Comparison of Niti and TiNbTaZr Archwires During Initial Orthodontic Alignment

THESIS

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By

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Abstract

Title: Comparison of NiTi and TiNbTaZr archwires during initial orthodontic alignment

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Introduction: The purpose of this prospective, double-blind, randomized clinical trial was to compare the clinical efficiency of nickel-titanium and niobium-titanium-tantalum-zirconium (TiNbTaZr) archwires during initial orthodontic alignment.

Methods: All subjects (ages between 12 to 20 years old) underwent nonextraction treatment using .022 brackets. All patients were randomized into 2 groups for initial alignment with .016 NiTi archwires (n=14), or with .016 TiNbTaZr archwires (n=14). Digital scans were taken during the course of treatment; these scans were used to compare the improvement in Little’s Irregularity Index and the changes intercanine and intermolar widths.

Results: There was approximately a 27% reduction in crowding during the first month by the use of .016 TiNbTaZr (Gummetal) wire, and an additional 25% of decrease in
crowding was observed during the next month. There was no significant difference between the two treatment groups in the decrease in irregu

larity over time (P=0.29).

There was no significant difference between the two groups in the changes in intercanine and intermolar width (P=0.80).

**Conclusions:** It can be concluded that Gummetal wires and conventional NiTi wires possess a similar ability to align teeth, and Gummetal wires have additional advantages over conventional NiTi such as formability and use in nickel allergy patients.
Dedication

This document is dedicated to my family, especially my fiancée Kate for all her patience and support.
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CHAPTER 1

INTRODUCTION

Purpose

Since Nickel Titanium (NiTi) wires have a high elastic limit and high resilience with a low modulus of elasticity and low rigidity,\textsuperscript{1,2} NiTi wires are commonly used as the initial wire in orthodontic treatment. However, there are certain drawbacks to NiTi wires in certain situations. Some patients are allergic to nickel, and since one of the components of NiTi is nickel, these wires are not appropriate in patients who experience allergic reactions to nickel.\textsuperscript{3,4,5} NiTi wires are also preformed and are not shape formable. In a patient with a different initial arch form, the ideal size of a NiTi wire may not be available, and the use of an inappropriate size of the initial NiTi wire may cause canine and/or molar expansion or contraction. In patients where no archwire expansion is desired, or where it is not desired to level the curve of Spee, a shape-formable archwire is more appropriate. Additionally, NiTi does not hold bends well, meaning that detailing bends need to wait until stainless steel or TMA archwires are placed later in treatment. While detailing bends are typically not placed in the initial archwire, these bends can be useful from the start when ideal bracket placement is not possible due to partial eruption, rotations, crowding, or other factors.
When the situations described above occur, appropriate alternative archwires are needed. One such type of wire with the potential to address all of the above listed scenarios is a niobium based titanium archwire, with the chemical formula TiNbTaZr, the trade name Gummetal and manufactured by Rocky Mountain Morita Corporation in Japan. The wire is nickel-free, shape formable, and produces light-continuous forces. There have been several published lab studies testing the properties of niobium based archwires, and several animal studies testing the safety and allergenicity of titanium-niobium alloys. However, no randomized clinical trials comparing Gummetal to NiTi, as a favored initial wire, in human patients have been published.

The purpose of this study is to use digital models to compare the effectiveness of Gummetal wires to NiTi wires as the initial archwire in aligning teeth. Superimpositions of the digital models provide a visual representation of the changes that occur due to these archwires. The null hypothesis is that there is no significant difference in the performance of these two wires as measured by Little’s Irregularity Index and transverse width.
Literature Review

Description of properties of NiTi wires

In the process of orthodontic tooth movement, an archwire engages the bracket, generating a force. An ideal initial archwire would apply a light, continuous force. Light, continuous forces reduce undermining resorption and also reduce patient discomfort.\(^{20,21}\) A commonly used initial archwire is nickel-titanium (NiTi), which contains the properties of superelasticity and shape memory.\(^{22,23}\) When deformed and placed into orthodontic brackets, the wire exerts a light, continuous force as it reverts back to its original shape.\(^{20}\)

Desirable characteristics in orthodontic archwires are large springback, low stiffness, high formability, high stored energy, biocompatibility, low allergenicity, environmental stability, low surface friction, and the capability to be welded or soldered to attachments and auxiliaries.\(^1\) No single type of wire possesses all of these characteristics, and an appropriate wire can be selected based on the situation and the necessary compromises. Nickel-titanium archwires have good springback and low stiffness, but they have the disadvantage of not being shape-formable;\(^1\) this means that a custom archform cannot be created for each individual patient and patients are treated to a generic archform. Additionally, bends cannot be placed in a NiTi wire like they can with certain other types of wires. Placing bends in a wire allows the clinician to compensate for individual variation in tooth morphology that the prescription in the bracket does not account for, and it also allows the clinician to correct for errors in bracket placement.\(^{20}\)
Studies on NiTi

There have been numerous published laboratory and clinical studies comparing nickel-titanium wires to other types of wires. NiTi wires have been compared to braided stainless steel.²,²⁴,²⁵ Standard NiTi has been compared to variations of NiTi such as heat-activated NiTi, copper NiTi, and braided NiTi.²⁶,²⁷,²⁸,²⁹,³⁰ NiTi wires produced by different manufacturers have been compared against each other.²⁷,²⁹ NiTi wires have been tested in both round and rectangular cross-sections of varying dimensions.²⁹ However, there have been no in vivo studies comparing nickel titanium archwires to niobium titanium archwires.

In 2009 in “A Systematic Review Of Clinical Trials Of Aligning Archwires,”² Riley and Bearn identified seven in vivo clinical trials investigating aligning archwires. Of the seven studies, four were chosen for quality assessment, but a meta-analysis was not possible due to a lack of homogeneity in study design. Most of the studies failed to show a significant difference between the wires being tested. Only one of the four trials showed a statistically significant difference, but the clinical significance was questionable. A brief summary of the findings of the four trials included in the systematic review follows.

West et al²⁴ showed that NiTi was significantly quicker than braided stainless steel at aligning mandibular teeth, but the clinical significance was small. Evans et al²⁵ found no difference in performance between NiTi and braided stainless steel. O’Brien et al²⁶ found no significant difference in performance between Nitinol and Titanol. Cobb et
found no significant difference in performance among 0.016 NiTi (ion implanted), 0.016 NiTi, and 0.0175 multistranded stainless steel.

A summary of studies published after the systematic review follows.

Abdelrahman et al\textsuperscript{28} compared 0.014” superelastic NiTi, 0.014” thermoelastic NiTi, and 0.014” conventional NiTi and found no significant difference in performance among the wires.

Ong et al\textsuperscript{29} compared archwire sequences manufactured by three different manufacturers: (i) 3M Unitek, 0.014” Nitinol and then 0.017” x 0.017” heat activated NiTi; (ii) GAC international, 0.014” Sentalloy, 0.016” x 0.022” Bioforce; and (iii) Ormco corporation, 0.014” Damon Copper NiTi, 0.014” x 0.025” Damon Copper NiTi. The study found no significant difference in performance among the wires.

Sebastian et al\textsuperscript{30} compared 0.016” conventional superelastic NiTi to 0.016” coaxial superelastic NiTi in the lower anterior region over a period of 12 weeks. The study found that in a given amount of time, coaxial superelastic NiTi moves mandibular anterior teeth statistically significantly more than does traditional NiTi.

Although laboratory studies can often distinguish slight differences in wires, clinical studies have a more difficult time finding significant differences. The reason for this is that laboratory studies are more easily able to control for confounding variables, while no clinical trial can eliminate all confounding variables. There are certain limitations to clinical trials.
In clinical trials, no two patients present with the exact same malocclusion. To have a reasonable comparison, patients with similar levels of crowding should be selected.

Tooth movement is a biologic process, and besides identical twins, no two patients share the same DNA. Patients have different levels of bone density, different root lengths, different crown morphology, and different metabolic rates; all of these factors may play a role in the rate of tooth movement.

In clinical trials, a patient’s teeth cannot practically be measured daily; they are typically measured at each orthodontic appointment, and orthodontic appointments are often 4-6 weeks apart. If one wire produces the same amount of tooth movement in 2 weeks that another wire produces in 3 weeks, and then both wires produce no additional movement of teeth after this point, measuring the teeth at 4 week intervals will show no significant difference between the wires even though one wire produced its movement faster than the other wire. However, from an alternate perspective, if appointment intervals will be at 4 weeks no matter which type of wire is used, then there would be no practical advantage in a wire that achieves its results in two weeks versus a wire that achieves the same result in three weeks.

Compared to clinical studies, an advantage of laboratory studies is that they are better able to distinguish precise differences in the properties of wires. However, laboratory studies do not necessarily show whether the actual differences in wires lead to faster or improved orthodontic treatment in vivo.
Although clinical trials have certain limitations, they can also help answer questions that laboratory studies are unable to answer. In the case of this study, a clinical trial aims to answer the following question: given that patients have different biology, and given that no two malocclusions are exactly the same, and given that appointment intervals will be no more frequent than approximately every 4 weeks: on the whole does either wire produce better tooth alignment over the course of a typical 4-6 week appointment interval?

**Nickel allergy**

The most common contact allergy in the industrial world is to nickel, with a prevalence that some researchers have estimated at 30%. Other studies estimate a lower prevalence, with 11% prevalence in females and 2% prevalence in males.

Nickel sensitivity is a Type IV cell mediated delayed hypersensitivity called allergic contact dermatitis. With this condition, sensitization occurs when nickel enters the body for the first time, and there is usually no adverse response at the time of this first exposure. However, the immune system becomes primed for a future allergic response. A common cause of sensitization is jewelry that contains nickel, which could explain why nickel allergy is more prevalent in females than in males. The next time that the body encounters nickel, contact mucositis or dermatitis can occur, and this reaction can be triggered by nickel-containing orthodontic appliances.

Most individuals with nickel sensitivity or nickel allergy do not experience an allergic reaction to orthodontic appliances containing nickel, but some do. It is estimated
that 0.1% to 0.2% of orthodontic patients experience an adverse response to nickel in orthodontic appliances. The reason for decreased prevalence of allergic response to nickel in the oral environment when compared the skin is unknown.

Numerous orthodontic appliances and dental materials contain nickel, and some contain over 50% nickel by weight. There is wide variation in the release of nickel ions from orthodontic appliances into the oral cavity. Depending on the alloy, body fluid, temperature, mechanical stress, and pH, anywhere from 0.5 to 105.7 µg/l nickel can be released into the patient’s saliva.

As nickel-containing alloys remain in a patient’s mouth over time during the course of treatment, the concentration of nickel in saliva gradually increases. The nickel concentration in gingival crevicular fluid increases considerably after 1 month and 6 months of treatment with standard fixed orthodontic appliances.

As stated previously, many patients who have experienced cutaneous nickel allergy do not suffer from allergic reactions to nickel in contact with the oral mucosa. However, some patients with cutaneous nickel allergy do experience adverse effects to nickel in the oral environment. Reported adverse effects include inflammatory reactions, allergic reactions, cytotoxicity, and mutagenicity.

There have been case reports showing that a nickel-titanium archwire can trigger an allergic reaction in some patients with nickel allergy, leading to swelling of the patient’s lips. Because some patients experience an allergic reaction to NiTi, archwires made from nickel-free materials are desired in patients with nickel allergy.
Niobium

Rocky Mountain Morita Corporation is manufacturing a titanium based alloy which it reports to have high springback while still being highly formable. The wire is a nickel-free alloy of TiNbTaZr (titanium-niobium-tantalum-zirconium); it has the tradename Gummetal®. Gummetal® was first developed in 2003 in Japan at the Metallurgy Research Section of Toyota Central R&D Laboratories. Previous studies have shown that niobium based titanium wires have low stiffness and are shape-formable. In vitro studies also show that the wires generate lighter, more continuous forces than nickel-titanium, and that these wires can be a suitable replacement for NiTi. Additionally, Gummetal has a low coefficient of friction.

According to a study by Murakami et al., the composition of Gummetal by weight is 58.4% titanium, 35.7% niobium, 3.0% zirconium, 2.6% tantalum, 0.2% molybdenum, and 0.1% tin. As a comparison, the composition of TMA is 75.2% titanium, 14.1% molybdenum, 5.9% zirconium, and 4.8% tin. The composition of GAC Sentalloy NiTi according to its manufacturer is 54.5% nickel and 45% titanium.

According to Rocky Mountain Morita Corporation, Gummetal possesses high elastic deformation ability and a low Young’s Modulus, while also having good formability and sufficient stiffness. In a stress-strain curve, they claim that Gummetal has a non-linear elastic deformation behavior with force levels similar to NiTi, but without hysteresis. Gummetal is available in pre-formed archforms and also in straight wire form. It is available in both round and rectangular cross-sections of various diameters.
Dalstra et al compared 0.017 X 0.025” TiNb wires to 0.017 x 0.025” stainless steel wires (all wires produced by Sybron Dental Specialties Inc., Orange, CA) in a laboratory setting. They found that in bending, TiNb wires have a stiffness 48% lower than that of steel, and a springback 14% lower than that of steel. In torsion, the TiNb wires have a stiffness of 36% of that of steel, while the springback in torsion of TiNb is slightly higher than that of steel, meaning that TiNb wires can theoretically be used for third-order corrections. This article also demonstrated that it is possible to weld segments of TiNb together.7

In a study by Suzuki et al,8 the authors compared a titanium-niobium-aluminum alloy (TiNbAl) to NiTi. The study examined 0.012” round Ti-Nb-Al wires (73% titanium, 24% niobium, 3% aluminum) that were manufactured by Furukawa Techno Material Co Ltd (Kanagawa, Japan). The control wires in the study were 0.012” round NiTi wires manufactured by 3M United (Monrovia, California). In a laboratory study, the force magnitude during unloading was measured when the wire was deflected 2 mm. The authors found that TiNbAl produced a lower and more constant force magnitude than NiTi for the entire deflection range. The initial force magnitude of TiNbAl was half the initial force magnitude of NiTi. Therefore, the TiNbAl wire produced a lighter force than the NiTi wire. In an animal study, the authors also tested the two types of wires in rats over a 17 day period, measuring the amount of tooth movement that these wire produced. They found that there were no significant differences between TiNbAl and NiTi in terms of the amount of tooth movement achieved.
In terms of safety, TiNbTaZr is highly resistant to corrosion and has excellent biocompatibility.\textsuperscript{9,10,11,12,13,14,15,16} Titanium, niobium, tantalum, and zirconium are non-toxic individually and also in the form of TiNbTaZr.\textsuperscript{11,14,15,16} Niobium, tantalum, and zirconium are known as harmless titanium-alloying elements.\textsuperscript{11} The Gummetal® wire has been cleared for marketing by the FDA under regulation number 872.5410, and in this study it was used in accordance with its approved labeling. Because niobium is nickel-free, it can be used in patients with nickel allergy or sensitivity.

**Little’s irregularity index**

Little described his Irregularity Index in 1975.\textsuperscript{42} In this measurement system, the linear displacement of the anatomic contact points is measured from the mesial of the left mandibular canine to the mesial of the right mandibular canine. The measurements are performed in millimeters. In total, five measurements are made and then added together. Perfect alignment would have a score of zero; the greater the irregularity or malalignment, the greater the score. An advantage of this measurement system over some others is that it is not necessary to compare the position of teeth to a subjectively determined ideal arch form. In a measurement system that requires determining an ideal arch form, there is decreased reliability in the system because different raters will create different ideal arch forms. The Irregularity Index represents the total distance that anatomic contact points would need to be moved in order to achieve ideal alignment. Little’s Irregularity Index is not an arch length assessment; rather, it is a way to quantify irregularity.
The irregularity index is not the same as measuring crowding or arch length deficiency. In cases where a tooth is severely displaced labiolingually with no arch length shortage, there will be a high irregularity index. The index does not measure arch length deficiency; it measures the total distance that the contact points need to move in order to be in alignment. Experiments have found Little’s Irregularity Index to be both reliable and valid.\textsuperscript{42}

Although Little described the Irregularity Index as a way to measure mandibular anterior irregularity, in this study, the same methods are used to describe irregularity not just from canine to canine, but also from first molar to first molar. In this study, the Irregularity Index is applied not just to the mandibular arch, but also to the maxillary arch.

So that a meta-analysis can be possible in the future, one of the recommendations from Riley and Bearn’s systematic review was that future clinical trials would use a valid and reproducible measurement system such as Little’s Irregularity Index to measure alignment.\textsuperscript{2}

**Transverse width**

Orthodontic treatment has the potential to alter a patient’s dental archform. To achieve treatment stability, many orthodontists believe that the mandibular arch form should not be altered during treatment because it represents a state of functional balance for the patient.\textsuperscript{43} In a survey of the opinions of orthodontists, a majority of clinicians felt that the preservation of the pre-treatment arch form was important.\textsuperscript{44} Numerous
published papers have supported the concept that to improve stability, the mandibular intercanine width should not be changed during orthodontic treatment.\textsuperscript{45,46,47,48} Additionally, numerous clinical studies on postretention results confirm this theory.\textsuperscript{49,50,51} Therefore, for improved posttreatment stability, the intercanine and intermolar widths should not be expanded.

In order to avoid dental expansion during orthodontic treatment, the shape and width of the wire must be coordinated with the patient’s archform. Because stock archwires will not precisely match the archform of many patients, it is necessary for the orthodontist to customize the shape of the wire. However, while the width and shape of stainless steel and TMA wires can be customized, the width and shape of NiTi wires cannot be customized by the clinician.\textsuperscript{1,22,23}

**Elastomeric ties**

Another factor to consider in the performance of an archwire is its method of ligation. Archwires can be ligated to brackets using steel ties, elastomeric ties, or self-ligating brackets. Variations in the method of ligation could potentially lead to differences in performance of the wire. A very tight ligation will allow the prescription in the bracket to more fully express itself, while a looser ligation will more easily allow the wire to slide through the bracket as the teeth begin to move.

Additionally, elastomeric ties produced by one manufacturer may produce different force levels and lead to different results when compared to elastomeric ties produced by another manufacturer. O-ties of different colors produced by the same
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manufacturer may produce different force levels. In an examination of elastomeric ties manufactured by GAC, it has been shown that different color elastomeric ties made by this manufacturer produce similar force delivery and force decay.

Accuracy of digital models

There have been numerous studies demonstrating the accuracy of digital impressions, indicating that both intraoral scanning and extra-oral scanning are appropriate and acceptable for clinical use. In an examination of laser-scanned plaster models, it was found that laser scanned models are highly accurate, and that they can be used as an alternative to plaster models. In a systematic review of studies on digital impressions, the review found that digital models are a valid alternative to plaster models.

There are several intra-oral and extra-oral scanners currently made by different manufacturers. In a study comparing digital scanners, Hayashi et al found that the Trios 3Shape scanner is reliable and highly accurate. In a separate study, Flügge et al found that the Trios scanner has greater precision than iTero. Based on these studies, we can conclude that the Trios scanner is an acceptable method of recording a patient’s dentition.

Accuracy of measurements taken on digital models

Once a patient’s dentition has been captured in a digital scan, it is important to consider whether measurements made using computer software on the digital models are as accurate as measurements made by hand on plaster models. In a comparison of these
two methods, Sousa et al took twenty dental casts and digitized them using a Trios 3Shape scanner. They made eleven linear measurements on each cast, including arch length and width. They found that there were no statistically significant differences between the measurements made on the plaster models compared to the measurements made on the digital models, and they concluded that linear measurements on digital models are accurate and that measurements of arch width and length on digital models are reliable.\(^{58}\)

In an experiment where ten dry human skulls were digitally scanned and then measured, Cuperus et al found that digital models made with an intraoral scanner were a valid and reproducible method for measuring distances in a dentition.\(^{59}\)

In a study comparing digital intraoral scans to plaster models, Wiranto et al found that intraoral scanning was a valid, reliable, and reproducible method to obtain dental measurements for diagnostic purposes.\(^{60}\)

In another study comparing digital impressions to plaster models, Dalstra et al found that virtual measurements made on digital models are less variable than measurements performed with a caliper on plaster models. They found that measuring distances on plaster models leads to greater intra- and inter-observer variability than measuring the same distances on digital models using measuring tools within the software program.\(^{61}\)

In a study where 50 pre-treatment plaster models were digitally scanned, Goonewardene et al measured Little’s irregularity index on both the plaster models and
on the digital models. They found that measuring the irregularity index on digital models was reliable when compared to measuring it on plaster models.\textsuperscript{62}

**Accuracy of superimposition**

A potential advantage of digital models over plaster models is that digital models can be superimposed on top of each other to visually demonstrate any differences between the two sets of models. This is not possible with plaster models. In a study in which pre-treatment and post-treatment plaster models were digitized, Thiruvenkatakchari et al found that superimpositions are a valid way to visualize differences between two sets of models, and that stable reference points such as palatal rugae should be used as the basis of the superimposition.\textsuperscript{63}
CHAPTER 2

METHODS

Study type

This experiment is a randomized, double-blind prospective clinical trial involving patients undergoing orthodontic treatment.

In this study, 0.016” round NiTi wires were used in half of the patients for the initial wires, and 0.016” round TiNbTaZr wires were used in the other half of the patients for the initial wires. A 0.022” slot orthodontic appliance was used on all patients.

Inclusion criteria

Subjects had Little’s Irregularity Index greater than 2mm, and were all treated without any extractions. All subjects were between the ages of 12 and 20 inclusive, and could be of any gender or ethnicity. Older adult patients were excluded due to potential differences in bone density and potentially slower tooth movement. Subjects could be of any skeletal pattern (Class I, II, III). All permanent teeth were required to have been fully erupted from first molar to first molar. There must have been no history of trauma involving periodontal structures. The subjects must have had no history of bisphosphonate use. The subjects were required to have no known allergy to nickel or to
any other metal. There must have been no root abnormalities visible on the patient’s panoramic radiograph such as developmentally short roots, resorption, or dilacerations. There must have been no periodontal disease as determined by radiographs and also by having no pocket depths greater than 3 millimeters. No additional active or passive appliances such as a quad helix, RPE, TPA, or lower lingual holding arch were used on these patients. Both maxillary and mandibular arches were studied.

**Sample size calculation/power analysis**

Based on a previous study comparing 0.016” NiTi to coaxial 0.016” NiTi, a standard deviation of .6 could be expected. With alpha risk of .05 and power of .80, to distinguish a 1.0 mm difference in tooth movement would require a sample size of 28 subjects (14 in each group). A difference of 1.0 mm in tooth movement was chosen because any differences of less than 1.0 mm cannot be considered clinically significant.

**IRB approval**

The study protocol was reviewed and approved by The Ohio State University Institutional Review Board.

**Recruitment of subjects**

Subjects were recruited from The Ohio State University Orthodontic Clinic for this study and were provided informed consent. Participation in this study was
completely optional. Subjects were offered a $20 gift card if they chose to be a part of the study. Subjects were treated by residents under faculty supervision.

**Randomization**

Subjects were assigned into either the control (NiTi) or the experimental (Gummetal) treatment groups using simple randomization according to a computer generated randomization list.

**Blinding**

The operator and patient were both blinded as to the type of archwire being used.

**Measurements**

After the digital scans were performed on the patients, two raters measured Little’s Irregularity Index and also measured the transverse widths of the digital models; the raters were blinded as to which wire was used in each patient. Each rater performed each measurement twice in order to calculate reliability. One rater is a dentist and the other rater is a non-dentist.

**Placement of wires**

Once the patients were recruited and ready to begin orthodontic treatment, .022 slot orthodontic brackets were bonded, and the initial orthodontic archwire was either .016 NiTi (GAC Sentalloy, DENTSPLY GAC, Islandia, NY) or .016 TiNbTaZr.
(Gummetal, Rocky Mountain Morita, Japan). A photograph of the two types of wires can be seen in Figure 1. Before giving the wires to the operators, the gummetal wires were contoured to the original archform based on pre-treatment study models. For the NiTi group, because the archforms cannot be modified, the operators were given stock Sentalloy wires.

If the patient’s bite was deep, posterior bite turbos were placed to prevent bracket interferences. The archwires were ligated as fully as possible into the bracket using elastomeric modules manufactured by GAC. Steel ties were not used due to potential differences in how tight or how loose the steel ties would be engaged. Self-ligating brackets were not used. Any color elastomeric module could be used, and all elastomeric modules were manufactured by GAC, as different color o-ties from this manufacturer have been shown to produce similar force delivery and force decay. O-ties produced by some manufacturers can produce different force levels and different results. Both the maxillary and mandibular arches were studied and compared.

**Frequency of scan, method of scan**

A digital scan was obtained on each patient before bonding the brackets. Then, every 4-6 weeks for an additional 2 appointments, another digital scan was obtained to measure tooth movement. The scanner used in this study was manufactured by Trios, and the software used to make the measurements was 3Shape OrthoAnalyzer (TRIOS; 3Shape, Copenhagen, Denmark).
Once brackets were bonded, the same archwire (.016 NiTi in half the patients, and .016 Gummetal in the other half) was religated for 2 subsequent appointments at 4-6 week intervals. During this time period, the archwire was religated with no modifications to the wire, to the brackets, or to the teeth (no interproximal reduction).

If brackets debonded at any point in treatment, the brackets were rebonded at the next appointment, the patient was recorded as having a debond, and the patient data would continue to be recorded. If there were approximately equal numbers of debonds in both treatment groups, then the data from the patients with broken brackets was analyzed in the final results, both separately and combined with the patients with no debonds. If there were significantly more debonds in one group than the other, then the patients with broken brackets were excluded from the study and more patients would be recruited. However, no patients in the study experienced broken brackets, so this was not a factor.

As this is a study of initial orthodontic alignment, after the 2-3 month duration of the study, subsequent phases of treatment continued with whichever materials and techniques the clinician felt appropriate; these steps were not a part of this study. After the first three months of treatment, the patient’s participation in the study was considered complete and comprehensive orthodontics was performed to completion on all patients with standard archwires. For most patients, typical treatment time with braces is 18-24 months, so this study was only using experimental wires for the initial portion of treatment, and standard archwires and approaches were used for the remainder and the majority of the treatment.
Superimposition

After the digital models were captured, superimpositions of the digital models provided a visual representation of the improvement in alignment that occurred during the study. To perform the superimpositions, the initial and final study models were selected in the OrthoAnalyzer software program. Three stable reference points were selected in each arch. For the stable reference points, palatal rugae and other distinctive anatomic features were marked on each digital model. Because the mandibular arch does not have palatal rugae, finding appropriate stable reference points was more difficult for the mandibular arch than for the maxillary arch. For the mandibular arch, the stable reference points included distinctive indentations in the gingiva and non-bonded second molars. The software then coordinated the reference points from the pre-treatment model with the reference points from the post-treatment model, allowing for an overlay of the two images based on the stable reference points. In the superimposed images, structures which underwent no change appeared as a single image, while structures which moved appeared as a double image. The double image showed the extent to which the teeth moved during treatment.

Superimpositions of pre-treatment and post-treatment digital models are presented in Figures 2 and 3.

Risks to patients

Risks to the patients who chose to participate in this study included: slightly longer appointments during the first three months of treatment due to the need to take
digital scans that are not typically part of the appointment; potentially slightly longer total treatment time if the experimental archwire performance was inferior to the control archwire. However, it was also possible for patients to experience slightly faster total treatment time with the Gummetal wire depending on the performance of the wire. Because this study tracked each patient for no more than three months, and the typical duration of orthodontic treatment is over 18 months, the overall increase or decrease in total treatment time was expected to be negligible. The end result of treatment would be the same regardless if the patients were in the NiTi group, the Gummetal group, or if patients declined to participate in the study. There were no expected health risks to the subjects participating in the study. There was no radiation exposure from the digital scans. There was no expected increased risk of root resorption because the force levels produced by the wires are similar. There was decreased risk of allergic hypersensitivity to the Gummetal wire because it was nickel-free.

Measurement of data

3Shape OrthoAnalyzer was used to measure crowding and transverse expansion. Decreases in crowding were measured in millimeters using Little’s irregularity index. Intermolar and intercanine widths were measured. Canine measurements were made from cusp tip to cusp tip, and molar measurements were made from central fossa to central fossa. An example of these measurements can be seen in Figures 4 and 5. The dependent variables were the change in Little’s irregularity index, the change in intermolar width, and the change in intercanine width.
To make these measurements, two research assistants were recruited. These research assistants were trained to use the OrthoAnalyzer software, and were blinded to the type of archwire used in each patient. Both research assistants measured every subject at every time point, and repeated the measurements so that both intra-rater reliability and inter-rater reliability could be calculated. The repeated measurements occurred at least 2 weeks apart. In total, there were 4 measurements for each time point for each patient.

Data from each dependent variable was analyzed using a repeated-measures analysis of variance with wire type, jaw, tooth, and evaluation period as the independent variables. Post hoc testing was done using the Tukey-Kramer procedure.
CHAPTER 3

MANUSCRIPT

Comparison of changes in irregularity and transverse width with NiTi and TiNbTaZr archwires during initial orthodontic alignment in adolescents: a double blind randomized clinical trial

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ABSTRACT

Introduction: The purpose of this prospective, double-blind, randomized clinical trial was to compare the clinical efficiency of nickel-titanium and niobium-titanium-tantalum-zirconium (TiNbTaZr) archwires during initial orthodontic alignment.

Methods: All subjects (ages between 12 to 20 years old) underwent nonextraction treatment using .022 brackets. All patients were randomized into 2 groups for initial alignment with .016 NiTi archwires (n=14), or with .016 TiNbTaZr archwires (n=14). Digital scans were taken during the course of treatment; these scans were used to compare the improvement in Little’s Irregularity Index and the changes intercanine and intermolar widths.

Results: There was approximately a 27% reduction in crowding during the first month by the use of .016 TiNbTaZr (Gummetal) wire, and an additional 25% of decrease in crowding was observed during the next month. There was no significant difference between the two treatment groups in the decrease in irregularity over time (P=0.29).
There was no significant difference between the two groups in the changes in intercanine and intermolar width (P=0.80).

**Conclusions:** It can be concluded that Gummetal wires and conventional NiTi wires possess a similar ability to align teeth, and Gummetal wires have additional advantages over conventional NiTi such as formability and use in nickel allergy patients.

**INTRODUCTION**

Since Nickel Titanium (NiTi) wires have a high elastic limit and high resilience with a low modulus of elasticity and low rigidity,\(^1,2\) NiTi wires are commonly used as the initial wire in orthodontic treatment. However, there are certain drawbacks to NiTi wires in certain situations.

Some patients are allergic to nickel, and since one of the components of NiTi is nickel, these wires are not appropriate in patients who experience allergic reactions to nickel.\(^3,4,5\) NiTi wires are also preformed and are not shape formable. In a patient with a different initial arch form, the ideal size of a NiTi wire may not be available, and the use of an inappropriate size of the initial NiTi wire may cause canine and/or molar expansion. In patients where no archwire expansion is desired, or where it is not desired to level the curve of Spee, a shape-formable archwire is more appropriate. Additionally, NiTi does not hold bends well, meaning that detailing bends need to wait until stainless steel or TMA archwires are placed later in treatment. While detailing bends are typically not
placed in the initial archwire, these bends can be useful from the start when ideal bracket placement is not possible due to partial eruption, rotations, crowding, or other factors.

When the situations described above occur, appropriate alternative archwires are needed. One such type of wire with the potential to address all of the above listed scenarios is a niobium based titanium archwire, with the chemical formula TiNbTaZr, the trade name Gummetal and manufactured by Rocky Mountain Morita Corporation. The wire is nickel-free, shape formable, and produces light-continuous forces. There have been several published lab studies testing the properties of niobium based archwires, and several animal studies testing the safety and allergenicity of titanium-niobium alloys. However, no randomized clinical trials comparing Gummetal to NiTi in human patients have been published.

In 2009 in “A Systematic Review Of Clinical Trials Of Aligning Archwires,” Riley and Bearn identified seven in vivo clinical trials investigating aligning archwires. Of the seven studies, four were chosen for quality assessment, but a meta-analysis was not possible due to a lack of homogeneity in study design. Most of the studies failed to show a significant difference between the wires being tested. Only one of the four trials showed a statistically significant difference, but the clinical significance was questionable. So that a meta-analysis can be possible in the future, one of the recommendations from the systematic review was that future clinical trials use a valid and reproducible measurement system such as Little’s Irregularity Index to measure the alignment.

Specific objectives
The purpose of this study is to use digital models to compare the effectiveness of Gummetal wires to NiTi wires as the initial archwire in aligning teeth. Superimpositions of the digital models provide a visual representation of the changes that occur due to these archwires. The null hypothesis is that there is no significant difference in the performance of these two wires as measured by Little’s Irregularity Index and transverse width.

**MATERIALS AND METHODS**

**Trial design**

The study protocol was reviewed and approved by The Ohio State University Institutional Review Board.

This experiment was a randomized, double-blind prospective clinical trial involving patients undergoing orthodontic treatment. In this study, 0.016” round NiTi wires were used in half of the patients for the initial wires, and 0.016” round TiNbTaZr wires were used in the other half of the patients for the initial wires. A 0.022” slot orthodontic appliance was used on all patients.

**Participants, eligibility criteria, and setting**

Subjects had Little’s Irregularity Index greater than 2mm, and were all treated without any extractions. All subjects were between the ages of 12 and 20 inclusive, and could be of any gender or ethnicity. Older adult patients were excluded due to potential differences in bone density and potentially slower tooth movement. Subjects were of any skeletal pattern (Class I, II, III). All permanent teeth were required to have been
fully erupted from first molar to first molar. There was no history of trauma involving periodontal structures. The subjects must have had no history of bisphosphonate use. The subjects were required to have no known allergy to nickel or to any other metal. There were no root abnormalities visible on the patient’s panoramic radiograph such as developmentally short roots, resorption, or dilacerations. There was no periodontal disease as determined by radiographs and documentation of no pocket depths greater than 3 millimeters. No additional active or passive appliances such as a quad helix, RPE, TPA, or lower lingual holding arch were used on these patients. Both maxillary and mandibular arches were studied.

Subjects were recruited from The Ohio State University Orthodontic Clinic and informed consent was obtained. Participation in this study was completely optional. Subjects were offered a $20 gift card if they chose to be a part of the study. Subjects were treated by residents under faculty supervision.

**Interventions**

Once the patients were recruited and ready to begin orthodontic treatment, .022 slot orthodontic brackets were bonded, and the initial orthodontic archwire was either .016 NiTi (GAC Sentalloy, DENTSPLY GAC, Islandia, NY) or .016 TiNbTaZr (Gummetal, Rocky Mountain Morita, Japan). A photograph of the two types of wires can be seen in Figure 1. Before giving the wires to the operators, the Gummetal wires were contoured to the original archform based on pre-treatment study models. For the NiTi group, because the archforms cannot be modified, the operators were given stock Sentalloy wires.
A digital scan was obtained on each patient before bonding the brackets. Then, every 4-6 weeks for an additional 2 appointments, another digital scan was obtained to measure tooth movement. The scanner used in this study was manufactured by Trios, and the software used to make the measurements was 3Shape OrthoAnalyzer (TRIOS; 3Shape, Copenhagen, Denmark).

Once brackets were bonded, the same archwire (.016 NiTi in half the patients, and .016 Gummetal in the other half) was religated for 2 subsequent appointments at 4-6 week intervals. During this time period, the archwire was religated with no modifications to the wire, to the brackets, or to the teeth (no interproximal reduction).

**Outcomes**

After the digital scans were performed on the patients, two raters measured Little’s Irregularity Index and also measured the transverse widths of the digital models; the raters were blinded as to which wire was used in each patient. Each rater performed each measurement twice in order to calculate reliability. One rater was a dentist and the other rater was a non-dentist.

3Shape OrthoAnalyzer was used to measure crowding and transverse expansion. Decreases in crowding were measured in millimeters using Little’s irregularity index. Intermolar and intercanine widths were measured. Canine measurements were made from cusp tip to cusp tip, and molar measurements were made from central fossa to central fossa. An example of these measurements can be seen in Figures 4 and 5. The dependent variables were the change in Little’s irregularity index, the change in intermolar width, and the change in intercanine width.
To make these measurements, two research assistants were recruited. These research assistants were trained to use the OrthoAnalyzer software, and were blinded to the type of archwire used in each patient. Both research assistants measured every subject at every time point, and then measured every subject again so that both intra-rater reliability and inter-rater reliability could be calculated. The repeated measurements occurred at least 2 weeks apart. In total, there were 4 measurements for each time point for each patient.

After the digital scans were captured, superimpositions of the digital models provided a visual representation of the improvement in alignment that occurred during the study. To perform the superimpositions, the initial and final study models were selected in the OrthoAnalyzer software program. Three stable reference points were selected in each arch. For the stable reference points, palatal rugae and other distinctive anatomic features were marked on each digital model. Because the mandibular arch does not have palatal rugae, in the mandibular arch, the stable reference points included distinctive indentations in the gingiva and non-bonded second molars. The software then coordinated the reference points from the pre-treatment model with the reference points from the post-treatment model, allowing for an overlay of the two images based on the stable reference points. In the superimposed images, structures which underwent no change appeared as a single image, while structures which moved appeared as a double image. The double image showed the extent to which the teeth moved during treatment.

**Sample size calculation**
Based on a previous study comparing 0.016” NiTi to coaxial 0.016” NiTi, a standard deviation of .6 could be expected. With alpha risk of .05 and a standard deviation of 0.6 mm a sample size of 28 subjects (14 in each group) was required to demonstrate a difference of 1.0 mm in tooth movement. Any differences of less than 1.0 mm can be considered clinically insignificant.

**Randomization**

Subjects were assigned into either the control (NiTi) or the experimental (Gummetal) treatment groups using simple randomization according to a computer generated randomization list.

**Blinding**

The operator and patient were both blinded as to the type of archwire being used. To conceal the identity of the wire from both the patient and the operator, the wires were placed in an unmarked envelope before giving them to the operator. When comparing the two types of wire side by side, the Gummetal wire appears darker in color than the NiTi wire, meaning that it could be possible for an operator to discern the wire being used based on its appearance.

**Statistical analysis**

Both the Little’s Irregularity Index and transverse width dependent variables were analyzed using a repeated-measures, mixed-models analysis of variance ANOVA. The independent variables were jaw, tooth, assessment period, and wire type. Patient sex was a random variable.
RESULTS

Participant flow

134 potential subjects were assessed for eligibility; of these, 106 were excluded due to not meeting the inclusion criteria. Three eligible subjects declined to participate. In total, 28 subjects enrolled in the study. No subjects withdrew from the study. See Figure 6.

Baseline data

Sample demographics and characteristics are presented in Tables 1 and 2. There were no significant differences between the two groups in age, gender, race/ethnicity, and occlusal class (P > 0.05).

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Intra-rater reliability of the measurements is presented in Table 4. Reliability of the transverse measurements had intra-rater reliability ranging from 0.93 to 0.99. The reliability of the measurements of Little’s Irregularity Index had intra-rater reliability ranging from 0.56 to 0.86.

Because the measurements were determined to be reliable, to determine the difference in performance between the two types of wires, only the first set of measurements was used.

A summary of the changes in Little’s Irregularity Index and in transverse width is presented in Table 5. With both types of wires, Little’s Irregularity Index decreased over time in each jaw, both in the anterior region and for the full arch. With both wires, there
was minimal change in the transverse dimensions over time. Figures 7 and 8 provide a visual representation of the numerical changes.

For the Little index, ANOVA showed a significant effect for jaw, tooth, assessment period, tooth by period interaction, and the jaw by wire type interaction. For the transverse measure, the ANOVA revealed a significant effect for jaw, tooth, jaw by tooth interaction, tooth by wire type interaction. Table 6 presents this analysis of the Little’s Irregularity Index measurements.

Table 7 presents the ANOVA numbers for the transverse measurements.

Charts of the significant ANOVA interactions are presented in Figures 9 and 10.

Harms

There were no adverse reactions or harms reported by any subjects in the study.

DISCUSSION

Main findings

In this study, there were no statistically significant differences between the two treatment groups in terms of age, gender, race/ethnicity, or occlusal classification. See Tables 1 and 2.

Intra-rater reliability was good. See Table 4. The reliability of Little’s Index ranged from 0.56 to 0.86. These numbers can be qualitatively described as fair to good. The reliability of the transverse measurements ranged from 0.93 to 0.99 for intra-rater reliability. The likely reason that the transverse measurements demonstrated greater
reliability than the Little’s Index measurements is that the transverse measurements are a single measurement of a large distance, while Little’s Index involves measuring several small distances and adding these numbers together; Little’s Index is more prone to error.

ANOVA results indicated no significant differences in performance between the experimental archwire and the control archwire treatment groups in terms of Little’s irregularity index and in terms of archwire expansion, regardless of the jaw studied, and regardless of whether the measurements were made from canine to canine, or from molar to molar. See Tables 6 and 7.

This study found that both the control and the experimental wire reduced Little’s Irregularity Index in patients, and that there was no statistical difference between the two types of wires in its reduction. There was also no statistically significant difference in the transverse expansion caused by the two types of wires, despite the fact that the Gummetal wires were preformed to the pretreatment archform. In fact, changes in transverse width were very minimal for both treatment groups and there was no statistically significant canine or molar expansion in either treatment group. Therefore, it is proposed that initial flexible wires have minimal effect on changes to a patient’s archform, regardless of whether the wire is a close match to the patient’s actual archform.

When looking at the irregularity of the full arch for both treatment groups, irregularity decreased by 27% during the first 4-6 months of treatment, and then by another 25% during the next 4-6 months of treatment, and these differences were statistically significant. When looking at the irregularity of the anterior region only for both treatment groups, irregularity decreased by 31% during the first 4-6 months of...
treatment, and this amount was statistically significant. The decrease in anterior irregularity during the second 4-6 months of treatment was 24% but was not statistically significant, indicating a plateauing of results as the irregularity decreased.

Although the two types of wires showed no difference in performance, other factors were statistically significant. Little’s Index improved over time with both types of wires. There were differences in the initial irregularity between the mandible and the maxilla with the maxilla presenting with greater initial irregularity; however the difference in their change in irregularity over time was not significant. There were also differences in comparing the full arch to the anterior segment, indicating that the patients’ crowding was not confined to the anterior segments. In terms of transverse widths, there were differences in the maxilla versus the mandible, and there were differences between the molar width and the canine width.

**Limitations**

It should be noted that although the performance of the two wires was shown to be comparable, after removing the wires from the patients’ mouths at the end of the study, the Gummetal wires appeared to undergo more permanent distortion than did the NiTi wires. Because Gummetal wires are shape formable when bent at a sharp enough angle, they also have the ability to experience deformation when ligated into brackets on teeth that are severely displaced. In cases of severe crowding, it is possible that Gummetal would underperform NiTi due to Gummetal’s shape formable properties. A future study focusing exclusively on severe crowding could test this theory.
In an in vivo experiment, it is not possible to account for every possible difference among subjects because no two subjects present with the exact same malocclusion. Potential confounding factors include differences in bone density among subjects and differences in occlusal forces among subjects. The goal of this study was to compare how these two types of wires behave in a clinical setting. To determine precise differences between the two types of wires, a laboratory study would be appropriate. Additionally, a larger sample size in an in vivo study might reveal a minor difference in performance between the two types of wires that this study was not able to detect; any such difference is expected to be of minimal clinical significance. Also, a study focusing exclusively on patients with severe crowding may reveal a difference in performance between the two wires. A study of the same archwires over a longer duration of treatment would be unlikely to demonstrate differences between the treatment groups because there was a greater reduction in irregularity during the first month of treatment than during the second month; religating the same wires for additional months would lead to diminishing returns.

**Generalizability**

This study produced similar results to previous laboratory studies. In vitro studies showed that Gummetal has low stiffness, low Young’s modulus, and generates light forces,\(^7,41\) meaning that its clinical performance should be comparable to NiTi. Suzuki et al used niobium-titanium archwires and NiTi archwires to produce buccal tooth movement in rats, and they found no difference in terms of tooth movement between the two types of wires.\(^8\) Our study confirms these results in humans.
Previous laboratory studies have shown Gummetal to have a torsional stiffness sufficient to produce third-order corrections. Therefore, it is suggested that Gummetal wires could be used to generate torque in patients. A future clinical study comparing the performance of rectangular Gummetal to either stainless steel or TMA could confirm this finding.

CONCLUSIONS

Based on our findings, we conclude

1. Because Rocky Mountain Morita Gummetal TiNbTaZr and GAC Sentalloy NiTi lead to similar reductions in crowding in patients, Gummetal is appropriate as an initial archwire in orthodontic treatment.

2. Because Gummetal is nickel free, it is an ideal initial archwire in nickel-sensitive patients.

3. Because Gummetal is shape formable, it is an ideal initial archwire when the clinician wishes to customize the archform or to place bends in an initial archwire.

4. Neither Gummetal pre-formed to the pre-treatment archform nor stock GAC Sentalloy lead to significant canine or molar expansion during the first two to three months of treatment.
CHAPTER 4

RESULTS

134 potential subjects were assessed for eligibility; of these, 106 were excluded due to not meeting the inclusion criteria. Three eligible subjects declined to participate. In total, 28 subjects enrolled in the study. No subjects withdrew from the study. See Figure 6.

The basic sample demographics and characteristics are presented in Tables 1 and 2. The experimental group (Gummetal) had a mean age of $15.43 \pm 2.31$ years (average ± SD), while the control group (GAC Sentalloy NiTi) had a mean age of $16.50 \pm 3.27$ years. This difference was not statistically different ($P = 0.3173$, Table 1). The differences between the two groups in the following variables were not statistically different: gender, race/ethnicity, occlusal class ($P > 0.05$, Table 2).

Table 3 is a chart that lists the independent variables and dependent variables. The independent variables are the jaw, the teeth measured, the time period, and the wire type. The dependent variables are Little’s Irregularity Index and the transverse width.

Reliability of the measurements made by the two raters is presented in Table 4. Reliability of the transverse measurements demonstrates can be described as excellent, with intra-rater reliability ranging from 0.93 to 0.99 and inter-rater reliability ranging from 0.92 to 0.98. The reliability of the measurements of Little’s Irregularity Index can be described as fair to good, with intra-rater reliability ranging from 0.56 to 0.86, and inter-rater reliability ranging from 0.45 to 0.84.
Because the measurements were determined to be reliable, to determine the difference in performance between the two types of wires, only the first set of measurements made by the more experienced rater was used. The second set of measurements made by this rater was used solely to calculate intra-rater reliability, and the measurements made by the second rater were used solely to calculate inter-rater reliability.

A summary of the changes in Little’s Irregularity Index and in transverse width is presented in Table 5. With both types of wires, Little’s Irregularity Index decreased over time in each jaw, both in the anterior region and for the full arch. With both wires, there was minimal change in the transverse dimensions over time. Figures 7 and 8 provide a visual representation of the numerical changes.

A four-way repeated-measures analysis of variance (ANOVA) was performed to determine the significance of the independent variables and to determine any interactions among these variables. Table 6 presents this analysis of the Little’s Irregularity Index measurements. Of the four independent variables, three of these variables had a P-value of less than 0.05: jaw, tooth, time period, indicating that these variables play a statistically significant role in Little’s Irregularity Index. Wiretype had a P-value of 0.6938, indicating that the type of wire used in treatment did not have a statistically significant effect on Little’s Irregularity Index. In terms of interactions among the four independent variables, the interaction of tooth and period had a P-value of 0.0006, indicating that this interaction is significant. All other interactions were not significant.
However, it should be noted that the interaction of jaw – wiretype had a P-value of 0.0594, meaning that this interaction was close to demonstrating significance.

Table 7 presents the ANOVA numbers for the transverse measurements. Jaw and tooth were determined to be statistically significant by having P-values < 0.05, while time period and wiretype were not. In terms of interactions among the variables, jaw – tooth, jaw – wiretype, and tooth – wiretype were determined to be statistically significant (P < 0.05), while all other interactions were not statistically significant.

Charts of the significant ANOVA interactions are presented in Figures 9 and 10.
CHAPTER 5

DISCUSSION AND CONCLUSIONS

In this study, there were no statistically significant differences between the two treatment groups in terms of age, gender, race/ethnicity, or occlusal classification. See Tables 1 and 2. For all of these factors, the P-Value was greater than 0.05, meaning that demographics should not be the cause of any differences between the two treatment groups.

Both inter-rater and intra-rater reliability were good. See Table 4. The reliability of Little’s Index ranged from 0.56 to 0.86 for intra-rater reliability, and from 0.45 to 0.84 for inter-rater reliability. These numbers can be qualitatively described as fair to good, meaning that it is unlikely that measurement error by either of the two raters had a significant impact on the numbers obtained for Little’s Index for the two treatment groups. The reliability of the transverse measurements ranged from 0.93 to 0.99 for intra-rater reliability, and from 0.92 to 0.98 for inter-rater reliability. These numbers can be qualitatively described as excellent, meaning that it is highly unlikely that measurement error by either of the two raters had a significant impact on the numbers obtained for the transverse measurements. The likely reason that the transverse measurements demonstrated greater reliability than the Little’s Index measurements is that the transverse measurements are a single measurement of a large distance, while Little’s Index involves measuring several small distances and adding these numbers together; Little’s Index is more prone to error.
Repeated-measures ANOVA calculations showed that there were no statistically significant differences in performance between the experimental archwire and the control archwire treatment groups in terms of Little’s irregularity index and in terms of archwire expansion, regardless of the jaw studied, and regardless of whether the measurements were made from canine to canine, or from molar to molar. See Tables 6 and 7.

The methodology of this study is sound. A power analysis was performed to determine an appropriate sample size. Stringent inclusion criteria were employed to keep the confounding factors to an absolute minimum. Subjects were randomly assigned into one of the two treatment groups, and the patients, the operators, and the raters were all blinded to the type of wire being used. Digital scans are highly accurate, and the raters measuring these scans were determined to have good reliability.

This study found that both the control and the experimental wire reduced Little’s Irregularity Index in patients, and that there was no statistical difference between the two types of wires in its reduction. There was also no statistically significant difference in the transverse expansion caused by the two types of wires, despite the fact that the Gummetal wires were preformed to the pretreatment archform; changes in transverse width were very minimal for both treatment groups. Therefore, it is proposed that initial flexible wires produce minimal changes to a patient’s archform, regardless of whether the wire is a close match to the patient’s actual archform.

Other studies have also measured changes in transverse width during treatment. Celikoglu et al compared the effects of self-ligating versus conventional brackets on transverse expansion when using .014 NiTi wires. After 8 weeks of treatment, they
found 0.87 mm expansion in intercanine width in the self-ligating group and 0.59 mm expansion in the conventional bracket group. During this same time period, they found 0.29 mm expansion in intermolar width in the self-ligating group and 0.35 mm expansion in the conventional bracket group. Atik et al measured the intercanine and intermolar expansion that occurred during the entire course of treatment, as measured before bonding any brackets and then measuring again after debond. They found a mean intercanine expansion of 2.03 mm with active self-ligating brackets, 2.02 mm with conventional brackets, and 2.53 mm with passive self-ligating brackets. They found mean intermolar expansion of 2.34 mm with active self-ligating brackets, 2.61 mm with conventional brackets, and 3.43 mm with passive self-ligating brackets. The study by Atik et al did not examine how much expansion occurred due to initial wires versus finishing wires.

When looking at the irregularity of the full arch for both treatment groups, irregularity decreased by 27% during the first 4-6 months of treatment, and then decreased by another 25% during the next 4-6 months of treatment; these differences were statistically significant. When looking at the irregularity of the anterior region only for both treatment groups, irregularity decreased by 31% during the first 4-6 months of treatment, and this amount was statistically significant. The decrease in anterior irregularity during the second 4-6 months of treatment was 24% but was not statistically significant, indicating a plateauing of results as the irregularity decreased. These results are in line with previous studies; however, different studies use different measurement systems and perform their measurements at different intervals.
Abdelrahman et al measured initial irregularity, as well as irregularity after 8 weeks. They found that .014 Superelastic NiTi reduced irregularity from a mean of 5.996 mm to 1.232 mm in 8 weeks, .014 thermal NiTi reduced irregularity from a mean of 5.968 mm to 1.108 mm, and .014 Nitinol reduced irregularity from 5.996 mm to 1.246 mm. Ong’s study kept the initial wire in place until the clinician felt that rectangular wires could be used, and measured the reduction in irregularity that had occurred up to this point. They found that during this time, .014 Nitinol reduced irregularity from a mean of 6.6mm to 2.2 mm; .014 Sentalloy reduced irregularity from a mean of 7.8 mm to 3 mm; .014 Damon CuNiTi reduced irregularity from a mean of 5.8 mm to 2.1 mm. On then placed rectangular wires into the brackets, and found that irregularity reduced from 2.2 mm to 2.0 mm with .017x.017 heat activated NiTi, irregularity decreased from 3.0 mm to 2.1 mm with .016 x.022 Bioforce wires, and decreased from 2.1 mm to 2.0 mm with .014 x .025 Damon CuNiTi wires. Sebastian et al did not report irregularity; they measured mean total tooth movement at 4 weeks, 8 weeks, and 12 weeks. They found that .016 NiTi led to a total of 1.552 mm tooth movement after 4 weeks, 2.327 mm after 8 weeks, and 3.103 after 12 weeks. They found that .016 coaxial NiTi led to 4.934 mm tooth movement after 4 weeks, 7.4mm after 8 weeks, and 9.867mm after 12 weeks.

Although the two types of wires showed no difference in performance, other factors were statistically significant. Little’s Index improved over time with both types of wires. There were differences in the initial irregularity between the mandible and the maxilla with the maxilla presenting with greater initial irregularity; however the difference between their change in irregularity over time was not significant. There were
also differences in comparing the full arch to the anterior segment, indicating that the patients’ crowding was not confined to the anterior segments. In terms of transverse widths, there were differences in the maxilla versus the mandible, and there were differences between the molar width and the canine width. This is due to the inherent difference is size of the two arches and the anterior and posterior distances measured.

This study produced similar results to previous laboratory studies. In vitro studies showed that Gummetal has low stiffness, low Young’s modulus, and generates light forces, meaning that its clinical performance should be comparable to NiTi. Suzuki et al used niobium-titanium archwires and NiTi archwires to produce buccal tooth movement in rats, and they found no difference in terms of tooth movement between the two types of wires. Our study confirms these results in humans.

Previous laboratory studies have shown Gummetal to have a torsional stiffness sufficient to produce third-order corrections. Therefore, it is suggested that Gummetal wires could be used to generate torque in patients. A future clinical study comparing the performance of rectangular Gummetal to either stainless steel or TMA could confirm this finding.

It should be noted that although the performance of the two wires was shown to be comparable, after removing the wires from the patients’ mouths at the end of the study, the Gummetal wires appeared to undergo more permanent distortion than did the NiTi wires. Because Gummetal wires are shape formable when bent at a sharp enough angle, they also have the ability to experience deformation when ligated into brackets on teeth that are severely displaced. In cases of severe crowding, it is likely that Gummetal
would underperform NiTi due to Gummetal’s shape formable properties. A future study focusing exclusively on severe crowding could test this theory.

Although as many confounding factors as possible were controlled for, in an in vivo experiment, it is not possible to account for every possible difference among subjects because no two subjects present with the exact same malocclusion. The goal of this study was to compare how these two types of wires behave in human patients. To determine precise differences between the two types of wires, a laboratory study would be appropriate. Additionally, a larger sample size in an in vivo study might reveal a minor difference in performance between the two types of wires that this study was not able to detect. Also, a study focusing exclusively on patients with severe crowding may reveal a difference in performance between the two wires.

Based on our findings, we conclude

1. Because Rocky Mountain Morita Gummetal TiNbTaZr and GAC Sentalloy NiTi lead to similar reductions in crowding in patients, Gummetal is appropriate as an initial archwire in orthodontic treatment.

2. Because Gummetal is nickel free, it is an ideal initial archwire in nickel-sensitive patients.

3. Because Gummetal is shape formable, it is an ideal initial archwire when the clinician wishes to customize the archform or to place bends in an initial archwire.
4. Neither Gummetal pre-formed to the pre-treatment archform nor stock GAC Sentalloy lead to significant canine or molar expansion during the first two to three months of treatment.
References


Measuring 3-dimensional tooth movement with a 3-dimensional surface laser  

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alignment with SmartClip self-ligating and conventional brackets: A single-center  
prospective randomized controlled clinical trial. Korean J Orthod. 2015  
Mar;45(2):78-94.

65. Atik E, Akarsu-Guven B, Kocadereli I, Ciger S. Evaluation of maxillary arch  
dimensional and inclination changes with self-ligating and conventional brackets  
APPENDIX: TABLES AND FIGURES

Table 1: Age Distribution of Subjects

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Table 2: Demographics of Subjects

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<td>P value</td>
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Table 3: List of Independent and Dependent Variables

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<tr>
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<th>UCB_{95}</th>
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Table 5: Performance Comparison

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<table>
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<td>Little's Index Width</td>
<td>Little's Index Width</td>
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Table 6: ANOVA Summary Table – Little’s Index

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Table 8. Least Squares Means – Little’s Index

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Table 9. Least Squares Means – Transverse Width

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<td>NiTi</td>
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Figure 1: Wires used in the study

Photograph of stock GAC Sentalloy NiTi wire (left) and Rocky Mountain Morita Gummetal TiNbTaZr wire (right). The Gummetal wire is slightly darker in color.
Figure 2: Examples of NiTi Superimpositions
Figure 3: Examples of Gummetal Superimpositions
Figure 4: Examples of Measurements (Maxillary Arch)
Figure 5: Examples of Measurements (Mandibular Arch)
Figure 6: Flow diagram of patient recruitment

1. Enrollment
   - Assessed for eligibility (n=134)
   - Excluded (n=106)
     - Not meeting inclusion criteria (n=103)
     - Declined to participate (n=3)
     - Other reasons (n=0)

2. Randomized (n=28)

3. Allocation
   - Allocated to intervention (n=14)
     - Received allocated intervention (n=14)
     - Did not receive allocated intervention (give reasons) (n=0)
   - Allocated to intervention (n=14)
     - Received allocated intervention (n=14)
     - Did not receive allocated intervention (give reasons) (n=0)

4. Follow-Up
   - Lost to follow-up (give reasons) (n=0)
   - Discontinued intervention (give reasons) (n=0)
   - Lost to follow-up (give reasons) (n=0)
   - Discontinued intervention (give reasons) (n=0)

5. Analysis
   - Analysed (n=14)
     - Excluded from analysis (give reasons) (n=0)
   - Analysed (n=14)
     - Excluded from analysis (give reasons) (n=0)
Figure 7: Performance Comparison – Little’s Index
Figure 8: Performance Comparison – Transverse Width
Figure 9. ANOVA Interactions – Little’s Index
Figure 10. ANOVA Interactions – Transverse