IN VIVO FORCE DECAY OF NITI CLOSED COIL SPRINGS

Crystal R. Cox, DDS

A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the School of Dentistry (Orthodontics).

Chapel Hill
2012

Approved by:

Ching-Chang Ko, DDS, PhD

Tung Nguyen, DMD, MS

Lorne Koroluk, DMD, MSD, MS

ABSTRACT

CRYSTAL R. COX: *In Vivo* Force Decay of NiTi Closed Coil Springs
(Under the direction of Dr. Ching-Chang Ko)

Nickel-titanium(NiTi) closed coil springs are purported to deliver constant forces over extended activation ranges. *In vivo* studies supporting this claim are limited. **Objectives:** Evaluate force decay properties of NiTi coil springs after clinical use. **Methods:** Force-deflection curves for 30 NiTi coil springs(used intra-orally) and 15 laboratory springs were generated pre- and post-retrieval to evaluate force loss following 4, 8, or 12 weeks of use. *In vivo* and *in vitro* data were compared to evaluate effect of the oral environment on force properties. **Results:** Springs showed force decrease (~12%,$p<0.01$) following 4 weeks of clinical use, with a further significant decrease (~7%,$p=0.03$) from 4-8 weeks; force levels remained steady thereafter. Space closed at an average rate of 0.91mm/month. *In vivo* and *in vitro* force loss data were not statistically different. **Conclusions:** NiTi closed coil springs do not deliver constant forces when used intra-orally, but still allow for space closure rates of ~1mm/month.

ACKNOWLEDGEMENTS

I would like to thank the following for their significant contributions to this project:

Dr. Ching-Chang Ko, for his mentorship, encouragement, and support throughout the development and completion of this project.

Dr. Tung Nguyen, for the generosity he showed in time, advice, and input, as well as his invaluable guidance.

Dr. Lorne Koroluk, for his thoughtful insight, positivity, and direction.

Dr. Ceib Phillips, for her insight and expertise with statistical analysis.

John Whitley, for his hard work, assistance, and input.

I thank my parents, ***Bruce and Betty Cox***, for their encouragement of my studies, their wise advice, and their unwavering support. I could not have made it to this point without you both pushing me to success and I love you for it. I am grateful to my sister, ***Shellie Quinn***, for always being there for me, loving me, and encouraging me to stay focused on my dreams.

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I. LITERATURE REVIEW

In orthodontics, space closure is a common procedure, especially in extraction cases. The two major types of techniques used to accomplish space closure include loop mechanics and sliding mechanics. Loop mechanics utilize closing loops bent in the archwire which when activated deliver forces that result in tooth movement and closes the space. Such a force system has the disadvantage of requiring continuous re-activation of the closing loop. With each re-activation there is the potential for very high initial forces that may decay to zero until the next activation. Poorly scheduled activations may compromise the efficiency of the treatment. With sliding mechanics, teeth with bonded brackets move in response to forces that slide the brackets along an archwire with a push or pull force. This force may be applied via a number of different techniques, but it is generally accomplished using a metal alloy coil spring [stainless steel (SS), cobalt-chromium-nickel (Co-Cr-Ni), or nickel-titanium (NiTi)], or some type of elastomeric material such as elastomeric chain, elastomeric ligatures/modules, or intra-oral elastics. Depending on the material used, sliding mechanics may generate lighter and more continuous forces for space closure over a longer activation range when compared to loop mechanics.

There appears to be a consensus among orthodontists that light, continuous forces provide more favorable tooth movement with fewer negative side effects such as periodontal trauma or root resorption(1). According to Goldman and Gianelly, force magnitude may play a role in tooth root resorption(2). Reitan noted that the use of light forces allows for the creation of smaller hyalinized zones than with heavier forces by which bone can be more readily resorbed allowing for more rapid tooth movement(3). Quinn and Yoshikawa theorized a linear relationship between rate of tooth movement and stress magnitude up to a point. However, beyond a certain point, an increase in stress did not cause any considerable increase in tooth movement. For this reason, in order to conserve posterior anchorage, they advocated the use of treatment methods that decrease stress magnitudes applied to posterior teeth while applying maximally efficient stress to the anterior teeth. In order to achieve this, they recommended the use of mechanics with fairly constant moment/force ratios and low load-deflection rates(4). Yee et al. confirmed these effects using a split-mouth study design that compared a 300gm NiTi closed coil with a 50gm NiTi closed coil during bilateral canine retraction into a first premolar space. While the overall amount of space closure over 12 weeks was greater with the heavier force springs, the percentage of space closure from canine retraction was greater with the light force spring and the light force group showed less negative effects such as posterior anchorage loss and loss of canine rotation control(5). For these reasons, NiTi closed coil springs, which have been purported to deliver light, continuous forces over long activation ranges, have become a popular material for delivering the space closure force with sliding mechanics.

NiTi alloys are frequently termed shape memory alloys and/or superelastic alloys. These properties are made possible by the martensitic and austenitic phase transitions that occur within the material over a certain temperature transition range. Since they exhibit a high amount of recoverable elastic strain (~8%), they are able to be significantly deflected (wires) or stretched/compressed (coils) and still return to their original shape(6). This shape-memory phenomenon is possible because NiTi alloys possess the ability to alter their atomic bonding as a function of temperature or stress without permanent deformation. The stress-induced phase transitions often allow for the property of superelasticity whereby NiTi materials exhibit a relatively flat (non-linear) load-deflection curve signifying their ability to deliver a constant force whether they are stretched or compressed over a long range of activation. Upon unloading, martensite transforms back to austenite in a process of de-twinning whereby the molecular arrangements of NiTi are altered but atomic compositions remain unchanged and no plastic deformation occurs(7, 8). This provides a long elastic range for the material, which is represented by a relatively flat load-deflection curve. A micro X-ray diffraction study of three different NiTi orthodontic wires by Iijima et al. confirmed that there was an increased ratio of martensite to austenite within the wires that were subjected to greater bending deformation(9).

Each of the previously mentioned materials when used to apply forces for space closure with sliding mechanics are effective at moving teeth, but the question for many orthodontists is which material will move teeth most efficiently and with the most predictable force levels. If constant forces are desired for efficiency, then the force degradation properties of materials used to supply these forces is critical. With respect to force levels, *in vitro* studies have been conducted on common metal alloy coil springs demonstrating their force decay properties in a laboratory setting. Angolkar et al., in an *in vitro* study, showed that all SS, Co-Cr-Ni, and various NiTi coil springs lost force over time, with most springs exhibiting the majority of force loss within the first 24 hours. The coil springs, in general, when stretched on specially designed racks in the laboratory to a given extension and maintained in a salivary substitute material at 37 ˚C between testing intervals, showed an 8-20% force loss after 28 days(10). Stainless steel (SS) coil springs, which have been shown by Angolkar to perform similarly to Co-Cr-Ni coil springs, have greater extremes in forces during space closure compared to NiTi coils(10, 11). An *in vitro* study by von Fraunhofer et al. demonstrated that NiTi closed coil springs delivered light, continuous forces over a 6mm range of activation while SS springs produced much heavier forces over an activation range of only 1mm and increased even further with continued activation(12). Further, Miura et al. conducted an *in vitro* study comparing Japanese NiTi, SS, and Co-Cr-Ni coil springs which showed that NiTi springs had better super-elastic and springback properties and were able to deliver constant light, continuous force over a long range. The NiTi closed coil springs in this study, with a diameter of 0.009 inches and a lumen of 0.030 inches showed no permanent deformation despite being stretched to 500% of their original size. The load-deflection curves of the SS and Co-Cr-Ni closed coil springs exhibited linear relationships up to their proportional limit while the Japanese NiTi coil springs showed relatively flat load-deflection curves due to their relatively small increases in stress despite increasing the strain(13). With these results, NiTi coil springs have become a popular choice among the metal alloys for space closure.

In addition to the metal alloy coil springs, elastomeric polymers are widely used for force application with sliding mechanics. Elastomeric chain, elastomeric modules and intra-oral elastics are commonly used materials. When a material is stretched and the internal stress increases proportionally to the applied strain, the material is said to exhibit elastic behavior. A perfectly elastic material would thus have identical loading and unloading stress-strain curves. Unfortunately, the elastomeric materials used in orthodontics, lose energy when stretched and do not exhibit perfectly elastic properties. Instead, their unloading curve, which is of the greatest interest to orthodontists as it represents the force being delivered to the teeth, shows that for a given amount of stretch, less stress is established than for the loading curve. This phenomenon is known as hysteresis. The energy loss is caused by many factors including sliding and friction among the molecular chains within the polymer, the presence of water that can weaken intermolecular forces, and chemical degradation. With time these materials apply less force to teeth and this force decay is of concern for orthodontists who want to know how frequently the elastomeric chains, modules, or elastics must be changed to maintain force levels high enough for tooth movements that result in efficient space closure.

Force decay of elastomeric materials has been closely examined by several different research teams. Taloumis et al. found that elastomeric ligatures stretched in a simulated intra-oral environment showed decreased force levels over time with a rapid drop in force levels (53% to 68%) occurring within the first 24 hours(14). Lu et al. conducted an *in vitro* study showing that the force applied by elastomeric chain degrades quickly, with most of the force decay occurring within the first hour of use(15).

NiTi coil springs have been purported to have certain advantages over elastomeric materials including the lack of rapid force decay, such that they are able to supply a constant, steady force during space closure. However, in a randomized clinical trial conducted by Nightingale and Jones which evaluated differences in force retention between elastomeric chain and NiTi coil springs, a rapid loss in force of NiTi coil springs occurred over a 6 week period after which force values leveled out. Additionally, over a period of 22 weeks, only 46% of the springs were able to maintain at least 50% of their initial force. For comparison, over a 15 week time period, 59% of the elastomeric chain samples were able to maintain at least 50% of their initial force(16). Santos et al. also compared the force decay of elastomeric chain and NiTi coil springs and found that chains showed a higher percentage of force loss during the first 24 hours of use with force decay continuing progressively thereafter while NiTi coil springs exhibited a progressive but gentle decay of force over a 28 day period. At the end of the 28 day time period tested, the elastomeric chains suffered from significantly greater overall force decay than the NiTi closed coil springs tested(17).

Maganzini et al. tested 14 different types of NiTi closed coil springs from 5 different companies at set extension points using a force gauge and found that most of the springs tested did not exhibit physiologic peak load forces or constant deactivation forces. Only six of the 14 coil types tested showed mean changes in unload forces of 50 grams or less over the deactivation range of 9 to 3mm, indicating that most NiTi coil springs on the market are not delivering the expected constant unloading forces. GAC-Sentalloy coils were shown to be the most efficient, supplying fairly constant unload forces over their deactivation range of 9mm to 3mm(11). Melsen et al. also tested several closed coil springs from six different manufacturers with the finding that only light (100 gm) and medium (150 gm) GAC springs were able to demonstrate true super elastic properties at room temperature. Many of the other springs tested were delivering low forces without demonstrating true super-elasticity(18). Manhartsberger and Seidenbusch noted that although the relatively constant martensitic plateau does exist for the GAC

Sentalloy closed coil springs, there is a significant discrepancy between their findings and those reported by the manufacturer regarding activation ranges. They did not find an absolute constant load-deflection curve over the full 12mm activation range reported by the manufacturer and noted a decrease in force delivery following four weeks of maintaining the springs at a total 10mm stretch length (7mm of activation) at 37˚ +/- 1˚ C in the laboratory, which they referred to as a relaxation phenomenon(19).

With regard to efficiency of tooth movement, several clinical studies have compared commercially available NiTi coil springs and elastomeric materials for space closure. Samuels et al showed in a clinical split-mouth study of space closure in seventeen patients with premolar extractions that 150 gm nickel-titanium closed coil springs produced a significantly greater and more consistent rate of space closure than did an elastic retraction module (elastomeric module tied and activated with a SS ligature). A clinical examination of these patients demonstrated no clinically observable differences in tooth position or angulation between these two retraction techniques at the conclusion of treatment(20). A later study by Samuels et al further showed that while 150 or 200 gm NiTi coil springs produce an increased rate of space closure in comparison to elastic modules or 100 gm NiTi coil springs, there was no significant difference in space closure rates between the 150 gm and 200 gm NiTi coil springs(21). In a clinical split-mouth study by Sonis of twenty-seven patients comparing space closure with 150 gm Sentalloy NiTi closed coil springs versus daily changed 3/16", 180 gm intra-arch elastics, the NiTi springs were shown to produce significantly more tooth movement at a rate (0.51 mm/week) nearly twice as fast as that generated by the elastics (0.27

mm/week)(22). However, use of intra-arch elastics that are changed by the patient for space closure rely on patient compliance, which has the potential to be inconsistent.

In a split-mouth clinical study on twelve patients conducted by Bokas and Woods, the rate of premolar extraction space closure and the amount of molar anchorage loss was found to be similar for elastomeric chain versus NiTi coil springs with 28 day reactivation intervals. The mean space closure produced by NiTi coil springs, although statistically significant, was only 0.17mm/month greater than that produced by elastomeric chain(23). A randomized clinical trial consisting of 22 patients conducted by Nightingale and Jones found no difference in mean rate of space closure between elastomeric chain (0.21mm/week) and NiTi coil springs (0.26mm/week)(16). Dixon et al. conducted a clinical trial comparing space closure with elastomeric chain (10 patients), NiTi coil springs (11 patients), and active elastomeric ligatures (12 patients). Mean rates of space closure were only significantly different between the NiTi coil springs (0.81mm/month) and active elastomeric ligatures (0.35mm/month), while the rates of space closure between NiTi coil springs and elastomeric chain (0.58mm/month) were similar(24).

A systematic review of space closure with sliding mechanics conducted by Barlow and Kula found that NiTi coil springs generate a more consistent force and a faster rate of space closure compared to elastic modules (ligated with SS ligatures), but produce similar rates of space closure in comparison to elastomeric chain(25). With such similar clinical results between NiTi coil springs and elastomeric chain, it is not surprising that these two materials seem to be the more common methods of space closure via sliding mechanics used today. The bigger question seems to be whether the use of NiTi coil springs rather than elastomeric chain is worthwhile given their substantially greater cost.

This is especially true since the few existing *in vivo* clinical trials using NiTi coil springs seem to be demonstrating much greater force decay than expected from previous *in vitro* testing, in spite of their advertised ability to apply constant forces throughout space closure. *In vitro* studies do not always correlate well with actual *in vivo* clinical outcomes. Intra-orally, plaque accumulation on appliances and the array of oral bacteria with their highly varied by-products creates a unique environment that is not well simulated in the laboratory(26).

The wide temperature variations experienced intra-orally are also not well simulated in the laboratory and the mechanical properties of superelastic NiTi wires have been shown to be highly dependent upon temperature changes(27, 28). In the intra-oral environment, NiTi alloys may not fully express super-elastic properties, especially with transient temperature changes, and their fracture resistance can be reduced(26). Tripolt et al. demonstrated the effect of temperature on the force magnitudes delivered by GAC closed coil springs through a range of temperatures from 15˚C to 60˚C(29). Drinking cold liquids can reverse the phase transformation process of NiTi and lead to a reduction in its stiffness which may last for up to two hours. This effect can impact the performance of NiTi materials during space closure in the posterior segments(26). Nattrass et al. examined the effect of environmental factors (submersion in water, Coke®, and turmeric solution) and temperature on both elastomeric chain and NiTi coil springs. While the chain was affected by all test environments and showed force loss with increased temperatures, the NiTi coil springs were only affected by temperature and showed an increase in force at higher temperatures(30).

Wichelhaus et al. examined the effect of temperature cycles and mechanical loading cycles on force properties to evaluate the influence of transient intra-oral temperature changes and mastication or tongue play on NiTi coil springs. They determined that the effects of mechanical microdeflections and temperature changes will cancel each other out since thermocycling led to an increase of force levels while mechanical microcycling decreased them. They further examined the effect of initial activation on overall force properties, noting that there is a significant relationship between the two. A considerable amount of activation/deflection of NiTi coil springs is necessary to form sufficient stress induced martensite to allow for the phase transformation phenomenon that generates a clinical force plateau in the unloading curve. They recommended activating all springs to at least 15mm when attaching them to the appliance in order to generate a good constant force plateau region(31). Waters also noted that increased deflections produce greater force plateaus(32).

A further limitation in any study involving super-elastic NiTi materials is the high variability in properties, even within the same company. Wire properties may vary considerably from batch to batch. In a study conducted by Bourauel et al., modified Burstone T-loop retraction springs were fabricated from super-elastic NiTi alloys from different manufacturers and mechanical properties of the loops were tested. They found that only about 5% of the mechanical properties were reproducible, even within a single batch of the material, and recommended the individual calibration of any super-elastic NiTi device(33). Tonner and Waters tested the intra-batch variation in several load-deflection characteristics of thirteen different NiTi wires. They noted a 10% coefficient of variation for the intra-batch variation for unloading plateau values(34). Melsen et al. also noted variation on the forces delivered by the same batch of NiTi coil springs(18). Each individual spring can have significantly different mechanical properties with even small differences in alloy composition(31).

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II. MANUSCRIPT

INTRODUCTION

Space closure is an important aspect of orthodontic treatment. Using light, continuous forces over a relatively long activation range (e.g., 5-10 mm space closure) allows for more biologically favorable and clinically efficient tooth movement with fewer negative side effects(1-4). Some common orthodontic materials used for space closure deliver very high initial forces that decay rapidly prior to re-activation(5-8). NiTi materials are purported to overcome this rapid force decay problem and supply light, continuous forces over a long activation range(9, 10). The claim that they are able to deliver these more biologically favorable forces, and thus potentially lead to more efficient tooth movement, is how many clinicians have justified their use despite their relatively greater cost compared to other common space closing materials such as elastomeric chain or closing loops.

NiTi alloys possess the unique properties of shape memory and superelasticity because of their capacity to alter their crystalline bonding patterns between the martensitic and austenitic phases as a function of temperature and applied stress without permanent dislocation of atoms(11, 12). Thus, these materials exhibit a relatively flat (non-linear) load-deflection curve signifying the superelastic characteristic of NiTi in which it delivers a low, constant force over a long range of activation.

Unfortunately, several *in vitro* laboratory studies and limited *in vivo* studies have suggested that NiTi closed coil springs may not be delivering constant forces (5, 13-17). Maganzini et al. examined 14 different types of NiTi closed coil springs *in vitro* from 5 different companies and concluded that most of the springs tested did not exhibit constant deactivation forces or physiologic peak load forces(5).

It is known that *in vivo* clinical outcomes correlate poorly with *in vitro* studies(18). Intra-orally, plaque accumulation on appliances and the array of oral bacteria with their highly varied by-products creates a unique environment that is not well simulated in the laboratory(18). Additionally, the mechanical properties of NiTi products have been shown to be highly dependent upon intra-oral temperature changes(12, 18, 19). Eliades et al. highlighted the need for post-clinical retrieval analysis in order to fully understand the *in vivo* material properties(18). Clinical data examining force loss in the NiTi coil springs is limited, but *in vivo* results from Nightingale and Jones demonstrated average 48% force loss values following 22 weeks of intra-oral use(14). This current project is aimed at evaluating the intrinsic force decay properties of NiTi closed coil springs following clinical use with the hypothesis that they will experience force decay proportional to stretch duration and thus affect efficacy of space closure. Comparisons with matched laboratory analysis will elucidate the overall effect of the intra-oral environment on spring properties.

Understanding the force decay properties of NiTi closed coil springs during intra-oral use will enable the clinician to make more cost effective decisions and empower them to deliver more efficient and effective treatment.

MATERIALS AND METHODS

Subjects

Patients in active treatment at the University of North Carolina School of Dentistry graduate orthodontic clinic or dental faculty practice that met the inclusion/exclusion criteria outlined below were eligible to participate in this study. Following IRB approval (study #10-1802) from the Institutional Review Board of the University of North Carolina, 11 patients were consecutively enrolled and data collected based on the following criteria:

Inclusion Criteria

- Have space closure treatment need
- Space closure performed with sliding mechanics using 150 gm GAC-Sentalloy NiTi coil springs
- Consent to participate in the study

Exclusion Criteria

- Springs that showed permanent deformation prior to or at the removal stage

Springs

All springs used in this study were GAC Sentalloy closed coil springs of medium grade (Figure 1), which were advertised by the manufacturer to deliver a force of 150gm without deformation or force change when stretched in a range of 3 to 15mm(9). These commercially available springs are approximately 9mm long (eyelet to eyelet) and consist of a 3mm length of coil with eyelets at each end. All springs used were from the same lot number (Lot No. B3X0).

<u>Mechanical Testing using Dynamic Mechanical Analysis (DMA) and Instron</u>

Pre-Testing: Initial (pre-use) force levels for each spring were tested using Dynamic Mechanical Analysis (DMA). DMA is a technique that incorporates stress/ strain force measurements to study the mechanical properties of a material. DMA was chosen for this study due to its ability to 1) accurately control temperature (± 1^{o}C) during force analysis and 2) perform a load-controlled test. Ten separate springs were stretched during preliminary testing and pseudoelastic force-deflection curves were generated for each. While there were small variations in force levels from each spring, the ideal testing force for DMA was determined to be 300 gm. At this force level, many of the preliminary springs were able to achieve almost the full 12mm activation range recommended by the manufacturer while beyond this force level, many springs were stretched beyond the 12mm guideline and possibly distorted. All 55 springs used in this study were tested on a DMA apparatus (Model, 2980, TA Instruments, New Castle, Delaware – Figure 2). Temperature was controlled using a combination of liquid nitrogen and thermal heating to maintain temperature at 37˚C +/- 1˚C. Force was ramped at a rate of 0.5N/min up to 2.942N (300gm) and then back down to zero at the same rate. Each spring was pre-loaded to 0.24N (2.4gm) and maintained at the isothermal temperature of 37˚C for 2 minutes prior to force ramping. Springs were attached to 0.032” SS hooks, which were gripped by the DMA film tension clamp (Figure 3).

Post-Testing: The final (post-use) testing of the springs was conducted on an Instron universal testing machine (Model 4411, Norwood, Massachusetts – Figure 4), which uses a tension load cell to measure forces and activations and generate load-deflection curves. Instron used displacement control rather than force control, which stretched each individual spring to the same length it was activated in pre-testing via DMA. The springs were stretched to this length at a rate of 5mm/min and then allowed to return to their original relaxed state at the same rate. The Instron was equipped with a +/-500 N static load cell (Instron, Serial Number UK 27) attached to the crosshead. A 0.032" SS hook was attached to the load cell to hold the upper loop of the coil spring. The opposite end of the coil spring was held by a 0.032" SS rod, which was inserted within a special testing jig that was attached to the instrument base. The spring and the special jig were contained within a double jacketed water chamber and submerged in water (Figure 5). The temperature of the water within the inner bath (37˚ +/- 1˚C) was maintained by circulating temperature controlled water through the outer closed chamber. This temperature was carefully regulated by a water circulating temperature controller (Haake, Germany). The monitoring thermocouple for the water circulator was placed within the inner chamber. The springs were maintained in the water bath for 2 minutes prior to stretching.

Groups

Following DMA pre-testing, the springs were randomly distributed to 3 different groups: 1) Clinical, 2) Laboratory, 3) Control.

1. Clinical springs (n=30): Thirty of the pre-tested springs were used during the treatment of patients in the orthodontic clinics at the University of North Carolina at Chapel Hill, from May 2011-December 2011. Once a patient met the above inclusion criteria, they were enrolled in the study and initial data regarding space closure was gathered. The springs were attached from the canine hook to the molar hook and ligated to the canine hook to prevent loss (Figure 6). Intra-oral measurements were made for spring activation range and interdental spacing using a Boley gauge. In addition, bracket slot size, wire size, and wire material were recorded. Patients were seen on their normal recall schedule of 4 weeks. At each recall, the springs were checked for signs of obvious distortion and maintained undisturbed until time of collection if no distortion was noted. Ten springs were collected for each of the time points in the study (4, 8, and 12 weeks). Upon removal of the springs, final measurements regarding spring activation length and remaining space were recorded. The springs were cleaned in a 10% Formalin solution for 10 minutes, rinsed with de-ionized water and stored dry in plastic bags for final force testing on the Instron.

Depending upon space closure needs of the patient, up to 4 springs could be collected from the same patient at a given time (one per quadrant). If additional space closure was needed following retrieval of the springs, new springs could have been placed in the same patient and collected after another 4, 8, or 12 weeks. Overall, 11 patients (7 Female, 4 male) participated in this prospective study (Average age 23.2 years, range 13-43 years). The slot size and type of archwire used for each clinical spring is summarized in Table 1.

2. Laboratory springs (n=15): Fifteen of the pre-tested springs were placed on SS plates with SS attachment pegs set at a distance of 20mm apart, which correlates to 11mm of coil activation (Figure 7). These springs were stored stretched in the laboratory in a salivary substitute material at 37˚C and tested at time intervals of 4 weeks, 8 weeks, and 12 weeks on the Instron universal testing machine. The salivary substitute material used was Fusayama-Meyer artificial saliva. The composition of this solution, which closely resembles natural saliva is: KCl (0.4 gm/L), NaCl (0.4 gm/L), $CaCl_2 \cdot 2H_2O$ (0.906 gm/L), $NaH_2PO_4 \cdot 2H_2O$ (0.690 gm/L), $Na_2S \cdot 9H_2O$ (0.005 gm/L), and Urea (1 gm/L)(20, 21). The solution was titrated to a pH of 6.5 using 5M NaOH.

3. Control springs (n=10): Ten of the pre-tested springs were analyzed on the Instron universal testing machine to identify the relationship between the two different machines used for pre- and post- testing.

Analysis

Initial and final pseudoelastic force-deflection curves were generated for each spring in the clinical, laboratory, and control groups. For all mechanical testing, each individual spring was stretched to approximately the same length for its post-testing on Instron as it was for its pre-testing on DMA. The maximum force attained by each spring at this length was used to compare the amount of force loss (force loss = maximum force reached by the spring at a given length pre-use – maximum force reached by the same spring at that same given length post-use).

At each time point, the loss in force was assessed using a one sample t-test to determine whether the mean loss was statistically significant. Unpaired t-tests were used to compare the control group force loss to the 4 week clinical data and separately to the 4 week lab data in order to evaluate for statistical significance beyond what is due to differences between different machines used for testing. One-way ANOVA was used to evaluate force loss differences between time points for the clinical springs, which had three mutually exclusive groups. Force loss differences between time points for the laboratory springs were evaluated using repeated measures ANOVA. Unpaired t-tests were used to compare force losses for the clinical groups at each time period to the laboratory values over that same time period. A linear regression model was performed to identify associations between the outcome variable of space closure/week and the predictor variables of sex, age, archwire type, slot size, initial coil stretch length, and individual coil stiffness (calculated by dividing the initial maximum force by the activation length of that particular spring).

RESULTS

Demographic: The clinical demographic information for each clinical spring used is summarized in Table 1. Space closure was carried out on 0.018 slot appliances (6 springs) and 0.022 slot appliances (24 springs) in addition to different wire dimensions: 18 SS archwire (7 springs), 18x25 SS (16 springs), and 16x22 SS archwire (7 springs). Overall, 11 patients (7 Female, 4 male) participated in this study (Average age 23.2 years, range 13-43 years).

Sample overall: None of the clinical springs showed signs of distortion upon retrieval so all 30 (10 per time point) were included in the analysis. During Instron testing at 4 weeks, two laboratory springs became distorted due to machine malfunction and were not used for analysis, giving a total of 13 laboratory springs for analysis. All 10 control springs were used for analysis.

Force: The initial and final pseudoelastic force-deflection curves for a single representative spring from the control group and each clinical time point group are shown in Figure 8 (control, 0 weeks), Figure 9 (clinical, 4 weeks), Figure 10 (clinical, 8 weeks), and Figure 11 (clinical, 12 weeks). These representative curves also illustrate the average force loss experienced by their respective group as summarized in Table 2.

The average and percent force loss values of all clinical, laboratory, and control springs are summarized in Table 2. All groups of springs (control, clinical, and laboratory) showed a statistically significant decrease in average force level from initial to final testing over each of the time periods evaluated ($p<0.01$). The control group springs showed only a 1.71% force loss. The clinical springs retrieved following 4 weeks of use showed an average force loss of 11.57% while those retrieved after 8 weeks of use showed an 18.88% force loss and after 12 weeks of use showed a 17.79% force loss. The laboratory springs showed an average force loss of 12.12% after 4 weeks of stretch, 17.36% after 8 weeks of stretch, and 19.44% after 12 weeks of stretch.

The amount of force loss experienced by the clinical and laboratory springs was significantly greater than that of the control springs, suggesting that the force loss was beyond an amount that can be attributed to differences between mechanical testing machines. Table 3 showed that the difference between the amount of force loss experienced by the control group springs and the amount of force loss experienced by the clinical and laboratory springs following 4 weeks of stretch was already statistically significant ($p<0.01$).

One-way ANOVA among the 3 mutually exclusive clinical groups revealed that there was a statistically significant relationship between the difference in force and the amount of time the springs were used ($p=0.04$). Table 4 shows pair-wise comparisons that indicated, on average, there was a statistically significant force loss between the 4 and 8 week time periods for the clinical springs of 21.90gms ($p=0.04$). However, the further force loss from the 8 to 12 week time points was not statistically significant ($p=0.93$).

Repeated measures ANOVA among the 3 time points for the single laboratory group revealed that there was a statistically significant relationship between the difference in force and the amount of time the springs were used ($p<0.01$). Table 5 revealed that, on average, there was a statistically significant force loss between the 4 and 8 week time periods for the laboratory springs of 15.70gms ($p<0.01$). However, the further force loss from the 8 to 12 week time points was not statistically significant ($p=0.06$).

No statistically significant differences between the clinical groups at 4, 8, or 12 weeks and the laboratory group tested at 4, 8, and 12 weeks with respect to average force loss over the given time periods were demonstrated (Table 6).

Space closure: There were no statistically significant differences between the average amount of change in coil stretch length and the average amount of space closed for any of the clinical time periods (p=0.47 for 4 week group, p=0.48 for 8 week group, and p=0.58 for 12 week group). Figure 12 shows the average space closure distance for each time period (4 week group = 0.98mm, 8 week group = 1.70mm, and 12 week group = 2.71mm) with an overall average rate of 0.91mm/ month. The differences in space closure among three different time periods were statistically significant (P=0.01).

Table 7 summarizes linear regression data analyzing the association between space closure rate and the predictor variables of sex, age, archwire type, slot size, initial coil stretch length, and coil stiffness. None of these predictor variables demonstrated a statistically significant association with rate of space closure (Table 7).

DISCUSSION

Although a limitation of this study was that initial and final testing of the springs was performed on two different mechanical testing machines, the unloading force-deflection curves for the control group springs on DMA and Instron were quite comparable (Figure 8). In addition, the average difference in maximum force values between the two machines was only 1.71% (Table 2). Furthermore, there was a statistically significant difference between the force loss experienced by the control group springs (1.71%) and the force loss experienced by the clinical and laboratory springs (approximately 12%) following 4 weeks of stretch (p<0.01, Table 3). This suggests that the force decay experienced by the springs over a 4 week period was due to its intrinsic properties rather than measurement discrepancy between machines. Similar results are found for the 8 and 12 weeks clinical and laboratory springs.

Our reported force decay following 4 weeks of use for clinical springs was 11.57% and for laboratory springs was 12.12%. This is in agreement with an *in vitro* study conducted by Angolkar et al. that showed an overall 8-20% drop over 28 days in force levels among various metal alloy coil springs(13). A higher force decay percentage of 48% over a 22 week time period was reported in an *in vivo* study by Nightingale and Jones, which could be due to the fact that their values were measured with an intra-oral force gauge at the spring stretch lengths and thus likely included both the intrinsic force loss within the spring material itself as well as a large contribution from the fact that the coil spring length had decreased between time measurements due to space closure(14). However, none of the springs tested in these studies were from the GAC company and since manufacturing conditions play a major role in force properties of these springs, the data is likely not very comparable with our study.

There were several *in vitro* studies by Maganzini et al, Manhartsberger and Seidenbusch, and Tripolt et al. that included data on the medium grade GAC Sentalloy springs used in our study(5, 16, 22). However, the absolute value of our measured forces cannot be directly compared with their findings because all of our springs were not initially stretched to the full 12mm activation range that theirs were. It has been shown that the initial activation length of NiTi coil springs can have a significant influence on their force properties and effects both the length and absolute value of the constant force plateau regions of these springs(23). However, an interesting finding of these studies that is in concordance with our results is that GAC NiTi springs do not exhibit constant force of the reported 150gm over the entire 12mm activation range as claimed by the manufacturer(5, 16, 22). The super-elastic force plateau region occurs over a much more limited range than advertised.

Our study noted a significant drop in force of ~7% (clinical group) and ~5% (laboratory group) over the 4-8 week time interval with force levels appearing to maintain thereafter. Such findings agree with those of Nightingale and Jones who showed in a randomized clinical trial that NiTi coil springs experienced rapid loss in force over a 6 week period, after which force values leveled out. Nightingale and Jones hypothesized that this was because their initial activation lengths created force values higher than the super-elastic plateau and so it took a certain amount of space closure to reach a point where the springs were at a length to exhibit force within the constant plateau region(14). The force-deflection curves in our study also demonstrated that our initial coil stretch lengths were beyond the constant force plateau region of these springs even though 23 of the 30 clinical springs we used were initially stretched less than the 12mm reported by GAC to be within the constant force plateau region and the average over-extension of the remaining seven springs was only 0.86mm. However, it is likely not the fact that the springs were initially activated beyond their force plateau that caused this initial rapid force loss in the springs over an 8 week time period because our initial and final measurements were taken with the springs at the same activation length and were thus unaffected by space closure. The initial force loss appears to be related to the intrinsic properties of the spring itself.

The fact that the clinical and laboratory data in our study showed no statistically significant differences with respect to force values is interesting since it has been noted that in most cases *in vitro* research gives a much different material profile from what is actually being used clinically(18). Our findings agree with Wichelhaus, who demonstrated via *in vitro* thermo-cycling and mechanical micro-cycling tests, that the oral environment does not seem to be a major influence on the mechanical properties of NiTi coil springs(23). Additionally, NiTi coil springs have been shown by Nattrass et al. to be unaffected *in vitro* by the specific environmental factors of water, Coke ®, or turmeric solution(24). The biggest difference between the *in vivo* and *in vitro* environments that seems to concern researchers with respect to NiTi springs is the transient temperature changes experienced intra-orally because it has been shown that NiTi force properties are highly dependent upon temperature(19). However, the force properties of the springs seem to be only altered while the spring is at that temperature rather than succumbing to some type of permanent deformation as a result of the transient temperature changes. Thus, temperature fluctuations only transitorily affect the force values supplied by the springs. Since our testing was performed at the constant temperature of 37˚C for both clinical and laboratory springs, it makes sense they would demonstrate similar force values.

The rates of space closure obtained in our study, which averaged 0.91mm/month (0.23mm/week) were comparable to those reported in several other *in vivo* studies on NiTi coil springs, which ranged from 0.20-0.26mm/week(14, 25, 26). The similar results in our study as compared to those of Dixon et al. was re-assuring as their method of space closure measurement with Vernier calipers on casts was likely much more accurate than our intra-oral Boley gauge measurements(26). These studies were also better controlled than ours with respect to clinical and biomechanical variables. Since we still had similar reported space closure rates, it adds weight in support of our finding that none of the variables of sex, age, slot size, archwire, or initial coil stretch length are strongly associated with rate of space closure (Table 7). However, our study was really not powered to detect such relationships.

An interesting observation was the high degree of variability in force values supplied by each of the closed coil springs used in this study, especially since they were all obtained from the same manufacturer lot number. In order to represent this graphically, the maximum initial force value of ~300gm that each spring was tested to was plotted against that individual spring's activation length when this force was reached (Figure 13). At a force of 300gm, the activation length of the springs in this study ranged from 5.15mm to 11.90mm, and there was a great amount of variability between these values. It should be noted that each of these activation lengths is still within the 12mm activation range reported by the manufacturer to be on the constant 150 gm force plateau. This is quite a wide range of variability and is consistent with the findings of many other studies(17, 27). There is a great deal of applicability of this information. Importantly, it indicates the need for tighter manufacturing guidelines to ensure advertised force levels are reached by the majority of springs. Further, clinicians need to be aware of the variability that exists between products because they are investing money in a system they believe to be delivering more biologically favorable forces than some of the cheaper space closure materials available such as elastomeric chain, which has been shown to close space at a comparable rate to NiTi coil springs(14, 26, 28). It also highlights the fact that clinicians should really consider using an intra-oral force gauge when activating these springs to ensure that the force levels desired are actually being delivered.

CONCLUSIONS

- NiTi closed coil springs lose ~12% of their initial force following 4 wks of clinical use. An additional drop in force (~7%) occurs between 4 and 8 weeks of use, but force levels appear to stabilize. Therefore, force decays in a non-linear proportion to spring stretch duration.
- *In vivo* (clinical) and *in vitro* (laboratory) force loss data were not statistically different.
- Despite statistically significant decreases in force levels supplied by the NiTi closed coil springs, space closure appears to proceed at a rate of approximately 1mm/month.
- There is a significant diversity in force levels supplied by 150 gm GAC Sentalloy NiTi closed coil springs, even among springs with the same lot number.

FIGURES

<u>Figure 1. GAC Sentalloy NiTi Closed Coil Spring.</u>

<u>Figure 2. DMA Apparatus Used for Initial Mechanical Testing.</u>
*Portion of figure enclosed in white dashed square is enlarged in Figure 3.

Figure 3. Film Tension Clamp With Hooks Used to Attach Coil Springs for DMA Testing.

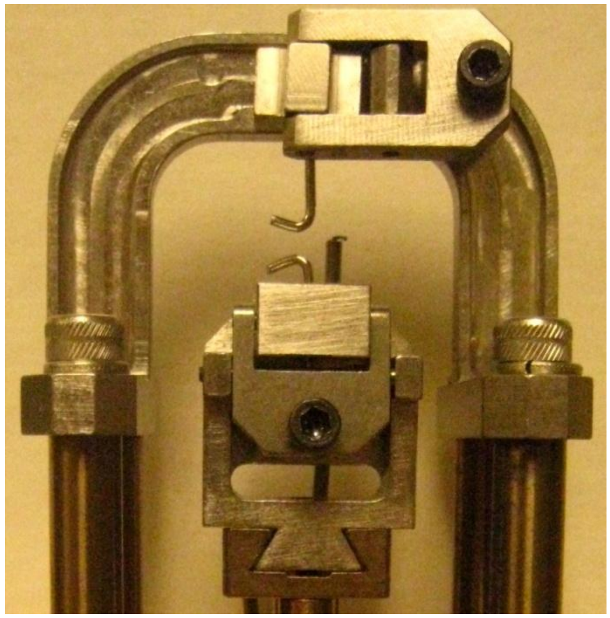


Figure 4. Instron Machine for Post-Use Mechanical Testing.

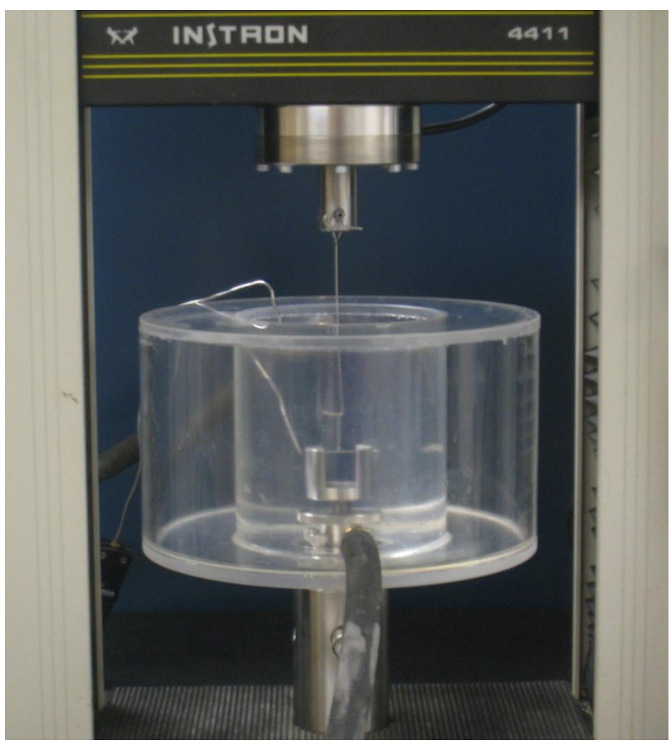


Figure 5. Apparatus for Temperature Controlled Instron Post-Use Mechanical Testing.

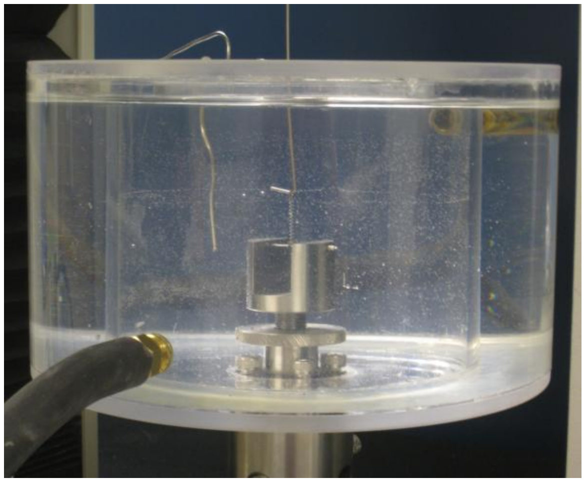


Figure 6. Example of Coil Spring Attached During Treatment of Clinical Group.

Figure 7. Apparatus to Maintain Laboratory Springs at 11mm Activation Between Time Intervals.

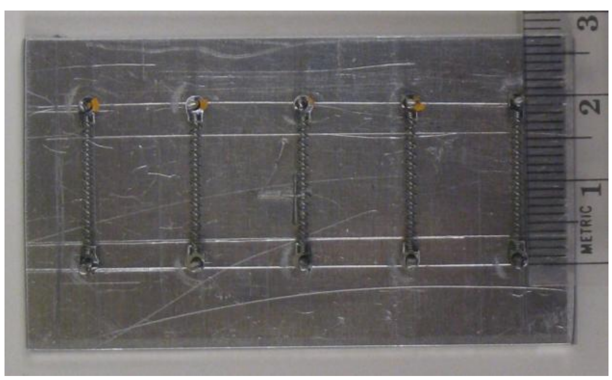


Figure 8. Initial and Final Force-Deflection Curves for Representative Control Group Spring.

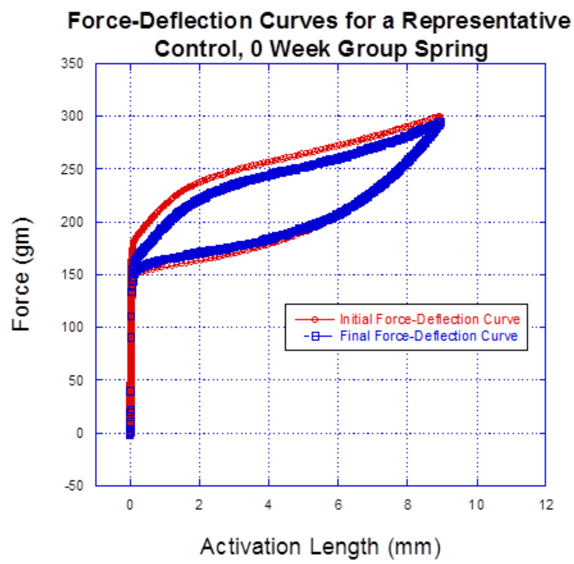


Figure 9. Initial and Final Force-Deflection Curves for Representative Clinical, 4 Week Group Spring.

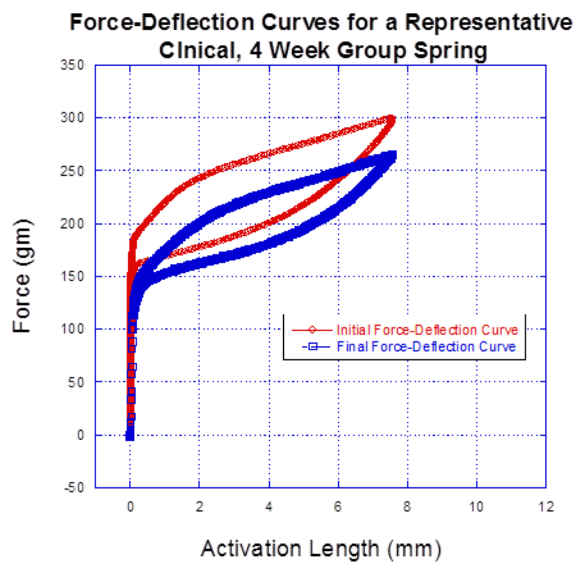


Figure 10. Initial and Final Force-Deflection Curves for Representative Clinical, 8 Week Group Spring.

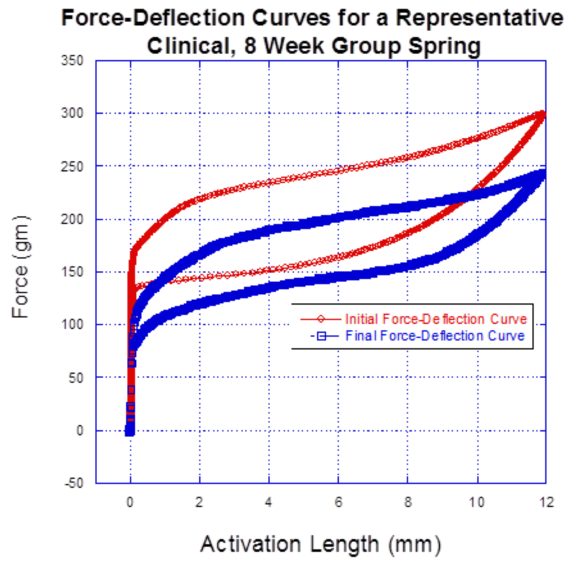


Figure 11. Initial and Final Force-Deflection Curves for Representative Clinical, 12 Week Group Spring.

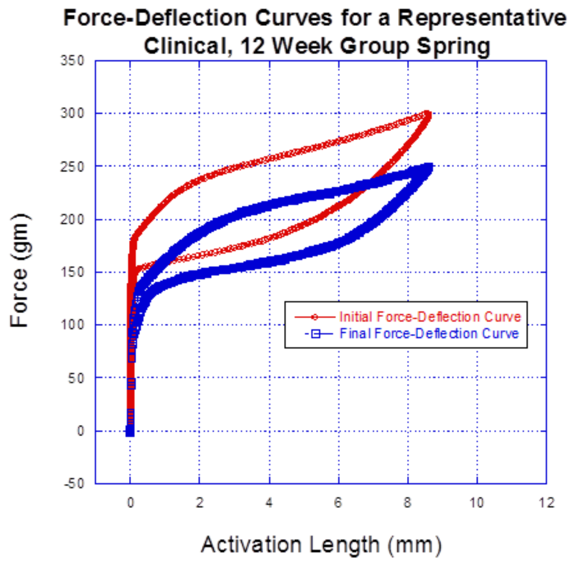


Figure 12. Representation of Average Space Closure Amounts, With 95% Confidence Intervals, Over Each Time Period.

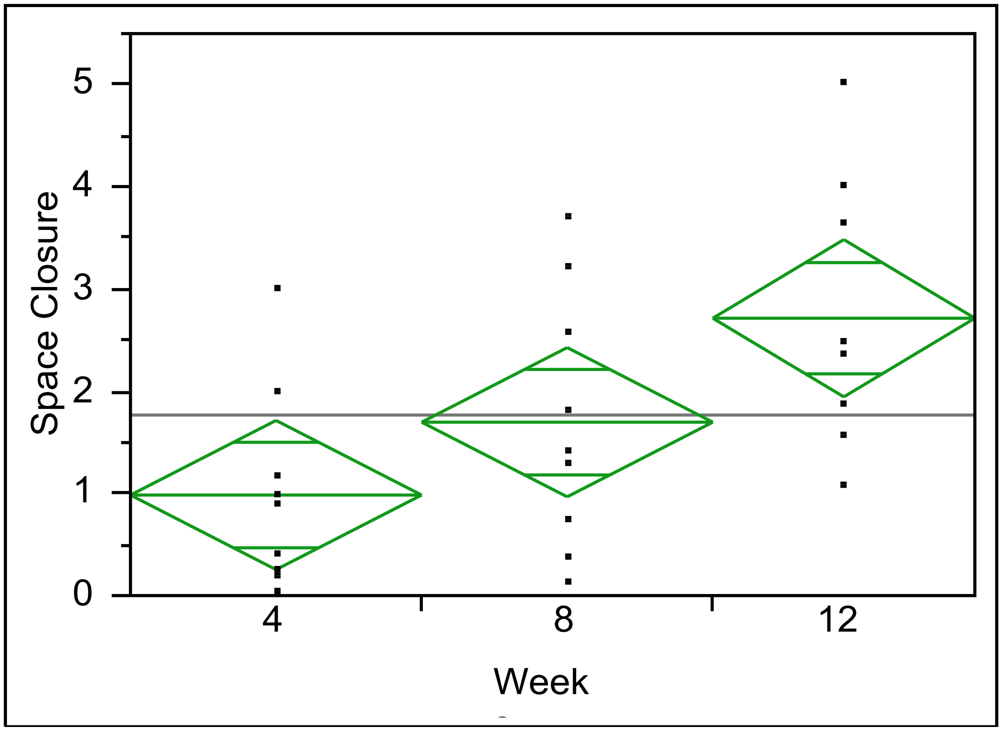
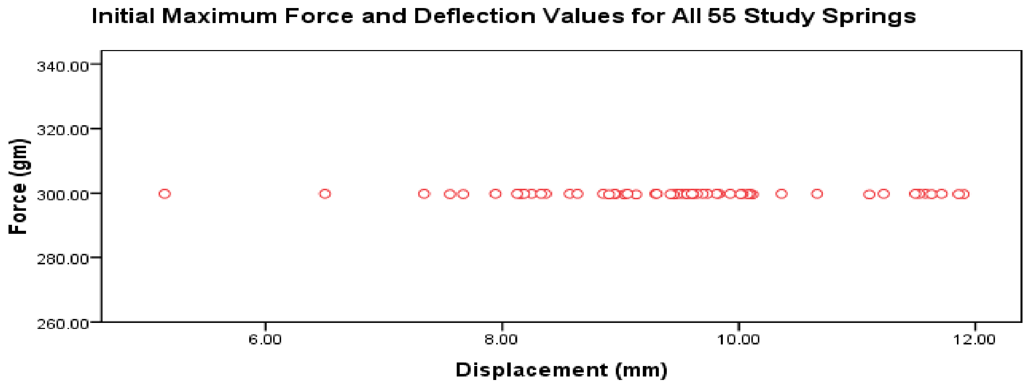


Figure 13. Representation of Force Variability Among All 55 Springs.



TABLES

Table 1. Demographic Data for All Patients and Clinical Springs.
*Values highlighted in yellow indicate the average amount of space closed and the average change in coil stretch length for all springs in that time period.

Spring ID #	# Wks	Sex	Age	Slot Size	Archwire	Amount of space closed (mm)	Change in stretch length (mm)
17	4	F	14	0.018	18 SS	2	2
67	4	F	14	0.022	18 x25 SS	0.9	0.95
68	4	F	14	0.022	18 x25 SS	0.4	0.47
69	4	M	32	0.022	18 SS	0.17	0.23
70	4	M	32	0.022	18 SS	0.23	0.14
71	4	F	18	0.018	16 x22 SS	0.04	0.02
72	4	F	18	0.018	16 x22 SS	0.97	0.92
73	4	M	25	0.022	18 x25 SS	0.96	0.81
74	4	M	25	0.022	18 x25 SS	1.17	1.47
75	4	F	14	0.018	18 SS	3	2
						0.984	0.901
12	8	F	43	0.022	16 x22 SS	2.56	3.1
13	8	F	43	0.022	16 x22 SS	0.72	1.4
20	8	F	43	0.022	16 x22 SS	0.38	1.5
21	8	F	43	0.022	16 x22 SS	0.12	0.5
25	8	F	18	0.018	16 x22 SS	1.29	1.39
28	8	F	22	0.022	18 x25 SS	1.4	0.8
29	8	F	22	0.022	18 x25 SS	1.8	0.9
36	8	F	22	0.022	18 x25 SS	1.8	1.2
48	8	M	13	0.022	18 x25 SS	3.2	5.2
49	8	M	13	0.022	18 x25 SS	3.7	3.1
						1.697	1.909
1	12	F	14	0.022	18 x25 SS	2.46	1.53
2	12	F	14	0.022	18 x25 SS	2.36	3.34
4	12	M	15	0.022	18 x25 SS	3.65	3.62
5	12	F	27	0.018	18 SS	no data	2.15
10	12	F	12	0.022	18 x25 SS	4	4.9
11	12	F	12	0.022	18 x25 SS	5	4.5
14	12	M	32	0.022	18 SS	1.08	2.2
15	12	M	32	0.022	18 SS	1.85	2.21
22	12	M	25	0.022	18 x25 SS	2.46	2.69
23	12	M	25	0.022	18 x25 SS	1.57	0.77
						2.714444444	2.791

Table 2. Average and Percent Force Loss for Clinical, Laboratory, and Control Springs Over Each Time Period.

	Time (weeks)	Mean Force Loss (gm)	S.D.	Percentage Force Loss (%)	P-Value
Baseline	0 Weeks	299.8	0.1		
Control	0 (n=10)	5.12	3.53	1.71	<0.01
Clinical	4 (n=10)	34.69	19.99	11.57	<0.01
	8 (n=10)	56.59	18.93	18.88	<0.01
	12 (n=10)	53.33	19.10	17.79	<0.01
Laboratory	4 (n=13)	36.32	11.52	12.12	<0.01
	8 (n=13)	52.02	15.58	17.36	<0.01
	12 (n=13)	58.27	23.60	19.44	<0.01

Table 3. Difference in Force Loss Between Control Group (0 Week Interval) and Clinical & Laboratory Groups (4 Week Interval)

Force Loss Comparisons	Mean Force Difference (gm)	S.E.	P-Value
Control (0 week) Vs Clinical (4 week)	29.57	6.42	<0.01
Control (0 week) Vs Laboratory (4 week)	31.21	3.79	<0.01

Table 4. Force Changes for Clinical Springs Between Time Intervals.
*Negative values for force indicate a loss over that time period while positive values indicate an increase in force.

	Time Period (Weeks)	Mean Force Difference (gm)	95% Confidence Interval		P-Value
Clinical Springs (n=30)	4-8	-21.90	-43.35	-0.45	0.04
	4-12	-18.64	-40.10	2.81	0.10
	8-12	3.26	-18.19	24.71	0.93

Table 5. Force Changes for Laboratory Springs Between Time Intervals

	Time Period (Weeks)	Mean Force Difference (gm)	S.E.	P-Value
Laboratory Springs (n=13)	4-8	15.70	1.56	<0.01
	4-12	21.95	3.99	<0.01
	8-12	6.25	2.99	0.06

Table 6. Differences in Force Losses Between Clinical Springs and Laboratory Springs at Each Time Period.

	Mean Force Difference (gm)	S.E.	P Value
Loss at 4 weeks (Clinical Vs Lab)	1.64	6.61	0.81
Loss at 8 weeks (Clinical Vs Lab)	4.57	7.19	0.53
Loss at 12 weeks (Clinical Vs Lab)	4.94	9.16	0.60

Table 7. Summary of Linear Regression Data

*Outcome variable: amount of space closed (adjusted to mm/week); Predictor variables: sex, archwire type, slot size, age, initial coil stretch length, and coil stiffness (gm/mm).

Variable	F Value	P Value
Sex	1.06	0.31
Archwire Type	1.66	0.21
Slot Size	1.24	0.28
Age	0.01	0.94
Initial Coil Stretch Length	0.29	0.59
Coil Stiffness	1.10	0.31

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