“SureSmile, An Unbiased Review”

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*I, declare that neither I nor any member of my family have a financial arrangement or affiliation with any corporate organization offering financial support or grant monies for this continuing education presentation, nor do I have a financial interest in any commercial product(s) or services I will discuss in this presentation.

OVERVIEW

• Orthodontists today are faced with many new products and systems, each one being touted as the means to a better, faster, and more efficiently accomplished orthodontic treatment.

• Clinicians are challenged to scientifically evaluate promotional remarks and claims before utilizing new methods for the routine treatment of patients.
SURESMILE® (SS) METHOD

• “Suresmile” (SS) by Orametrix is a relatively new concept (founded in 1998) in computer aided treatment.

• In the present context, the method is used to facilitate orthodontics finishing.

• The first step for the SS system is to digitally capture a 3D image of the teeth and brackets in real time via an intraoral scanner or by cone beam computed tomography (CBCT).

• This digital information is then incorporated into a computer software, which develops a working 3D therapeutic model of the patient’s dentition.

• The doctor then uses this working model to create a virtual treatment plan within the software by digitally aligning the teeth and occlusion to the desired position of treatment outcome.

• Finally, the data from the digital treatment plan is used to direct a computer-aided robot to bend wires to move the teeth into the preprogrammed final position.
In a series of articles, Sachdeva et al. (2001-2009) described the SS process and philosophy of treatment:

- They defined a “patient-centered” practice as one that delivers high quality care with minimal patient discomfort, compliance demands, and chair time while completing treatment on time in as short a period as possible.
- SS is designed to substantially reduce errors in treatment resulting from appliance management, (bending wires) therefore shortening treatment time without sacrificing the quality of results.

ABO OBJECTIVE GRADING SYSTEM

- In 1998 the American Board of Orthodontics-Objective Grading System (CRE) was introduced to help determine the quality of an orthodontic finished case
ABO DISCREPANCY INDEX (DI)

• It was necessary to ensure that patient records submitted for board certification documented a sufficiently complex malocclusion to test the clinical skills of the candidate.

• There have been several methods developed to measure treatment difficulty, or need, as assessed by the world community: Peer Assessment Rating (PAR) index, the Dental Aesthetic Index (DAI), and Index of complexity, outcome and need (ICON).

• Since none of the established methods was deemed sufficient for board certification purposes, the ABO Discrepancy Index (DI) was developed.

• Subsequently the ABO DI and ABO CRE have evolved as the gold standards for determining malocclusion complexity and outcome quality for use in the board certification process.
REPORTED SS TREATMENT TIMES

• SS users initially were reporting a forty-eight percent drop in treatment time when utilizing the SS treatment protocol but this was on a limited number of patients.

• More recently, Moles (2009) reported an average treatment time of 13.1 months for the 500 patients he has treated with SS since incorporating this technology into his practice.

• Furthermore, Dr. Sachdeva’s (2005) initial group of patients had outcome scores that averaged 7.5 when using the ABO-CRE.

SS CLAIMS

• Both reduced treatment times and superior ABO-CRE scores require thorough documentation.
• What we are going to do is review the published literature. We will also review any problems associated with the publications.
  • Saxe, et al
  • Sachdeva, et al
  • Alford, et al
  • Groth, et al
  • Rangwala

SAXE AK, LOUIE LJ, MAH J, EFFICIENCY AND EFFECTIVENESS OF SURESMILE. WORLD J ORTHODONTICS 2010; 11:16-22

• Purpose
  • To examine the efficiency and effectiveness of the SureSmile process using the standards of the American Board of Orthodontists Objective Grading System
SAXE, ET AL

- 62 most recent consecutively completed SureSmile and conventionally treated patients
  - 38 SureSmile
  - 24 conventional
- Pretreatment models DI (No radiographs)
- Post-treatment models ABO-CrE (no radiographs)
- 3 offices of Board Certified Orthodontists provided the casts
- 2 calibrated examiners
- Treatment time was time from bonding to debond
- Exclusion criteria incomplete casts, articulator mounted casts, pts with missing molars, orthognathic surgery, prosthodontic restorations

SAXE, ET AL

RESULTS

- Data normally distributed with little skew and no kurtosis
- Mean scores of all data combined grader 1=27.3 (SD=7.8 SE=0.99) grader 2=28.7 (SD=8.1 SE=1.03)
- Pearson rank 0.96 between two graders but one was consistently higher
- ABO-CRE scores at P < .005
  - SureSmile: 26.3
  - Conventional: 30.7
- Individual components (authors state 14 components)
  - 11 were lower for SureSmile
  - 2 were equal
  - 1 was lower for conventional
SAXE, ET AL

• RESULTS
  • Treatment time: Independent samples difference of the means P < .001
    • Suresmile: 14.7 months
    • Conventional: 20 months
  • Level of difficulty: (Pairwise correlation analysis between DI and treatment time)
    • No meaningful correlation between the level of difficulty and the treatment result
    • This suggests there is no relationship between the level of difficulty and the treatment result.

SAXE, ET AL - CONCLUSIONS

• The treatment time for the Suresmile system compared to conventional orthodontics was significantly shorter by about 25%

• The ABO-CRE score for the SureSmile patients was, on average, 14.3% better than for those patients treated with conventional appliances
SAXE, ET AL

- Sample: 38 Suresmile and 24 conventional
  - Convenience sample not randomized
  - This size of sample is small
  - 3 offices—unsure how many came from each office or how the distribution between conventional and Suresmile from each office.
  - DI no radiographs. This is not a DI more like a PAR analysis which the ABO deemed insufficient to measure treatment difficulty
  - Table 5 of their paper they used and n of 76 for the Suresmile DI and an n of 48 for the conventional cases effectively doubling the sample size from what was actually used therefore not sure if samples are really different

SAXE, ET AL

- ABO-CRE authors state that for 5 of the 14 components of the OGS there is a statistical difference. However there is only 7 (when you exclude the panoramic radiograph) components not 14.
- Also, the authors used an n of 76 for Suresmile and an n of 48 for conventional for ABO-CRE
- Tx time was shorter is not surprising as that is what we found when we measured some of the same cases
TREATMENT TIME: SURESMILE VS CONVENTIONAL
SACHDEVA, ARANHA, EGAN, GROSS, SACHDEVA, CURRIER, KADIOGLU, SCIENTIFIC INNOVATION VOL.13:2012

• Purpose: To understand the efficiency of SureSmile treatment vs conventional treatment
  • Sample: 12,335 completed patient histories
    • 9,390 Suresmile patients
    • 2,945 Conventional patients
  • Variables measured
    • Treatment time in months from bonding to debonding
    • Angle classification (I, II, or III)
    • Age <18 or >18
    • Patient visits (total number of patient visits)
    • Non-parametric tests used to analyze the data

SACHDEVA, ET AL

• Results
  • Median treatment time for Suresmile 15 months compared with 23 months for conventional
    • Class I Suresmile-15 months, Conventional-23 months
    • Class II (SS)-13 months, Conventional-22 months
    • Class III (SS)-16 months, Conventional-24 months
    • Age (SS)under 18-16 months, over 18-15 months, Conventional under 18-24 months, over 18-24 months
    • Treatment visits median (SS) -14 visits, conventional-18
SACHDEVA, ET AL

- Sample size—very large however as they admit there is no standardization of records.
- 142 offices: unsure of distribution of conventional and Suresmile
- Unsure of selection criteria of the records submitted
- What exactly is a class I, II, or III malocclusion ie. How does vertical dimension effect tx time, width etc. Not sure we are comparing apples to apples
- Treatment visits not defined. Perhaps it would be better to measure chair time per care cycle
- Effects of extraction: The authors state at most 4 month difference but if conventional sample overloaded with ext cases and Suresmile all non-ext then difference in tx time would be 4 months less

CLINICAL OUTCOMES FOR PATIENTS FINISHED WITH THE SURESMILE METHOD COMPARED WITH CONVENTIONAL FIXED ORTHODONTIC THERAPY. ANGLE ORTHODONTIST 2011 MAY; 81(3) 383-8: ALFORD, ROBERTS, HARTSFIELD, ECKARDT, AND SNYDER

- Purpose
  - Investigate treatment quality and the treatment times of one orthodontist who has opted to use the SS technique in his office.
  - Compare cases treated with conventional mechanics before the user started using SS to SS patients, relative to overall ABO-CRE scores and treatment times.
  - Use the DI to assess complexity of malocclusions between the groups at the start of treatment.
ALFORD, ET AL

• Sample: 132 consecutively treated cases
  • 63 Conventional
  • 69 SureSmile

• Patient records included beginning casts, final casts, beginning and final panoramic radiographs, as well as beginning and final cephalometric radiographs.

• All of the patients were treated by one orthodontist.

ALFORD, ET AL

• SELECTION CRITERIA
  • Patients were treated to an optimal result in the opinion of the treating orthodontist.
  • Second molars are erupted and in occlusion.
  • No congenitally missing teeth.
  • No documented compliance problems.
ALFORD, ET AL

- The DI was determined for each patient following the guidelines of the American Board of Orthodontics.
- The final records of all cases were scored to obtain a numerical score for each of the eight categories of the CRE as well as total ABO-CRE score.
- The groups were compared for a difference in total ABO-CRE score as well as for differences between each of the eight different components that comprise the total ABO-CRE score.

ALFORD, ET AL

- From the patient histories, total treatment times were determined for each patient.
- For individuals that were treated in two phases, only that time in active treatment was considered when determining total treatment time. The rest phase retention was not considered as part of the treatment time.
- Patients in both groups were divided into braces only (no orthopedic treatment) and braces plus orthopedic therapy.
- For the latter patients, treatment times were divided into time spent in full fixed appliance alignment versus the orthopedic treatment phase.
- The investigator was blinded during all aspects of the scoring process.
ALFORD, ET AL

- Two-sample t-tests were used to compare the conventional and SS groups for differences in age and discrepancy index.
- A chi-square test was used to compare the two groups for differences in sex and whether the patient was treated using braces only.
- Analysis of covariance was used to compare the groups for differences in the ABO-CRE outcomes and treatment times, with sex and DI included as covariates because they are known factors that can influence the ABO-CRE outcomes and treatment times.
- A logarithmic transformation of the ABO-CRE outcomes and treatment times was used because their distributions were skewed.

### Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Conventional (n=63)</th>
<th>Suresmile (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>Age (start of treatment)</td>
<td>12</td>
<td>60</td>
</tr>
<tr>
<td>DI (Discrepancy Index)</td>
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<td>A/R (alignment and rotations)</td>
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<td>10</td>
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<td>MR (marginal ridges)</td>
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<tr>
<td>BL (buccal/lingual)</td>
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<td>OJ (overjet)</td>
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<tr>
<td>OC (occlusal contacts)</td>
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<tr>
<td>OR (occlusal relationship)</td>
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<tr>
<td>IC (interproximal contacts)</td>
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<tr>
<td>RA (root angulation)</td>
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<tr>
<td>total ABO-OGS score</td>
<td>9</td>
<td>38</td>
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<tr>
<td>Tx time: total</td>
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<td>71</td>
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<tr>
<td>Tx time: in braces alone</td>
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</tr>
<tr>
<td>Tx time: braces-only patients</td>
<td>14</td>
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</tbody>
</table>
ALFORD, ET AL

• Conclusions
  • SS computer-aided treatment produced significantly lower ABO-CRE scores in the first order alignment and rotation (AR), and the interproximal space closure (IC) categories.
  • The SS cases had significantly less treatment time (about 7 months) for patients treated in two phases and for patients who were treated with just braces.
  • For the patients receiving two-phase treatment or any orthopedic treatment, the decreased treatment time was attributable only to the time in fixed appliances.
  • The decreased treatment time is tempered by less complex malocclusions (lower DI) in the SS group.

ALFORD, ET AL

• Non-randomized study
  • SS patients were significantly less complex malocclusions.
  • Although the same clinician treated both samples of patients, he may have been more inclined to remove appliances when first and second order alignment was improved with SS treatment.
  • It is not clear that the same guidelines for “an optimal” result were used for both samples of patients.
COMPUTER-ASSISTED ORTHODONTICS: A BLINDED, MULTI-CENTER ANALYSIS OF FINISH QUALITY IN PATIENTS TREATED WITHOUT EXTRACTIONS: GROTH, MCNAMARA, FRANCHI

• Purpose
  • To evaluate the efficiency and efficacy of a group of orthodontic patients treated with the SureSmile® system, compared to a matched sample of patients treated with conventional fixed appliance treatment

GROTH, ET AL

• Sample
  • Prospective study
  • 89 consecutively treated patients for each group
  • Five practices six tx groups with one practice contributing to both SS and conventional groups
  • Age 12-18
  • Samples matched for DI, slot size, angle class
  • All patients non-extraction
GROTH, ET AL

• Records collected
  • Initial and final panoramic and cephalometric radiographs
  • Digital or stone models at T1 and stone models at T2
  • Treatment notes for each patient
    • Age at T1
    • Age at T2
    • Treatment duration
    • Number of treatment appointments

GROTH, ET AL

• Statistics
  • Descriptive statistics of means and std deviations for age, treatment time, number of appointments, and for each ABO category of the CRE
  • Independent sample t-tests were used to compare treatment time and the number of appointments between SS and conventional groups and between each group
  • Spearman’s rank to compare DI and final CRE
  • Intrgrader reliability was .989
GROTH, ET AL

• Methods
  • All records were transferred to XXXX and randomized
  • All stone models were converted to digital format
  • A DI was determined on the digital models without cephalometrics
  • CRE hand scored on stone models
  • From the treatment notes age at T1, age at T2, treatment duration (bond date to debond date), number of adjustment appointments (non-emergency)

GROTH, ET AL

• Results
  • Chi Square showed no difference between groups in DI, age, or gender
  • Treatment duration was significantly different with SS groups averaging 13.4 months and the conventional tx groups 22.4 months
  • SS groups had significantly less treatment visits at 9.2 versus 17.2 for conventional
  • No statistical difference in total CRE score between groups
GROTH, ET AL

- SS groups had higher buccal-lingual angulation by 0.7 pts
- Conventional groups had higher scores in the root angulation category by 0.4 points
- Scatter plots show no difference between starting DI and CRE for these treatment groups

GROTH, ET AL

- Non-randomized sample
- Claim prospective study but really retrospective
- DI not properly calculated no cephalometrics therefore not taking vertical dimension into account so complexity not really known
- Comparing Dr. A to Dr. B in treatment timing. Dr. A may complete his cases faster than Dr. B no matter what method of treatment is used
TREATMENT OUTCOME ASSESSMENT OF SURESMILE COMPARED TO CONVENTIONAL ORTHODONTIC TREATMENT USING THE AMERICAN BOARD OF ORTHODONTICS GRADING SYSTEM: RANGWALA, (GRADUATE RESEARCH THESIS)

- The purpose of this study is to compare the orthodontic treatment outcomes of the SureSmile process to conventional treatment without computer-assistance, using the ABO-CRE method. This retrospective comparative cohort study, which accounts for pretreatment complexity, will attempt to provide evidence regarding which type of treatment provides better final results for moderately complex malocclusions.

RANGWALA

- Sample
  - Two groups of 33 each prescreened for DI's between 14-25
  - Picked for having “best outcomes”
  - Measurements for Group I (SureSmile) all made by one examiner
  - Measurements for Group II (Conventional) were made by “several residents”
  - All examiners checked for intra-examiner reliability
RANGWALA

- Statistics
  - Descriptive statistics for categorical variables (gender, extraction versus non-ext, and pass/fail CRE scores) were used
  - Means and standard deviations or medians and ranges were used for continuous variables (start age, debond age, treatment duration, DI scores, and CRE scores)
  - Chi Square tests were used to determine differences between categorical variables
  - For dichotomous outcomes (pass/fail) logistic regression analysis was used to control for pretreatment DI

RANGWALA

- Wilcoxon Rank Sum tests were used to test for differences in continuous variables
- Multiple regression analysis were used to control for pretreatment DI in the analysis of the association between groups (SS and Con) and each of the CRE and total CRE score
RANGWALA

• Results:
  • Chi-squared test showed:
    • No difference in gender between the two groups
    • A statistical difference in ext cases with 13 (39%) for Con vs 3 (9%) for SS
  • Wilcoxon Rank Sum Test:
    • No difference between mean DI between groups
    • Significant difference between CRE scores with SS lower (17.03) and Con (21.61)
    • SS lower in A/R, OJ, Occlusal contacts, Occlusal relationships
    • Con lower in marginal ridge
    • No difference in buccolingual, interproximal contacts, root angulation

RANGWALA

• Assuming a total CRE score of 20 is a passing grade Chi-squared test showed a significant difference in pass rates of SS (73%) and Conv (45%)
• Odds ration of 3.19 means SS 3 times more likely to get passing grade
• Wilcoxon Rank Sum Test showed a significant difference in treatment time with SS 1.51 years and Conv 2.47 years
Conclusions;

- Moderately complex malocclusions treated with SS had better final treatment outcomes than those treated with conventional treatment without computer-assistance.
- The “typical” SS cases had significantly lower total CRE scores than those “best treated” with conventional treatment.
- The SS group had significantly more passing CRE scores, as assumed by the ABO (20), than conventionally treated group.
- There was no significant difference in DI scores between groups.
- The treatment duration was significantly shorter for the SS group.

Non-random sample

- Multiple operators and graders (group one experienced Board Certified, group 2 multiple residents treating to “best results”)
- Not surprising that an experienced orthodontist would treat cases faster than multiple orthodontic residents.
- Unsure of what to means for a resident to treat to ”best results”
DISCUSSION

• 5 studies
  • Three refereed journals
  • Two masters thesis'
<table>
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<tr>
<th></th>
<th>CRE SS</th>
<th>CRE CON</th>
<th>TX TIME SS</th>
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<td>ALFORD</td>
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<td>20.8</td>
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<td>RANGWALA</td>
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<td>sig</td>
<td>21.61</td>
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<td></td>
</tr>
</tbody>
</table>
• ALFORD: 7 MO

• GROTH: 4.9MO (Practice 1)

SUMMARY

• CRE scores: jury still out (Saxe, Rangwala showed lower scores. Alford and Grothe did not)

• Reasonably expect a decrease in tx time for relatively easy cases

• Economic issue which is different for each office
• Thank you very much