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Effects of Autoclave Sterilization on the Force Properties of an Eruption Spring

Jillian L. Shute

ABSTRACT

Introduction: Nickle-titanium coil springs are efficient and effective at moving impacted maxillary canines into the arch due to their "super elastic" properties.

Purpose: When exposing and bonding an impacted canine with a closed-flap technique, bacterial load should be minimized via sterilization to prevent infection. There is no current literature that demonstrates the effects of autoclave sterilization on the force properties of the Isoglide eruption spring.

Materials and Methods: Eighty Isoglide springs were distributed into sterile and non-sterile groups (autoclave 135ºC, 3 min). Within these groups, springs were held at extensions of 10mm for five months at 37 ºC to mimic fatigue in the oral environment. A universal testing machine was used to acquire load/deflection curves of the springs monthly. Data were statistically analyzed using Repeated-Measures ANOVA and Tukey.

Results: Repeated Measures ANOVA and Tukey showed a statistical significance between time and force degradation. A significant difference was also seen among time and treatment combined when compared to force degradation. There was no correlation between sterilization and force degradation.

Conclusion: Autoclaving does not affect the force properties of the Isoglide eruption spring. However, increased time under extension has a direct relationship with force degradation.

Background:

The maxillary canine is one of the most common impacted teeth in the dental arch, second only to third molars.[1] Its prevalence ranges from 1-3% and is twice as likely to occur in females as in males. When impacted, 8% occur bilaterally.[2] Currently, surgical exposure coupled with orthodontic traction is the treatment of choice for maxillary impacted canines (MIC).[3]

There are two popular surgical techniques for treating MIC: open and closed. While debatable, the closed technique for surgical exposure produces the most esthetic outcome, showing similar soft tissue architecture to the contralateral nonimpacted canine.[4, 5] This technique involves raising a full mucoperiosteal flap and, after crown exposure and bonding of an orthodontic device, repositioning the flap. With orthodontic traction, the MIC is gradually "erupted" through soft tissue, producing a more naturalistic result versus the open technique.[6] In general, traction employs light, continuous forces so optimal mechanics are applied to move the MIC along the treatment-planned path. This ensures minimal loss of alveolar bone support and injury to the tooth during traction, both of which are vital to the future periodontal health and esthetic outcomes.[7]

The ideal appliance used to extrude an impacted canine would have a force that is maintained through its entire range of deactivation.[8] A relatively constant force for a long period of time produces physiologically desirable mechanics for tooth movement.[9] Commonly used force systems include: ballista, K-9, cantilever springs, elastic and gold chains, ligature-wire, and closed-coil springs.[10]

Ballista, K-9, and cantilever springs tend to produce higher forces and stress rates on the impacted canine and the adjacent teeth than elastics.[11] For elastic chains, frequent reactivation is needed due to stress relaxation, a trait in which elastics can lose 42% of their original force after 24 hours of loading.[8, 12] Similarly, the use of ligature-wire requires frequent reactivation due to loss of force as the tooth erupts.[8] Thus, the use of elastics and ligature-wire requires more frequent appointments to maintain eruption forces on the MIC. Gold chains are costly, have a high incidence of ankylosis, and are painful due to soft tissue ingrowth between the chains.[13] Closed-coil springs tend to be the most efficient device due to the continuous, light force applied, reduced stress rates, and efficient movement of the MIC.

Nickel-titanium (NiTi) wires and springs were introduced to orthodontics in the late 1980's.[14] NiTi quickly became the favored alloy for orthodontic procedures, in which a long range of activation with relatively constant force is desired. This material exhibits "superelasticity" and "shape memory", and these behaviors are achieved through a reversible transformation between martensitic and austenite phases. This transformation can be induced not only by temperature but also by stress. For example, when stress is applied to a NiTi alloy, its deformation behavior is dependent on the elastic recovery of NiTi crystalline structures and orientations. Specifically, stress induces atomic-scale transformation, whereby the crystalline structure of the NiTi alloy is transformed from austenite to martensitic lattices. Upon release of the applied stress, the martensitic phase is then reverted back to the austenitic phase, whereby macroscopically the NiTi alloy also returns to its original shape.[9] Because of this phase transformation, the elastic limit of NiTi is extended. In contrast, heating a NiTi alloy induces its transformation from martensitic to austenite phase, whereas cooling encourages the opposite. Both, stress- and temperature-induced impositions, make NiTi an ideal material for orthodontic springs.[15]

The Isoglide eruption spring (IES) is a relatively new product that utilizes a NiTi coil spring and exerts small, continual forces to treat a MIC. The manufacturer claims that the product "requires little to no reactivation to bring the impacted tooth into the mouth" and will work three to five times faster than the conventional gold chain method in bringing the MIC into the arch. Therefore, it improves the efficiency of tooth movement, increased patient comfort due to light forces, and saves the orthodontist both money and time.[16]

During orthodontic traction, an ideal spring demonstrates only elastic deformation, meaning that once a force is removed, the spring returns to its original dimension, whereas all plastic deformation is nonreversible. It is also necessary for an orthodontic spring to maintain its tensile stress after sterilization. A decrease in tensile stress renders it more prone to plastic deformation and possibly breakage, which presents a problem for both the patient and provider. Sterilization has the potential to decrease the elastic limit of a NiTi spring, causing permanent deformation as well as imparting a reduced tensile force.

When utilizing an eruption appliance with the closed technique for exposure, infection control measures are paramount in order to eliminate bacterial load and prevent infection. Exposing a bacteria-free impacted tooth and introducing a nonsterile entity can cause post-surgical sequela. Moreover, if the surgical exposure is undertaken in a hospital setting, all instruments and appliances should be sterilized. Autoclaving is the current standard for sterilizing dental and medical equipment and devices (ideally at 134°C, 32 psi for 3 minutes).[17] The Isoglide does not come in pre-sterilized packaging. It is generally advised to sterilize devices from manufacturers if additional protection is sought. Currently, the effects of autoclave processes on the elasticity and tensile stress of the IES have not been studied, and there are no recommendations by the manufacturer on the sterilization process.

There is conflicting evidence on the effects of sterilization on NiTi wire. Mayhew and Kusy (1988) found that heat sterilization had no deleterious effect on the elastic modulus and tensile properties of NiTi wire.[18] Pernier & Grosgogeat (2005) echo this result in that autoclave sterilization had no adverse effects on the elastic modulus values of NiTi. However, Kapila et al. (1992) revealed significant differences between pre- and post-heat sterilizations of NiTi wires, observing a decrease in elasticity and increase in stiffness after sterilization.[19, 20] Moreover, Burstone et al. (1985) found that at a temperature of 60°C, NiTi exhibits greater permanent deformation and less elastic limit than oral temperatures (37°C).[21]

The aim of this study is to observe if autoclave sterilization will affect the force properties of the non-sterile packaged versus that of the sterilized IES.

Materials and Methods:

The tested IES contains 7 active coils (Zalinsky Ortho Parts, Charlotte, NC). See Figures 1a, 1b. Forty IES specimens were randomly distributed into two groups (n=20 per group). These groups were categorized as non-sterilized and sterilized groups, with 20 IES specimens per group. Following infection control and prevention standards, a steam sterilizer (MST-V 600, Belimed, North Charleston, SC) was used to autoclave the IES specimens at 135°C for 3 minutes. These groups were initially tested straight from the package and then underwent fatigue testing.

Jig Design

Custom jigs (n = 40) were designed using computer-aided design (CAD) software (SolidWorks, Waltham, MA) and printed using a Stereolithography printer (Form 3B, Formlabs, Somerville, MA) and material (Tough 2000, Formlabs, Somerville, MA). They were used to hold the two ends of an IES, making the jig-IES complex. See Figure 2a. In addition, the custom jigs were designed to intimately fit the apparatuses of the universal testing machine so a uniformed force magnitude along with a desired direction (i.e., force vector) can be applied to the testing IES specimen when mounted to a universal testing machine. See Figure 3a.

Fatigue

Custom platforms (n = 40) were designed using the same CAD software, printer, and printing material as described earlier. See figure 2a. These platforms were used to hold the jig-IES complex (n = 40), such that each IES specimen was stretched to a 10mm standardized distance. See Figure 2c. A total of 40 jig-IES complexes (20 non-sterilized and 20 sterilized) were fatigued via stretching on 40 custom platforms for a period of 150 days, representing a 5-month period of orthodontic traction. This time period is considered to be clinically relevant for treating MIC.[22] To simulate the oral environment, all jig-IES complexes along with their respective platforms were stored in an incubator (Forma Model 3110, Thermo Fisher, Waltham, MA) and deionized water at 37°C. On the 30th day, the force was measured. This was accomplished by transferring the jig-IES complex to the universal testing machine, whereby it stretched the IES specimen and measured the force. See figure 3b. Subsequently, the jig-IES complex was placed back onto the platform and subjected for another 30 days of stretching fatigue, stored under simulated oral environment. This process was repeated at the 60th, 90th, 120th, and 150th day. See figure 4.

Statistics

The effect size is estimated from previous studies and our experimental pilot study. Using four prospective tensile stresses (0.85, 1.05, 1.25, and 1.5 N), representing average separation across groups, and a standard deviation of 0.6, the required number of subjects per group, needed to satisfy a one-way ANOVA with a type I error of 0.05 (alpha = 0.05) and a power of 80% for detecting a difference amongst groups, is 18. This study had 20 specimens per group for any unwarranted tolerance.

For the statistical analysis, a student's t-test was used to compare the difference in force generated by the spring between non-sterilized and sterilized groups regardless of time points and at specific time points. A repeated-measures ANOVA/Tukey pos-hoc test was used to compare time points within each of the respective non-sterilized and sterilized groups

Results

Table 1 displays the mean forces and standard deviations of sterilized and non-sterilized IES at specific extension points over the course of five months.

Results of the Repeated Measure ANOVA and Tukey test revealed a significant correlation between time and force degradation of the IES. These results were consistent across all extension points (3mm, 5mm, 7mm, etc).

In addition, there was a statistical correlation between time and treatment combined and force degradation.

There was no statistical correlation between sterilization alone and degradation of force properties.

Discussion

Forty IES were analyzed in this study. The springs were separated into treatment groups of twenty, being either sterilized or non-sterilized. After initial measurements of force were taken, each group was held at a 10mm extension over the course of five months. These springs were held in a 37^{O}C thermal bath to mimic the oral environment and forces were measured approximately every thirty days for five months. The objectives of this study were to assess the changes in force after autoclave sterilization and with fatigue over time.

Changes in force properties by means of sterilization alone is important to note if using this device for the eruption of impacted teeth through a closed flap. It is best clinical practice to use sterile materials that traverse soft tissue to decrease bacterial load and risk of infection. Most orthodontic wires and springs come in isolated bags that are not subjected to sterilization. For maximum patient protection, it is best to sterilize prior to use.

According to the present study, there is no statistical difference between sterilized and non-sterilized IES when looking at sterilization alone. This coincides with the findings of Pernier and Mayhew who both found that sterilization has no effects on the properties of NiTi.[18, 19] However, the treatment of sterilization when combined with time does have a significant effect on the force properties of the IES.

Figure 5 illustrates a decrease in force from initial to final measurements over the course of five months. When focusing on a specific extension, such as 5mm, a drop in force for both sterilized and non-sterilized groups is observed. More specifically, a force reduction of approximately 40g and 25g for the sterilized and non-sterilized groups respectively was observed between initial and final months.

Though sterilization alone does not alter the springs' force properties, it does have a statistically significant effect when combined with the factor of time. Figure 6 illustrates the percentage of force degradation from initial to final time points. Once more, at the 5mm extension point, the sterilized group is at 73% of its original force after five months of use while the non-sterilized group is only at 50% of its original force.

In addition, the temperature affects are clearly seen with the force increase produced by the sterilized group. See Figure 7. During months 0-3, there is a consistent decline in force. This is absent in the non-sterilized group. We hypothesize that the NiTi in the non-sterilized group is still able to go through phase changes, producing a more constant force. On the other hand, the sterilized group stays in the austenite phase for several months. After month 4, the sterilized group behaves just like the non-sterilized group, which leads us to believe that the changes seen from the sterilization process are no longer present. It is apparent that time itself plays a significant roll in force degradation as well as collectively with sterilization treatment. This poses the question: What is the significance of this degradation in force?

When we look at the initial and final forces of the IES at the 5mm extension in Table 1, they range from 72-33(g). For non-sterilized, they range from 59-35(g). Proffit determined optimal forces for extrusion to be 35-60 grams.[15] A study by Wu determined the optimal force for extrusive tooth movement is a very specific 38-40 grams.[23] If we add in standard deviations, the springs at month five are at or below the low-end of the force range for extrusion. Thus, replacement or re-activation may we warranted.

Of clinical interest, we found that the IES' initial forces were higher than the non-sterilized springs. There are numerous studies that show similar results. A study by Potnis collected NiTi wires from patients after using them for specified time periods. These wires were either cold sterilized or autoclaved and subjected to mechanical testing procedures. He found that the autoclaved recycled wires became stiffer when compared to controls and cold sterilization.[24] This coincides with Danaei who found that autoclave sterilization can increase the force levels of NiTi closed-coil springs.[25] Research by Miura found sterilization in temperatures higher than 60^{o}C can create changes in the crystalline structure of NiTi and subsequently lead to changes in their mechanical properties.[9] We are unclear on the actual cause but hypothesize that the high heat of sterilization caused a change in phase transformation properties. More research is needed for a definitive answer.

Limitations

In this study, the springs were immersed in water during incubation. A more accurate simulation of the oral environment would have been achieved using artificial saliva.

During force measurement, it was noted that the number of coils wrapped around the attachment on the bracket reduced throughout the study. It's likely that throughout testing, unraveling at the attachment site occurred during the process of stretching when measuring the IES' forces. This could have impacted the measured forces, though it may have no clinical significance.

In this study, the specimens were not pre-stressed, which could have eliminated experimental error from mechanical play in the jigs and attachments.

Finally, force measurments were taken at loading, not unloading. Since springs exert their force during the unloading phase, it may have been more clinically accurate to measure forces during this stage.

Conclusions

From the present study, we can conclude:

- Autoclave sterilization does have a clinically significant effect on the force levels of the Isoglide eruption spring.
- The force levels of the Isoglide eruption spring degrade with time, which could impact tooth movement at extensions ≥ 5mm. Replacement or re-activation may be warranted after four months to achieve optimal extrusive force.
- A decrease in force levels is also seen when time and treatment are combined. However, it is likely that time has the greatest influence when the two elements interact.

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Figure 1a,b. Isoglide Eruption Spring

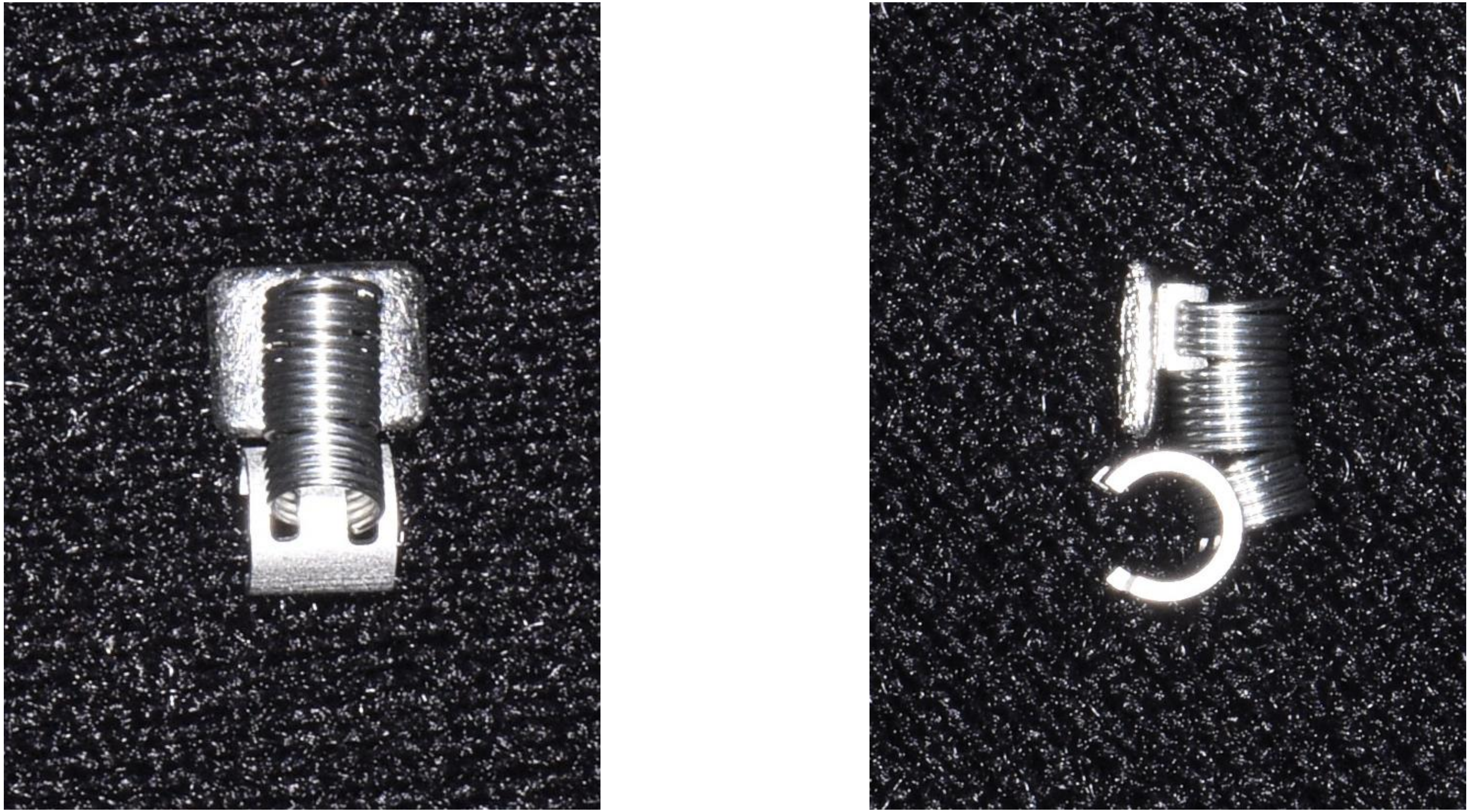
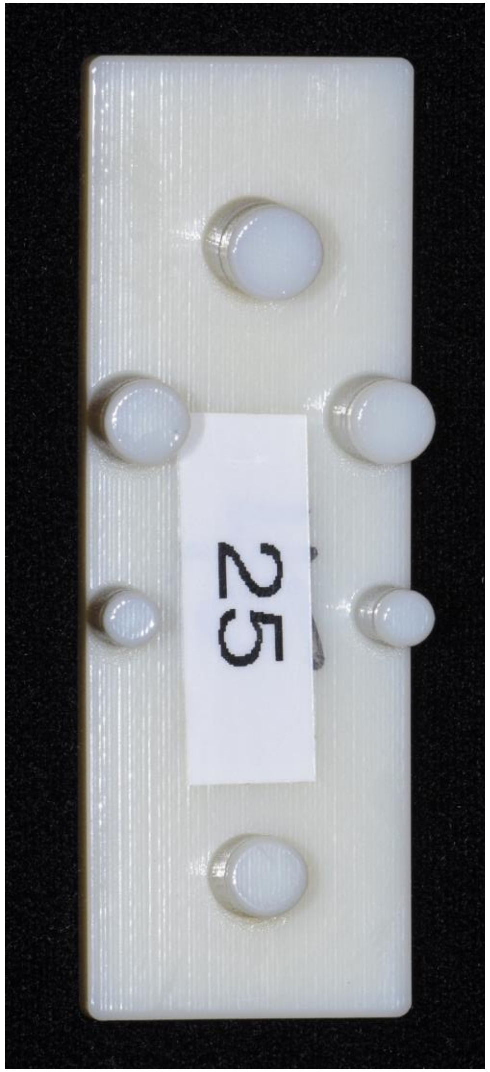


Figure 2a. Jig-Isoglide Eruption Spring Complex
Figure 2b. Platform with Pegs Set for 10mm Stretch
Figure 2c. Jig-Isoglide Eruption Spring Complex on platform stretched to 10mm



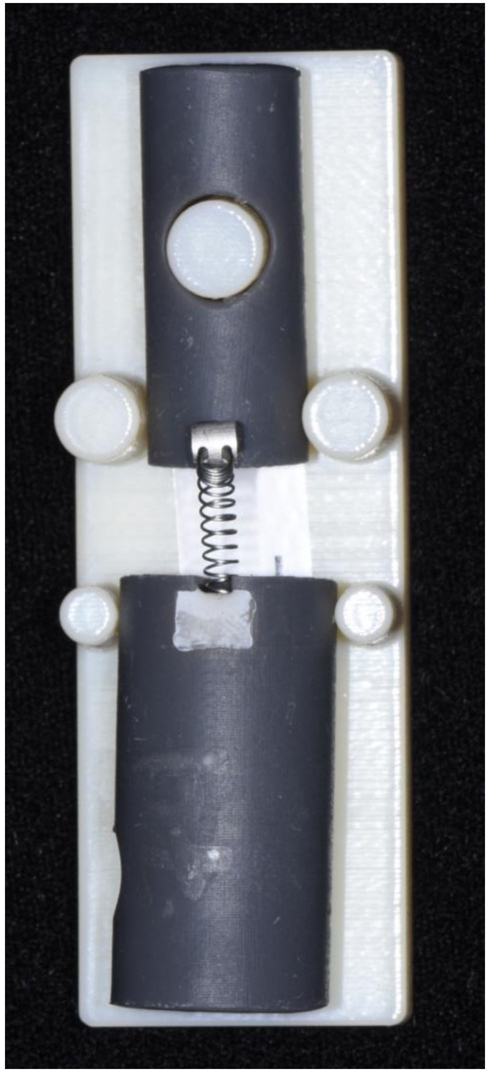
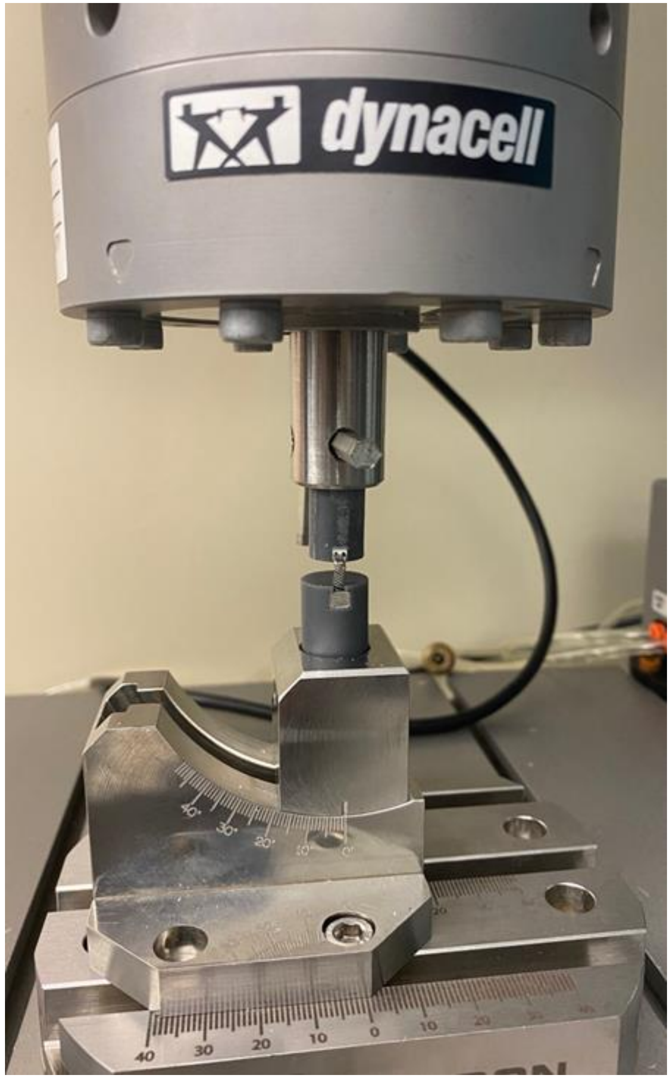


Figure 3a. Universal Testing Machine with mounted Jig-Isoglide Eruption Spring Complex
Figure 3b. Universal Testing Machine with mounted Jig-Isoglide Eruption Spring Complex during force measurement



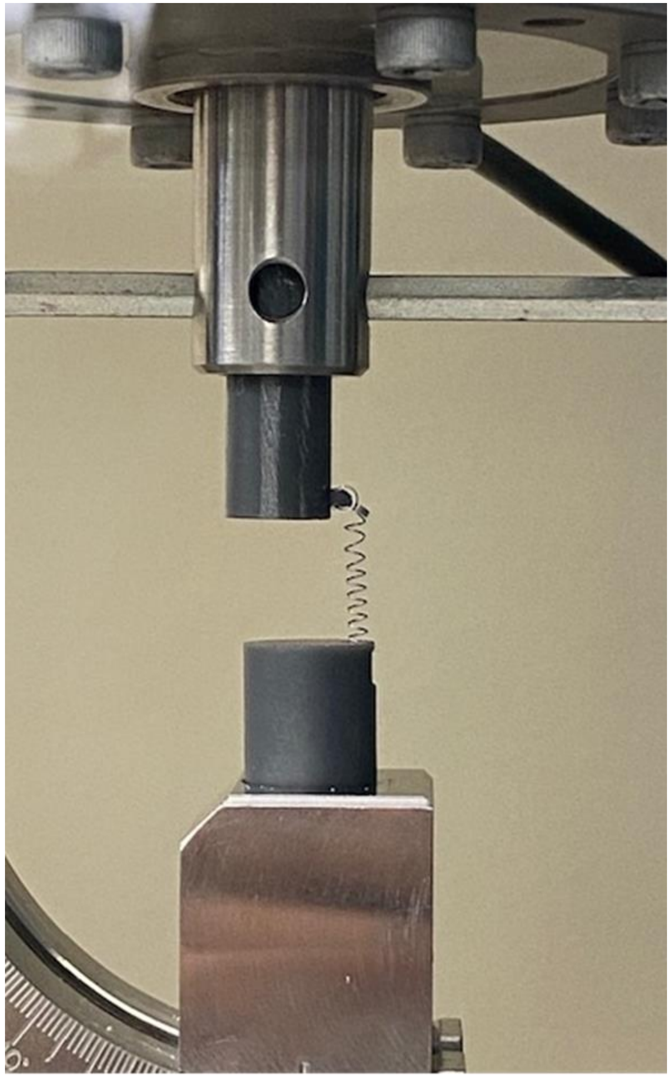
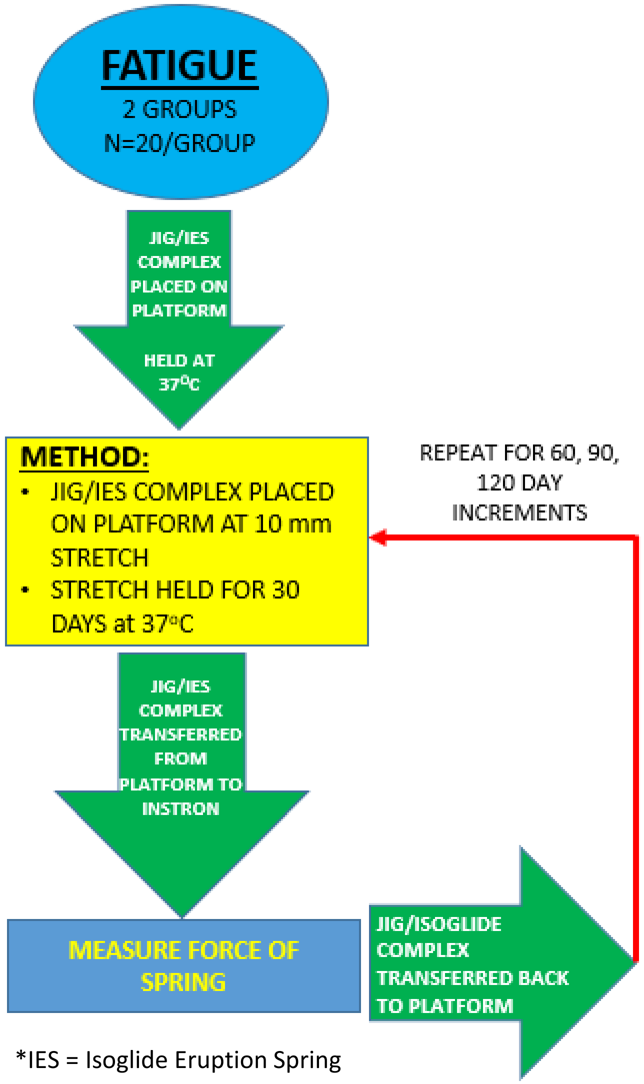


Figure 4. Process of Testing Force of Sterilized and Non-Sterilized Springs With Fatigue Holds Over Five Months



*IES = Isoglide Eruption Spring

Table 1. Mean Forces (g) and Standard Deviations of Sterilized and Non-Sterilized Springs at Specific Extension Points Over Five Months of Treatment

	Sterilized (mean & SD)												Non-Sterilized (mean & SD)											
	Month												Month											
mm	0		1		2		3		4		5		0		1		2		3		4		5	
1	25	9	30	18	15	12	13	12	23	21	5	6	22	6	22	10	13	14	8	11	14	13	7	7
2	40	4	40	10	29	12	18	13	28	21	12	6	31	2	33	14	25	16	20	11	21	15	14	8
3	51	10	50	10	35	12	26	13	36	21	19	6	40	4	41	17	33	13	28	10	29	12	21	10
4	61	9	63	12	43	11	36	13	43	21	27	7	49	7	53	16	39	12	34	11	38	13	28	11
5	72	11	65	12	51	11	43	11	51	22	33	7	59	8	61	16	48	14	46	8	45	13	35	12
6	78	6	76	12	60	13	49	11	57	23	42	7	63	9	61	20	56	17	54	8	53	15	42	14
7	83	4	81	17	64	18	60	12	65	24	49	8	71	9	71	18	65	18	59	8	60	15	49	15
8	92	5	89	14	75	13	65	14	71	25	57	8	75	8	75	18	71	17	68	11	68	17	56	17
9	98	3	91	12	81	12	72	11	75	25	62	8	80	10	78	22	77	18	72	9	72	17	60	17
10	102	7	95	15	85	17	74	16	81	25	67	9	82	8	79	20	81	14	81	11	77	16	65	18

Figure 5. Initial vs Final Force for Sterilized and Non-Sterilized Springs

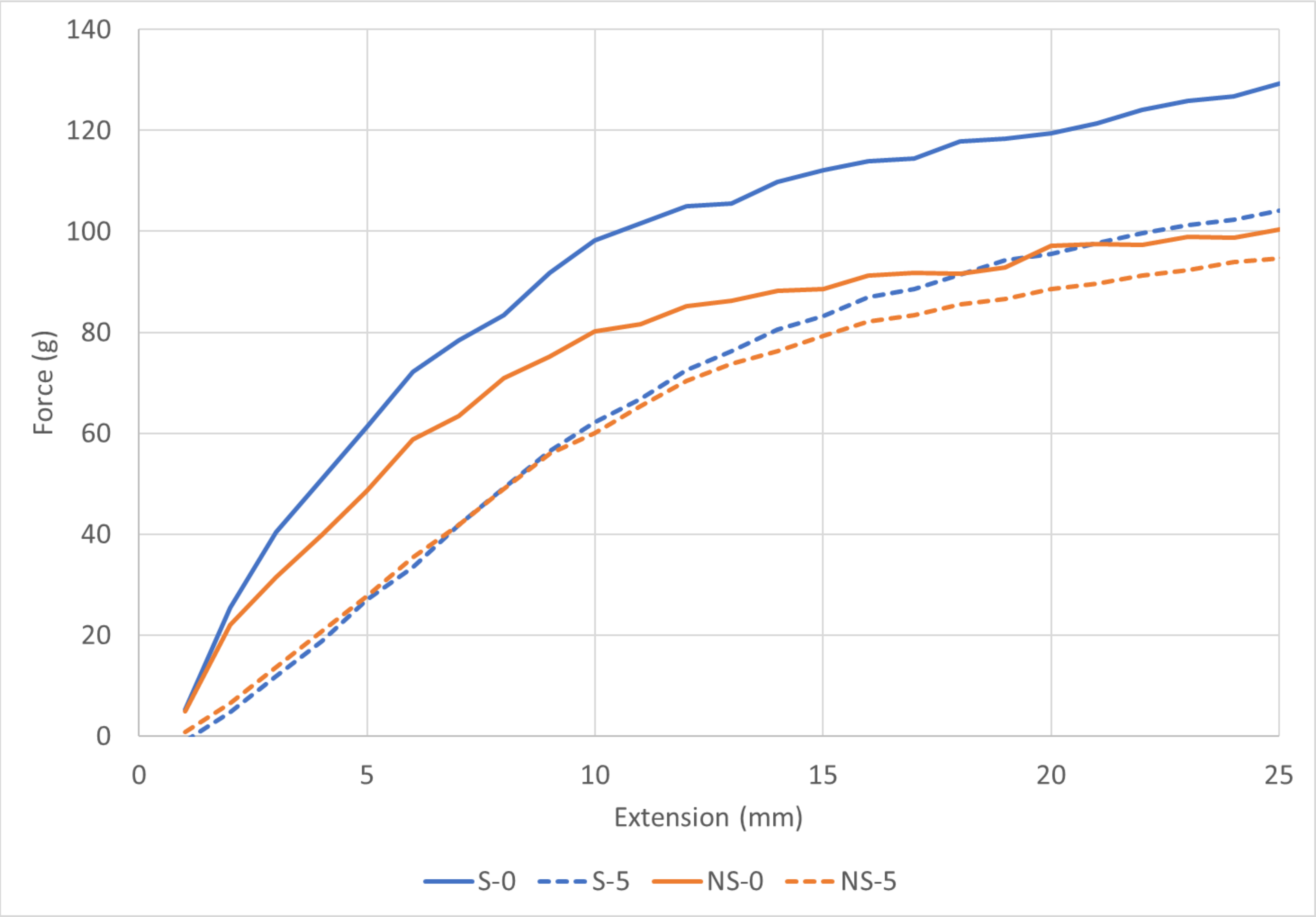


Figure 6. Percentage of Force Degradation for Sterilized and Non-Sterilized Springs Over Five Months of Treatment

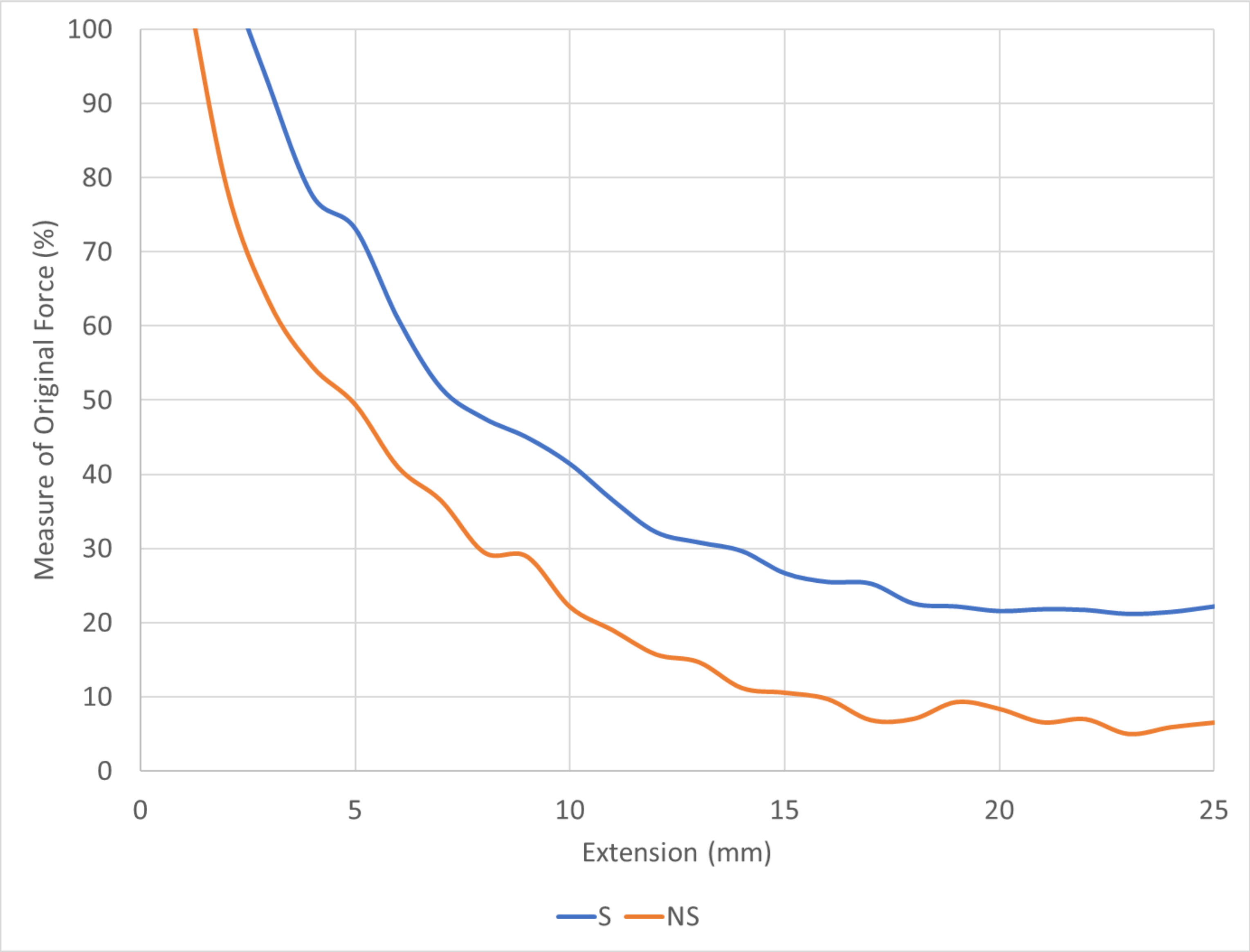


Figure 7. Least Squares Means Plot of Sterilized and Non-Sterilized Springs Over Five Months of Treatment