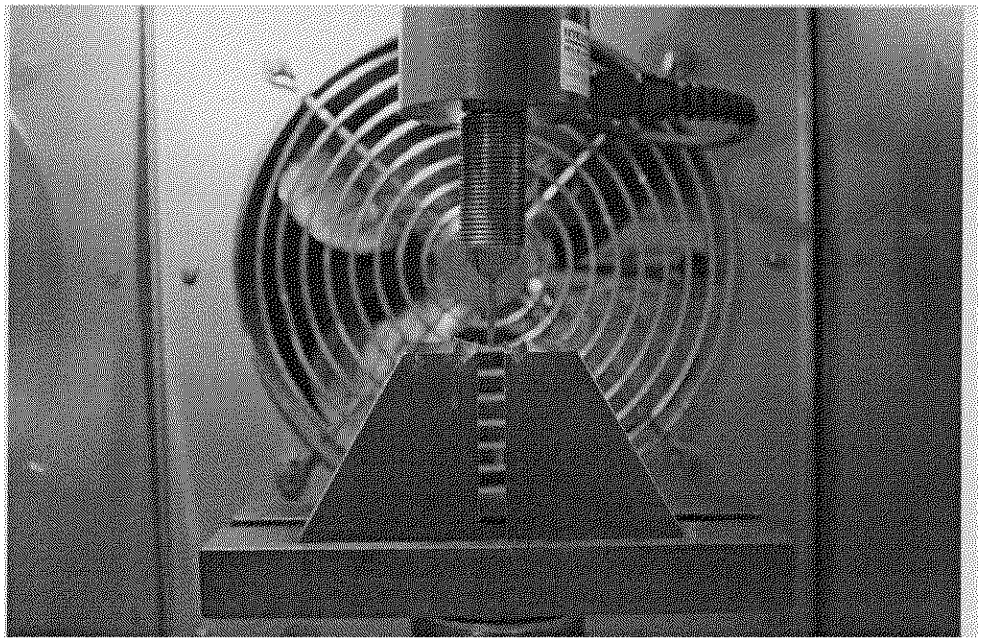
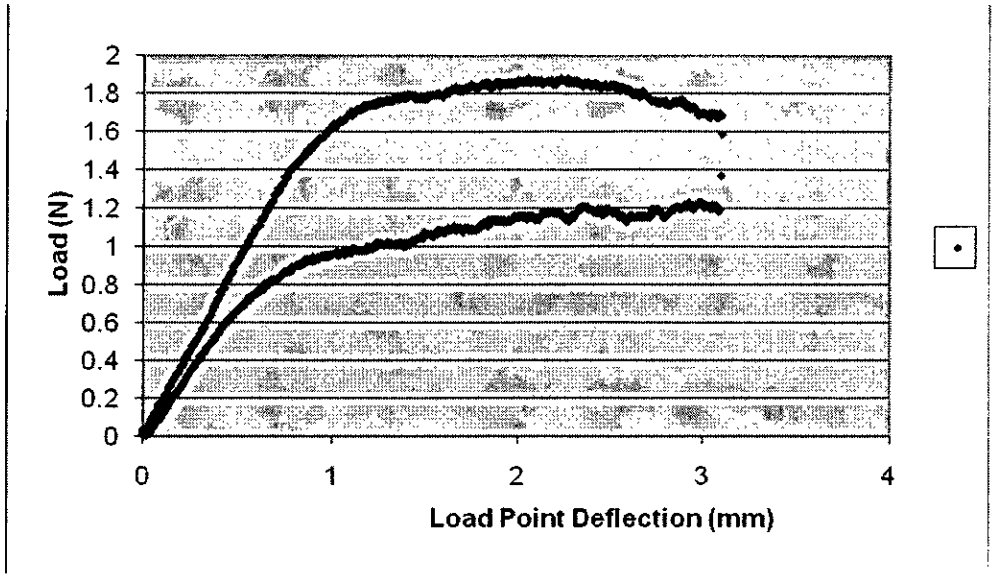
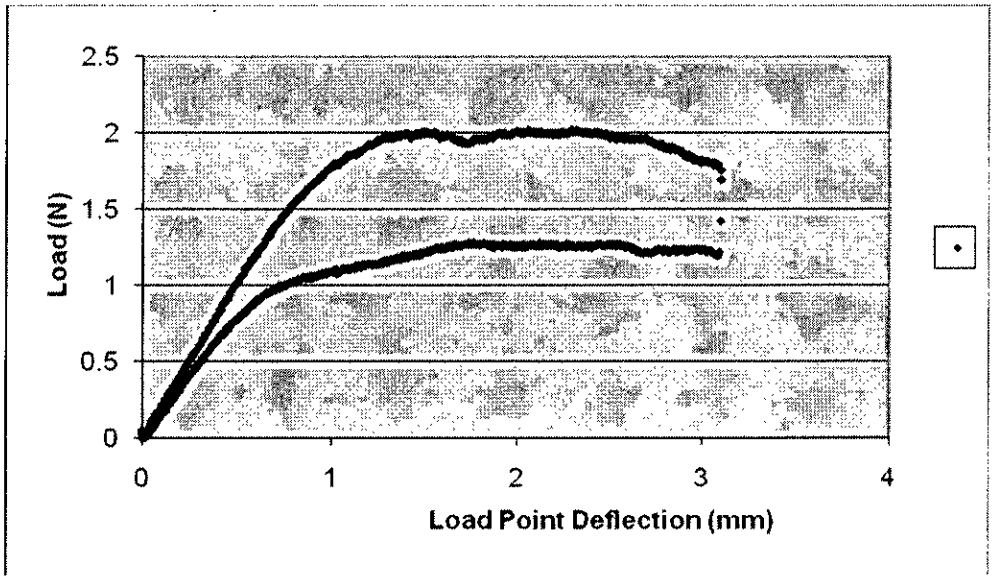


Figure 6: Example Pictures of Arch Wire Force/Deflection Data

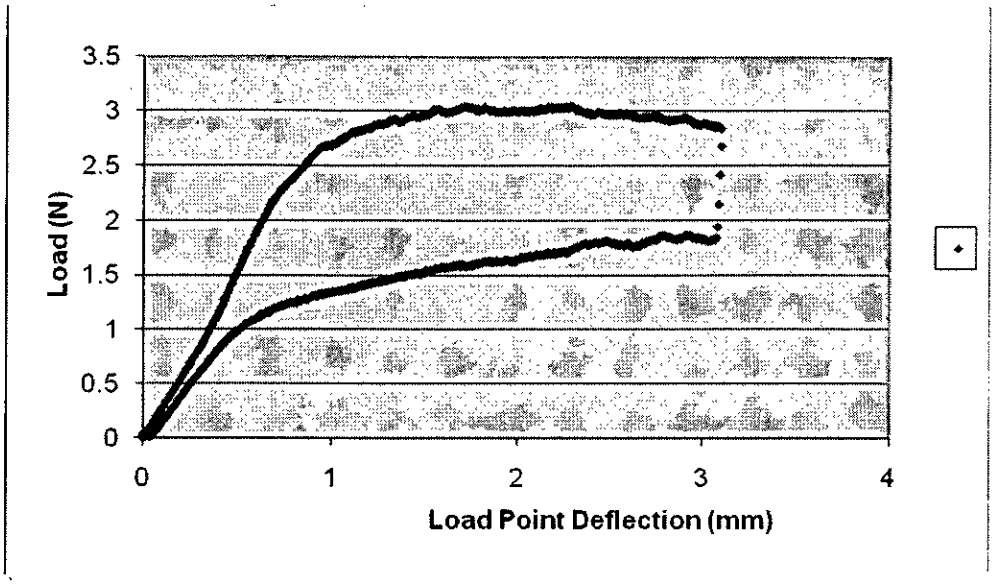
3M .014" New



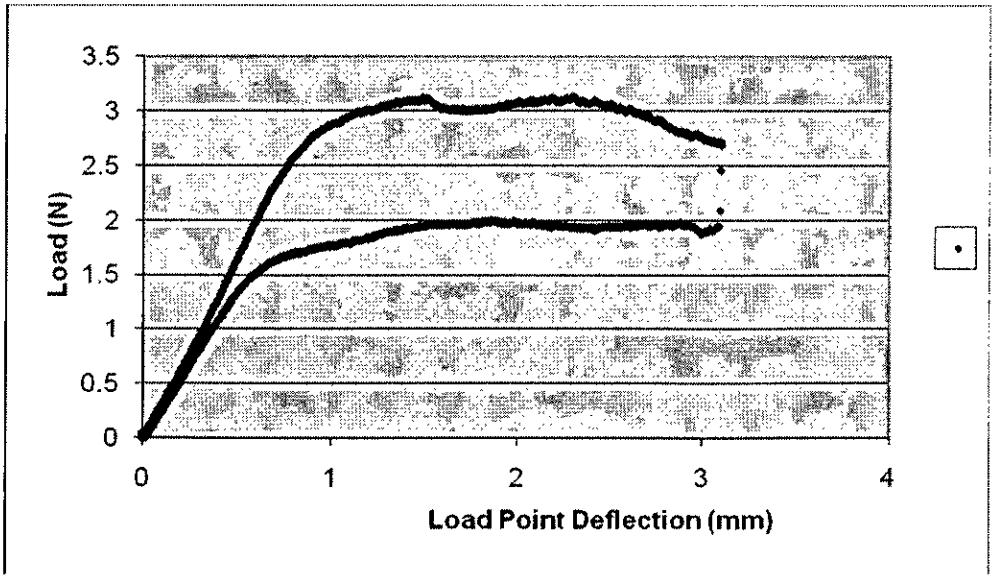
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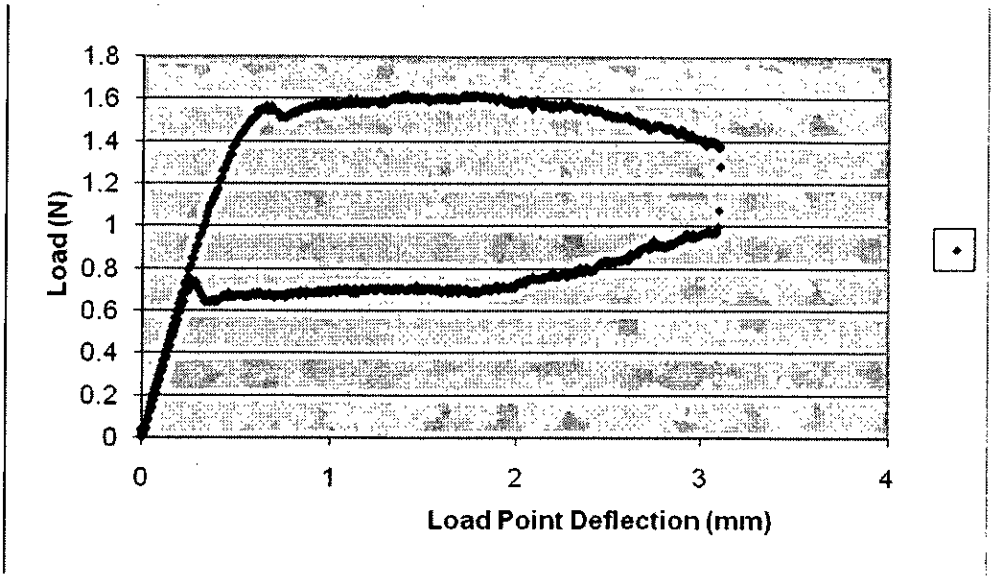
3M .016" New



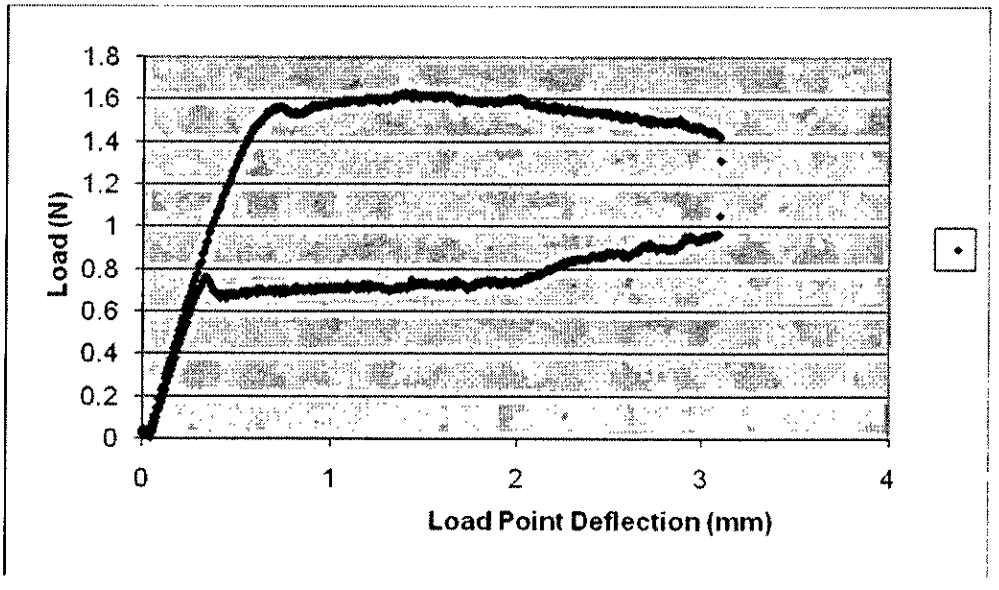
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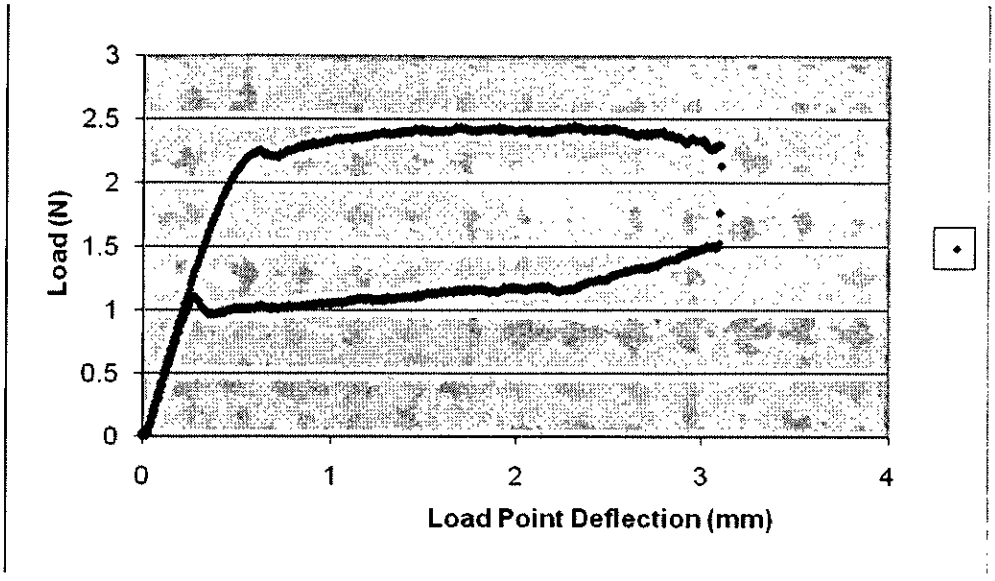
GAC .014" New



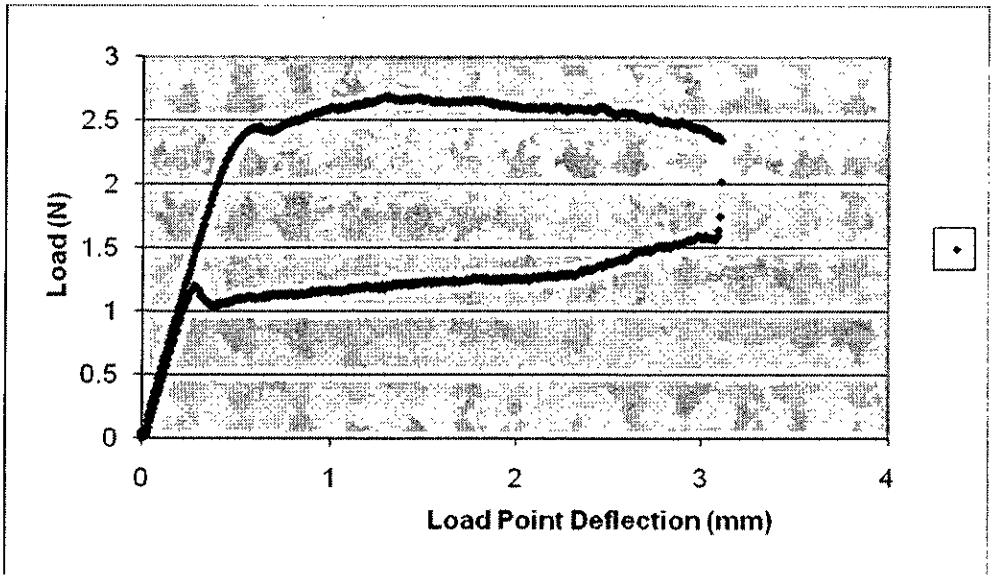
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GAC .016" New



GAC .016" Retrieved



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