SureSmile: A Report of Clinical Findings

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SureSmile* is a comprehensive, all-digital orthodontic care solution that uses threedimensional diagnostics and customized fixed appliances to deliver efficient, consistent, highquality treatment outcomes. With support services including training, marketing, management, and customer care, SureSmile relies on three key technological components¹⁻³:

• The OraScanner,* a unique, reference-free imaging system that uses structured white light (not lasers or x-rays) to capture accurate threedimensional scans of a patient's dentition in vivo or in vitro.

• SureSmile Diagnostics and Treatment Planning Software, which provide powerful threedimensional visualization tools for diagnosis, treatment simulation and evaluation, and customized appliance design. The doctor can review the digital setup with this software and use it to communicate with patients and with the Digital



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Lab at OraMetrix.

• Robotic technology, used for custom fabrication of prescription archwires at the Digital Lab.

The present article will describe the evolution of the clinical care protocol, discuss the impact of SureSmile on clinical operations, and report on the current quality and efficiency of various types of orthodontic treatment using this system.

Evolution of SureSmile Clinical Protocol

The clinical studies designed to evaluate SureSmile were planned in four phases, as out-lined below.

Phase I

This limited study was designed to evaluate the effectiveness of SureSmile technology on a sample of five patients who were already undergoing orthodontic treatment. Each patient was scanned in vivo, and setups were made to produce custom archwires. Phase I established that consistent outcomes could be delivered with the SureSmile system.

Phase II

The objective of the Phase II study was to

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evaluate a one-stage SureSmile approach in 10 patients. This involved taking initial in vivo scans of each patient, with brackets bonded at the same appointment, followed by an update scan. Within four weeks, the setup was designed and evaluated, and SureSmile prescription archwires were delivered. In each case, only one set of archwires—.017" × .025" Copper Ni-Ti**—was used from start to finish.

Phase III

Feedback from test sites suggested that the SureSmile clinical processes could be further streamlined to fit into the normal workflow of orthodontic practices-especially those that subscribe to the "one-step" approach to patient care. Two major changes in the protocol were recommended:

• Allow the practice to take the initial scans from the plaster casts rather than in vivo.

• Start treatment with straight-archwire mechanics, then, after three to five months of initial leveling and alignment, take an in vivo update scan to produce a SureSmile prescription archwire.

These recommendations formed the basis of the current two-stage SureSmile clinical protocol (Table 1). Case 1 illustrates the typical treatment process.

Phase IV

Phase IV clinical studies were designed to: · Validate SureSmile across a variety of practices, patients, and treatment philosophies.

• Determine the impact of in vivo scanning on clinical operations.

• Establish the clinical effectiveness of the system.

The following patient histories demonstrate the versatility of SureSmile in the treatment of various types of malocclusions, using different appliance systems.

(text continued on p. 312)

Practice	Assistant takes initial recordsAssistant takes initial scan of plaster cast
OraMetrix	 Processes scan to produce 3-D model
Practice	 Doctor uses model to establish 3-D treatment plan, bracket placement simulation, and patient communication Brackets are bonded, and partial leveling and alignment are achieved with conventional fixed appliances After three to five months of treatment, assistant takes update scan in vivo to capture bracket and tooth positions
OraMetrix	 Processes update scan to produce 3-D model
Practice	• Doctor evaluates 3-D model and provides additional treatment specifications if necessary
OraMetrix	Produces prescription setup
Practice	 Doctor evaluates prescription setup and digital prescription archwires
OraMetrix	 Delivers custom prescription archwires
Practice	 Inserts custom prescription archwires to complete treatment

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Case 1: Class I Crowding. A 51-year-old female presented with a Class I malocclusion, moderate upper crowding, and severe lower crowding (A). The OraScanner was used to produce a SureSmile 3-D Initial Model (B). The orthodontist planned a nonextraction treatment approach, including 1mm of anteroposterior advancement of the lower incisors and 4mm of interproximal enamel reduction (continued on next page).





Case 1 (cont.) After .018" Mini Diamond** brackets were bonded, .017" \times .025" Copper Ni-Ti A_f 35°C archwires were used for initial leveling and alignment (C). Following four months of active treatment, an in vivo update scan was taken to capture the current bracket and tooth positions (D). The doctor reviewed the resulting setup (E), and a custom archwire prescription was produced by OraMetrix from .017" \times .025" Copper Ni-Ti A_f 35°C archwires (F). Three months after the archwires were installed, the patient was debonded. Total treatment time was eight months (G). Note that the upper left second bicuspid was kept out of occlusion in preparation for a crown.

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Case 2: Severe Crowding. A 20-year-old female presented with a Class I malocclusion and severe crowding (A). The clinician selected .022" Damon System 2^{**} brackets. Treatment was initiated with .018" Copper Ni-Ti archwires, followed by .017" × .025" Copper Ni-Ti SureSmile prescription archwires (B), and finally .019" × .025" Copper Ni-Ti archwires with a single refinement. Treatment was completed in eight and a half months (C).





Case 3: Asymmetry. A 20-year-old male presented with a Class I crowded malocclusion and a Class II tendency on the left side (A). Bonded with .022" Damon System 2 brackets, he started treatment on .014" round Copper Ni-Ti A_f 40°C archwires. Class II and III elastics were used to correct the asymmetry with an upper .017" \times .025" TMA** archwire. After four and a half months, .017" \times .025" Copper Ni-Ti SureSmile prescription archwires were installed (B). The upper arch was further refined with an .019" \times .025" titanium niobium SureSmile prescription archwire. Treatment was completed in 12¹/₂ months (C).





Case 4: Crossbite. A 38-year-old female presented with a Class I dental relationship, a bilateral crossbite, and a mildly prognathic mandible (A). She was bonded with .022" Damon System 2 brackets, and treatment was initiated with .014" round Copper Ni-Ti A_f 40°C archwires, followed by .016" Copper Ni-Ti archwires and crossbite elastics. After four and a half months of treatment, the patient was still in crossbite, and .017" \times .025" Copper Ni-Ti SureSmile prescription archwires were delivered (B). Two months later, when the crossbite was partially corrected, .019" \times .025" Copper Ni-Ti SureSmile prescription archwires were inserted (C). Total treatment time was 13¹/₂ months (D).





Case 5: Anterior Open Bite. An 18-year-old female presented with a relapsed anterior open bite, two years after orthodontic treatment (A,B). After considering the surgical options, the patient elected to return to braces. Her treatment began with .016" \times .022" Copper Ni-Ti archwires, using .022" Orthos** 2 and Inspire Ice** brackets. After four months, her .017" \times .025" Copper Ni-Ti SureSmile prescription archwires were inserted, with anterior box elastics. Three months later, a lower .019" \times .025" Copper Ni-Ti SureSmile prescription archwire was installed (C); the corresponding upper archwire was placed after another month. The patient was debonded four months later, when it seemed certain that the bite would hold (D). Her total treatment time was 13 months.



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Case 6: Deep Bite. A 30-year-old female presented with a Class II malocclusion and deep overbite (A). After .018" Mini Diamond brackets and posterior Bite Turbos** were bonded, initial .017" \times .025" Copper Ni-Ti archwires were placed, with tipback springs used for leveling and alignment. The .017" \times .025" Copper Ni-Ti SureSmile prescription archwires were then installed (B), and the tipback springs were continued, along with Class II elastics. Treatment was completed in nine months (C).



Clinical Findings

To date, more than 200 cases have been completed using SureSmile. The reaction to the OraScanner from both patients and operators has been favorable. After about 30 scans, most practices develop enough proficiency to reduce scanning to a 35-minute procedure (Fig. 1). They have found they need to continue scanning regularly, however, to maintain this skill level.

The first seven consecutively treated patients were independently evaluated according to ABO standards by the faculty of the Department of Orthodontics, Louisiana State University School of Dentistry (Fig. 2). These cases received an average score of 7.5 points and were all well within the standard of quality established by the ABO. We are in the process of broadening the study on quality of care to include all our patients, with additional measurements such as root resorption, patient comfort, and decalcification.

The efficiency of SureSmile treatment was



Fig. 1 Average scanning time and quality.



Fig. 2 Quality evaluation of first seven consecutively treated SureSmile cases by faculty of Department of Orthodontics, LSU School of Dentistry (red line = ABO quality standard; green line = SureSmile average, 7.5).

studied in a sample of Class I nonextraction patients, which generally represent about 40% of a practice. Participating doctors were asked to provide records of their conventionally treated patients, as well as similar cases they treated with SureSmile. The total sample included 135 conventional and 96 SureSmile patients, both representing a broad age range of males and females. The average treatment time for the SureSmile patients was 12.1 months, compared to 23.1 months for the conventionally treated cases (Fig. 3). These average times for traditional Class I treatment have been corroborated in studies by Sameshima⁴ and Callaway.⁵

Discussion

Our results indicate that the SureSmile system can produce a 48% reduction in Class I treatment time and a 20% gain in chairside capacity. We believe the latter will increase as a practice becomes more familiar with process control. Furthermore, our initial observations are that similar efficiencies can be anticipated in the treatment of all types of malocclusions, because, as noted by both Sameshima⁴ and Callaway,⁵ there tends to be little correlation between the difficulty of the case and the length of treatment.

This reduction in treatment time is directly attributable to the effectiveness of the custom archwire prescription. Although SureSmile does offer a computerized bracket placement feature to simulate tooth movements with different bracket prescriptions, all bracket positioning techniques are limited by the following factors:

• Brackets can't always be placed ideally due to partially erupted teeth, unusual dental anatomy, or severe crowding.

• Manufactured bracket tolerances can vary.

• Torque is affected by vertical bracket position.

Even with indirect bonding, the clinician will not know whether the bracket positions are correct until the end of treatment. In most cases, detailing bends are required in the final archwires.

On the other hand, the custom archwire is a dynamic prescription with the following advantages:

• It can compensate for tolerance in any particular bracket slot.

• The orthodontist can order an updated scan at any point in treatment to produce a new pre-scription.



Fig. 3 Efficiency comparison of SureSmile and conventionally treated cases with average treatment time from Callaway study.⁵

Conclusion

SureSmile combines technology and process control to produce high-quality, efficient results. The system allows treatment planning to be proactive, rather than reactive. Our clinical findings to date can be summarized as follows:

• Scanning can be effectively integrated into a practice routine with minimal disruption of the schedule.

• Three-dimensional diagnosis, treatment planning, and evaluation are skills that must be developed by the doctor, but, with commitment and discipline, can generally be learned in a reasonable time.

• SureSmile achieves results independent of bracket system or treatment philosophy.

• Copper Ni-Ti archwires can produce controlled tooth movement in all three planes of space, with or without elastics.

• Refinement archwires are occasionally needed, but in most cases can be avoided through careful evaluation of the setup.

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