SmartArch® Multi-Force, Super-Elastic Archwires: A New Paradigm in Orthodontics

Abstract

SmartArch® (S-A) archwires are laser-conditioned CuNiTi wires with a differential force profile that is based on the optimal compressive stress in the periodontal ligament (PDL) to achieve rapid tooth movement with minimal necrosis. Compared to alignment with a progression of two CuNiTi archwires (0.016 and 0.018-in), a single 0.016-in S-A is significantly (p<0.02) more efficient in correcting interproximal discrepancies, decreasing deepbite, and leveling the Curve of Spee. Failure to bond and align lower second molars results in marginal ridge discrepancies of up to 3mm that substantially delay treatment. Beta testing of initial alignment with a 3mo each sequence of 0.016-in and 0.017x0.025-in S-A archwires in a 0.018-in slot Ti Orthos® brackets revealed that simultaneous leveling and aligning of deepbite malocclusions was achieved in ~6mo. Three of the 10 moderate malocclusions treated were finished to <26 points on a cast alignment evaluation (CAE). These optimal results broadened the focus of clinical investigation to address an important limitation of indeterminate mechanics in orthodontics: excessive treatment time due to the repetitive PDL necrosis, associated with frequent reactivations. The new paradigm in orthodontics is an emphasis on precise bracket positioning to enable simultaneous 3D alignment of both arches with the 2-Step S-A sequence. Intermaxillary mechanics (Class II/III) should be avoided until the arches are aligned, and finishing TMA or SS archwires are in place. Then utilize determinate mechanics by applying elastics to archwire lugs mesial to the canines for the correction of midlines and buccal interdigitation. Detailing bends (only if required) should be the last stage in mechanics before debonding. 2-Step S-A 3D alignment, in the context of precise bracket positioning and determinate major mechanics, is expected to decrease chair-time, improve outcomes, and decrease treatment time at least 50%. (J Digital Orthod 2019;55:66-79)

Key words:
Indeterminate and determinate mechanics, CuNiTi, accelerated treatment, decreased treatment deration, multforce, superelastic, multiple memory technology, ideal physiologic load, martensite-austenite transition, interbracket distance

Introduction

SmartArch® (S-A) is a new generation of multi-force archwire (MFAW) that has differential superelastic properties based on advanced concepts in materials science, and periodontal ligament (PDL) physiology. Shape memory alloys (SMAs) are materials that are resistant to permanent deformation (wire bending). They usually have a lower modulus of elasticity, compared to stainless steel (SS) and titanium molybdenum alloy (TMA) (Fig. 1A).1 Heat treatment adjusts the memory of SMAs such as copper nickel titanium (CuNiTi) to deliver different levels of superelastic force (Fig. 1B). The transformation factor is the level of stress-related deflection required to activate the martensite-austenite transition (Fig. 2). This important material property can be programmed with: 1. furnace heating, holding and cooling, 2. pulsed electric current with a Memory-
Shape-Memory Alloys (SMAs): *Multiple Superelastic Plateaus*

A. Shape memory alloys have a uniform initial modulus of elasticity and are resistant to permanent deformation. When loaded into the superelastic range, the unloading curve is relatively uniform for a given plateau of force. Titanol is a trademark for Forestadent (Pforzheim, Germany). See text for details.

B. Modification of the superelastic transition zone with heat treatment produces unloading curves with variable levels of unloading force. These illustrations are modified versions from an original article published by the senior author (WER).¹

Martensite-Austenite Transition Zone

- Stress at a Specific Temperature: triggers the transition zone that was previously programmed with heat-treatment:
  1. Furnace: heating, holding & cooling
  2. Pulsed electric field: Memory-Maker
  3. Pulsed with a high performance pumped laser (Khan)

- Multiple Memory Material (MMM) Technology: unique because multiple interdigital cross-sections of the wire (<0.001-in) can be programmed to deliver at least 10 different levels of superelastic load. Patent: WO 2011/014962

- Smart-Arch is programmed with specific engineering data to deliver ideal loads to each tooth relative to the configurations the malocclusion.

- Round and Rectangular S-A Two-Wire Sequence:
  1. Simultaneously level, align and control third order
  2. Continuous loads avoid repetitive PDL trauma

Fig. 1:

The level of stress (wire deformation) to enter the martensite-austenite transition zone is adjusted with heat treatment. This is a copy of a presentation slide explaining the concept relative to Md arch alignment in 3D. This illustration is a modification from an original article published by the senior author (WER).¹
Orthodontics is accomplished with both determinate and indeterminate mechanics. The determinate approach is more predictable because all the 3D forces and moments are known. However, there must be no more than two abutments: teeth, arches or segments. Any device (archwires or aligners) engaging multiple teeth at once is statically indeterminate. Loads are transferred throughout the periodontium in an unknown manner, resulting in PDL necrosis that delays tooth movement and induces root resorption every time the mechanics are reactivated. The ideal physiologic force for each tooth is based on interbracket distance, and the

### SMART-ARCH® TECHNOLOGY

- **Shape Memory Alloys (Superelastic or Pseudoelastic Properties)**
  - Multiple Stress Plates are Programmed with Heat, Electricity, or Lasers
- **Multiple Memory Material (MMM) Technology**
  - Selective Pulsed Laser Processing small interproximal transition zones <0.001-in
  - Fatigue Co-efficient: reduced for processed wires
- **Smart-Arch®** is progressively programmed with tooth specific parameters:
  - Interbracket Distance: wider in the maxillary anterior and molar regions
  - Maximum PDL Compressive Stress: P3 in Finite Element Analysis
  - One-Step Initial Alignment: aligns and levels the arch simultaneously
  - One-Step Third Order: continuous mechanics for 3D alignment

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**Fig. 3:**

Smart-Arch® technology and its clinical applications are summarized in a presentation slide.

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**Fig. 4:**

A presentation slide illustrates the MMM technology developed by Ibraheem Khan et al. to produce Smart-Arch® archwires. Variable interbracket distances are shown on the left (A). The lower right illustration depicts mechanical stress in the PDL (C). These critical PDL physiologic parameters were unknown when the manufacturing technology was developed. See text for details.

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**Fig. 5:**

PDL stress was defined by Rodrigo Viecilli with FEA for each tooth in the mouth except third molars. The optimal archwire force for four types of tooth movement was calculated to produce adequate PDL stress to move a tooth without inducing necrosis. See text for details.
average PDL compressive stress (P3) calculated with FEA for four types of tooth movement (Figs. 5 and 6).4 The S-A force profile is based on ideal physiologic loads, which are not achieved with common initial alignment archwires such as 0.014-in CuNiTi, and the previous generation of MFAW (Tri-Force™, G&H Orthodontics, Franklin IN or similar), a GAC-Dentsply (Harrisburg PA) product that is now out of patent. Figure 7 illustrates the relative force levels per tooth in a panoramic view of the maxillary arch. The inset on the upper right (blue background) shows a color-coded view of the superelastic levels programmed into the interbracket segments of a maxillary S-A archwire (Fig. 7).

S-A archwires are a unique concept in orthodontic mechanics (Fig. 8). They deliver physiologically optimized loads for an extended period of time. This advance in orthodontic materials helps control the indeterminate mechanics, and repetitive archwire reactivations that lengthen treatment and compromise outcomes. It is hypothesized that S-A

0.016-in round, and 0.018x0.025-in (0.022-in slot) or 0.017x0.025-in (0.018-in slot) rectangular archwires are efficient for initial alignment and leveling without presenting any unusual risks to the patients.

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**Fig. 6:** S-A is a modified CuNiTi archwire that was differentially tempered to deliver the ideal physiologic load for each tooth, as previously calculated by Viecilli (Fig. 5). Neither 0.014-in CuNiTi nor a 0.016-in Tri-Force™ archwires comply. See text for details.

**Fig. 7:** Three types of initial archwires are illustrated. 0.014-in CuNiTi is a uniform material that delivers variable force depending on interbracket distance. Tri-Force™ is a first generation MFAW that produces progressively increasing force from the canine to the second molar. S-A is programmed to fit the ideal force curve derived by Viecilli (Fig. 5). The color-coded drawing on the upper right shows multiple superelastic force levels programmed into the interproximal segments of a maxillary S-A archwire.

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**Fig. 8:** Smart-Arch® is a unique archwire concept that is available in a 0.016-in round and 0.018x0.025-in rectangular configurations. The 2-Step 3D alignment procedure utilizes each wire for 3mo to resolve a Class I malocclusion. Class II or III problems are corrected with determinate mechanics by applying elastics to lugs on the archwires mesial to the canines. See text for details.
Materials and Methods

All clinical records were retrospectively sourced from private practices with an industrial Institutional Review Board (IRB) approval: Solutions IRB.com, Protocol #2019/01/18.

- **Inclusion** criteria: 1. routine malocclusions requiring full fixed appliances in both arches, 2. late mixed or permanent dentition, 3. initial alignment accomplished with a S-A archwire, and 4. no additional mechanics such as bracket repositioning or intermaxillary elastics.

- **Exclusion** criteria: 1. craniofacial anomalies, 2. missing more than four permanent teeth, 3. periodontal compromise, and 4. treatment involving orthognathic surgery. With the patient’s permission (and parent if a minor, deidentified casts and intraoral photographs (start and finish) were sourced along with intraoral photographs at variable intervals when the patients were seen during the initial alignment process.

**Study 1.** The lower arch was initially aligned with a single 0.016-in S-A archwire in 0.022-in slot Damon Q® brackets (Ormco, Brea CA). Two of the authors, JAR (Indiana) and ST (California) submitted deidentified casts and intraoral photographs for 7 and 6 patients, respectively. The collective treatment times were 128.5±34.2 (range 72-190) days. S-A archwires were removed when sufficient alignment was achieved to progress to the next archwire. There were no casts, so all measurements were made on intraoral photographs and thermoplastic bite registrations (Heat & Bite®, Ormco, Brea CA).

**Study 2.** Treatment was identical to Study 1 except the brackets were 0.018-in Ti Orthos® (Ormco, Brea CA), and both arches were aligned with 0.016-in S-A. The treatment times were 143.0±34.1 (range 60-180) days. The retrospective clinical records were casts and intraoral photographs at the start and finish, as well as intraoral photographs when progress was evaluated.

**Study 3.** Treatment and records sourced were identical to Study 2 except the initial alignment sequence was 0.016-in CuNiTi for 3mo followed by 0.018-in CuNiTi for 3mo, and the treatment time was uniform for all patients (~180 days). Progress photographs and thermoplastic bite registrations were collected at varying intervals when patients presented for evaluation. This was an independent study conducted by two of the authors (WER, DMS), and submitted for publication. It was not supported or controlled by any commercial interests.

**Study 4.** Ti Orthos® brackets (0.018-in slot) were bonded on both arches of 10 consecutive, routine malocclusions. Initial leveling and alignment in 3D was accomplished with 0.016-in S-A for 3mo followed by a 0.017x0.025-in S-A for 3mo. A casts-only discrepancy index (C-O DI) was performed at the start of treatment. The method is identical to the American Board of Orthodontics (ABO) Discrepancy Index (DI) except there is no radiographic analysis (cephalometrics). Cast Alignment Evaluations (CAE) were performed at the end of each stage of the alignment phase. The CAE is similar to the ABO cast-radiograph evaluation (CRE) except it is a casts-only method with no evaluation of a panoramic radiographs.
**Records Assessment:** The interproximal discrepancy index (IDI) was the total malalignment for all marginal ridge discrepancies (MRDs). MRDs between mandibular first (L6) and second (L7) molars were deemed 7-6 discrepancies. They were measured separately on the casts and then summed to simplify the data presentation. In brief, the alignment of all erupted teeth was assessed in 3D on casts, and in 2D on photographs. Measurements were made under high intensity light at 2x magnification (*Opti-Visor*™ head-band loupes, Donegan Optical, Lenexa KS) to the nearest 0.5mm with an analog precision caliper (*Mitutoyo, No. 505-633-50, Kanagawa, Japan*), which has a resolution of 0.05mm. Overbite and overjet were measured to the nearest 0.1mm at the start and end of the study with the same caliper. Overjet, overbite and curve of Spee (CoS) measurements were made on start and finish casts for Studies 2 and 3. Data were summarized with means and standard deviations. Statistical significance was tested with the paired two-tailed t-test programmed into Microsoft Excel (*Redlands, WA*).

**Results**

Two patients, one in Study 1 and another in Study 2, experienced fractures of 0.016-in S-A archwires in the lower posterior segments in the same area: between the second premolars and the first molars. The problems were asymptomatic, and the fractured archwires were replaced within 7d. There were no problems with any of the rectangular S-A wires. The hypothesis is accepted that S-A archwires, in the 0.016-in, 0.017x0.025-in, and 0.018x0.025-in configurations, provide efficient continuous loads for initial alignment. None of the archwires presented any unusual risks to patients.

MFAW is the generic term for archwires that deliver variable loads. Smart-Arch® (S-A) is a second generation MFAW that delivers differential loads to individual teeth based on physiologically relevant PDL stress levels. The only uniform aspect of the beta testing across groups was initial alignment of the mandibular arch with 0.016-in S-A. Those comparative data are presented for studies 1-3 in Table I, and statistical tests are summarized in Table II. The IDI was significantly (*p<0.001*) reduced for all groups at 128-180d, as specified (*Fig. 9; Tables I and II*). There was no difference for the final IDI between groups, except for studies 3 vs. 1 (*p<0.001*). A 3mo each sequence for 0.016 and 0.018-in CuNiTi wires in 0.018-in Ti Orthos® brackets provided a baseline reference for routine initial alignment. The IDI was reduced from 11.3±4.2 to 3.9±2.5mm, which is a 61.4±26.6% correction in a standardized 6mo period (180d). A 0.016-in S-A archwire in same Ti Orthos® brackets was more effective (*p<0.03*) than CuNiTi in reducing the IDI from 15.8±6.5 to 2.5±2.7mm, which was a 82.2±19.5% correction in 143.0±35.3d. The same S-A archwire in a 0.022-in Damon Q® bracket was even more effective (*p<0.01*) for reducing the initial IDI for severe malocclusions from 21.4±6.4 to 1.1±1.2mm, which was a 94.5±6.2% correction in 128.5±34.2d (*Fig. 9*). The time course for initial alignment (*Study 2*) was compared for the maxillary (Mx) and mandibular (Md) arches by separating the progress (124±34d) from the finish (180d) data. There were no significant differences in IDI or percent correction data between the divided
Table I:
Correction of interproximal discrepancies in the lower arch with S-A or CuNiTi (3mo 0.016-in - 3mo 0.018-in) in two types of brackets: 0.022-in slot Damon Q®, and 0.018-in Ti Orthos®.

Table II:
Statistical comparison of Studies 1-3 was with paired t-tests. Compared to the initial IDI, the final IDI was significantly reduced (p<0.001) in all three studies. The S-A Damon Q® group (Study 1) had a significantly greater mean IDI (p<0.03) and were treated to the highest percent correction (P<0.01), compared to the other groups.

Two-Tailed T-Test for Statistical Significance (p<0.05)

Table: Statistical comparison of Studies 1-3 was with paired t-tests. Compared to the initial IDI, the final IDI was significantly reduced (p<0.001) in all three studies. The S-A Damon Q® group (Study 1) had a significantly greater mean IDI (p<0.03) and were treated to the highest percent correction (P<0.01), compared to the other groups.

Fig. 9: Correction of mandibular interproximal discrepancies with 0.016/0.018-in CuNiTi is compared to S-A 0.016-in in Ti Orthos® and Damon Q® brackets. All of the methods produced significant (p<0.001) decreases in the IDI. However, S-A delivered a significantly (p<0.01) better correction for more complex malocclusions in both types of brackets. See text for details.
samples. The IDI decreased to a minimal level of 1.40mm at progress sampling (124±34d), but then relapsed to 5.02mm at the prescribed 180d finish (Fig. 10; Table III). Leveling was assessed as the correction of deepbite (overbite), Curve of Spee (CoS), and Mx first and second molar (7-6) MRDs (Fig. 11; Tables IV-VI). Deepbite (overbite) of >3mm was prevalent in both the MFAW (83.3%) and CuNiTi (70%) samples (Table IV). Overbite was significantly (p<0.001) decreased ~2mm with S-A MFAW, but not with CuNiTi leveling. The initial CoS was ~0.7mm less (p<0.006) in CuNiTi compared to S-A MFAW patients (Table V). CuNiTi alignment failed to significantly level the lower arch. On the contrary, MFAW (S-A) archwires significantly decreased the deepbite (p<0.008) and CoS (p<0.001). In addition, there was a nonsignificant (p<0.11)
tendency to increase 7-6 MRDs in the lower arch, which resulted in combined bilateral discrepancies up to 5.5mm (Table VI). Three of the CuNiTi patients required posterior bite turbos, but they were not needed for the MFAW (S-A) group (Table V).

The group of 10 consecutive patients with routine malocclusions (C-O DI = 13.2) was selected to investigate 2-Step S-A 3D alignment procedure (Fig. 12). The demographics for the 10 patients were: age 16.0±14.9yr, 80% female, 90% Caucasian, 80% moderate Class II, 30% excessive overjet, 90% deepbite (>3mm), and 70% with at least 5mm of crowding. After 3mo of 0.016-in S-A archwire treatment, dental alignment was improved to a CAE of 41.0 points. Following 3mo of 0.017x0.025-in S-A third order alignment, the CAE decreased to

### Table IV:

<table>
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<tr>
<th>MFAW (S-A) 0.016-in Initial Align 6-6</th>
<th>CuNiTi 0.016-in 3mo, 0.018-in 3mo</th>
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<td><strong>Curve of Spee</strong></td>
<td><strong>Curve of Spee</strong></td>
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<td>MFAW vs. CuNiTi</td>
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During a uniform 180° aligning and leveling phase with a 6-6 fixed appliance, MFAW (S-A) archwires were more effective than CuNiTi for decreasing deepbite (p<0.001) and the CoS (p<0.001), but 7-6 MRDs tended to increase (p<0.1) CuNiTi had no significant effect in leveling the arches, but 7-6 MRDs also tended to increase. See text for details.

During initial alignment, there was a small decrease (0.78mm) in the curve of Spee (CoS) with MFAW (S-A) that was statistically significant (p<0.001), but there was no significant change in CoS with CuNiTi.

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**Fig. 11:**

During a uniform 180° aligning and leveling phase with a 6-6 fixed appliance, MFAW (S-A) archwires were more effective than CuNiTi for decreasing deepbite (p<0.001) and the CoS (p<0.001), but 7-6 MRDs tended to increase (p<0.1) CuNiTi had no significant effect in leveling the arches, but 7-6 MRDs also tended to increase. See text for details.
Table VI: The summed lower 7-6 marginal ridge discrepancies tended to increase in both the MFAW (S-A) and CuNiTi groups. The mean change was greater but not significant ($p<0.1$ for S-A. However, the value of the data is to demonstrate that alignment of lower 6-6 when the 7s are present is inefficient and extends treatment time.

![Fig. 12: The 2-Step 3D alignment procedure was performed on 10 patients with routine malocclusions (C-O DI of 13.2). After 3mo of alignment with 0.016-in S-A, a CAE scored residual discrepancies at a mean of 41 points. A subsequent 3mo of 0.017x0.025-in S-A correction resulted in a mean CAE of 28.7. After 6mo of 3D alignment, near optimal alignment was achieved (Goal of 26 points). See text for details.]

28.7 points ($P<0.001$) (Fig. 12). The predefined goal of 26 points for a well aligned dentition ("board-quality result") was achieved by three of the patients (shaded gray in Table VII).

**Discussion**

Aligning and leveling the arches of deepbite patients, without excessive bite opening, is a common problem because overbite of 3mm or more is prevalent (70-90% of the samples) (Tables IV and VII). Managing a deepbite and excessive CoS in the lower arch is one of the most challenging and time consuming aspects of orthodontics therapy, because conflicting archwire properties are required. Highly flexible, low force archwires such as CuNiTi are the most effective for correcting rotations and crowding (Fig. 9), but they lack the posterior rigidity to effectively level the arch (Fig 11). At least four and sometimes six CuNiTi and stainless steel (SS) archwires are required to align and level deepbite patients with an excessive CoS. Posterior bite turbos are commonly used during initial alignment to alleviate bracket interference (Table V). Bonding glass isomer cement on the occlusal surface of lower first molars is the most common approach. This short-term solution for bracket interference presents a risk of posterior openbite and/or incisal trauma, when the bite turbos are removed. No bite turbos were required for initial alignment with 0.016-in S-A Ti Orthos®
Table VII:
The 6mo S-A 2-Step 3D alignment procedure was evaluated in 10 consecutive, routine patients. The initial malocclusion was assessed with the casts-only discrepancy index (C-O DI) and alignment was measured with the cast alignment evaluation (CRE). Three patients (30%, shaded in gray) achieved the alignment goal of <26 points in <200d. Sex was designated as male (M) or female (F). Ethnic group was white Caucasian (C) or African American (AA). Patients with a deep overbite (OB) were classified as deepbite (DB). CAE is cast alignment evaluation. See text for details.

This favorable result is explained by the resistance of low profile titanium brackets to bonding failures, and the efficiency of S-A to open the bite by decreasing the CoS (Fig. 11; Table V). In addition, S-A leveling of the upper arch of a deepbite patient (Table III) intrudes and flares the maxillary incisors. Collectively, the stiffer buccal segments of upper and lower S-A archwires help to alleviate lower anterior bracket interference. Avoiding or only using posterior bite turbos for a short period of time considerably simplifies initial alignment and subsequent treatment of deepbite patients (Figs. 9-11; Tables III-V). If L7s are erupted, it is important to bond brackets and include them in the initial alignment and leveling process to avoid substantial 7-6 MRDs (Table VI). Using flexible, followed by stiff archwires, to correct 7-6 discrepancies delays treatment. Also, the deepbite correction may tend to relapse with transient use of flexible wires, and that problem considerably extends treatment time. It is clear that S-A archwires have considerable potential for enhancing outcomes and decreasing treatment times, but precise bracket positioning from 7-7 is essential.

The timing of archwire use has received little attention. The general rule is that superelastic archwires with a long range of action (deformation recovery) can be used in larger dimensions and for longer periods of time, but there is only
one study that has examined the timing for optimal performance of an archwire. Treatment planning for specific archwires is often arbitrary and the performance of a wire is rarely monitored. Simultaneous alignment and leveling with a 0.016-in S-A was expected to require about 6mo (180d) because that is the approximate timing with multiple archwires. However, analysis of progress records at a mean of about 124d indicated that optimal correction of interproximal discrepancies was much sooner than 180d (Fig. 10). A careful assessment of the progress for individual patients (Tables I and III) revealed that optimal resolution of interproximal discrepancies was at 90d or less for many patients. Furthermore, the failure to correct some discrepancies after ~180d was primarily related to incorrect bracket placement. It was concluded that 0.016-in S-A archwires are highly efficient for simultaneous alignment and leveling of both arches, but the optimal treatment time is 3mo (90d) and precise bracket positioning is critical.

The same differential load prescription based on FEA (Fig. 5) that defined 0.016-in S-A (Figs. 6 and 7) was utilized to laser condition rectangular CuNiTi archwires. S-A is now available in 0.017x0.025-in and 0.018x0.025-in for 0.018-in and 0.025-in slot brackets, respectively. The effectiveness for 2-step S-A alignment and leveling in 3D was demonstrated in 10 routine malocclusions using a 3mo round and 3mo rectangular wire protocol (Study 4). The brackets were 0.022-in Ti Orthos®, so the 2-step sequence was 0.016-in and 0.017x0.025-in S-A for 3mo each. The average alignment score (CAE) after about 198d of treatment was 28.7±9.4 points, which is near the pre-set goal of 26 points. Three of the patients exceeded the goal (Table VII). Residual problems for the other 7 patients were incorrect bracket positions and intermaxillary occlusal discrepancies (Class II or III). The latter should be corrected with intermaxillary elastics applied to the finishing archwires via lugs mesial to the 3s. Applying elastics to teeth particularly in the anterior region is indeterminate mechanics, which risk PDL necrosis because of the play of the wire in the bracket, and the tendency for a tooth to rotate when a force is applied on the buccal surface. In the posterior arch, molar hooks are acceptable because of the large amount of archwire engagement in molar brackets and tubes. If the latter proves to be a problem, elastic lugs can be mounted on the posterior aspects of the archwire.

All of the clinical data currently available from beta testing of S-A archwires indicates there are no unusual risks for patients. Furthermore, these new archwires offer some unique advantages for controlling the alignment and leveling inherent in initial aligning and leveling. The long range of differential action achieves optimal leveling and alignment in about 3mo with each archwire. An increased force to deflection ratio (stiffness) in posterior segments, combined with light force and resiliency in the anterior segments, is the combination of material properties that results in simultaneous leveling and aligning in 3D with only two archwires. However, residual discrepancies may not be corrected because of incorrect bracket positions. Contrary to routine clinical practice, it is undesirable to adjust archwires or reposition brackets because that involves additional indeterminate mechanics and PDL necrosis that delays treatment and risks root resorption. The preferable clinical
approach is is to prevent bracket positioning errors. This may be accomplished with a radiograph-guided indirect set-up. However, the most reliable approach is a computer aided design (CAD), and computer aided manufacture (CAM) custom appliance based on a digital set-up of the desired final alignment, e.g. Insignia™ (Ormco Corporation, Brea CA).

The presently reviewed proprietary research and development to produce and beta test the new S-A archwires is now adequate to define clinical protocols for independent testing of the 6mo - 2-step S-A dental alignment procedure. The senior author (WER) and four experienced clinicians have committed to evaluating this promising procedure at their own expense. Supplies and services will be purchased from Ormco (Brea, CA), and the patients will pay for their treatment, but the investigators will accept no support nor advice from any commercial interests. The records will be retrospectively sampled with IRB approval and patient permission. The results can be submitted for publication in the refereed orthodontic literature with no conflict of interest.

A baseline (control) study of initial alignment with 0.016 and 0.018-in CINiTi archwires (3mo each) in 0.018-in Ti Orthos® brackets is completed and recently submitted for publication. Under identical clinical conditions, a follow-up study utilizing an indirect set-up for positioning the brackets is underway to test the 6mo 2-step S-A 3D initial alignment procedure. Three additional clinicians will use Insignia® for custom appliances to test the 2-step S-A alignment method with three additional types of brackets: Damon Q®, Insignia SL™ (self-ligating), and Insignia Twin™. The Damon Q® appliance is an indirect set-up based on a CAD set-up of the final occlusion. The Insignia™ SL and Twin brackets are custom CAM brackets that have milled bases. S-A archwires are available in standard and broad archforms. They can be used with any bracket type depending the clinical objectives for a particular patient. The overall hypothesis for the new paradigm in orthodontics is that 3D alignment with S-A, followed by determinate intermaxillary mechanics will enhance outcomes, decrease treatment time, and help control risks.

Acknowledgment and Disclosures
Studies 1, 2 and 4 were beta testing evaluations of the 0.016-in and 0.017x0.025-in Smart-Arch® archwires supplied by Smarter Alloys™ (Waterloo, ONT, Canada). The clinical testing was supported by the Ormco Corporation (Brea, CA). Study 3 is an independent clinical evaluation conducted by two of the authors (WER, DMS) which is currently submitted for publication. The authors wish to thank Smarter Alloys™ for the graphics downloaded from their website (Figs. 4-7). We wish to thank the following for reviewing and editing the manuscript: Drs. Kelton Stewart, Evan Tsai, Jie Chen, Chris Chang, Sam Alauddin, Naphthali Brezniak, Ibraheem Khan.
References


