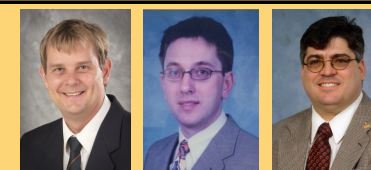# Patient compliance and pain perception using low-intensity pulsed ultrasound (LIPUS) to accelerate tooth movement

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INTRODUCTION

SmileSonica Inc. is a Canadian medical device company which produces the Aevo System™ to enhance or accelerate orthodontic tooth movement via therapeutic ultrasound (LIPUS).

When used for one 20-minute period per day as a complement to braces, the Aevo System enhances osteoblast and osteoclast activity resulting in accelerated alveolar bone remodeling and, therefore, faster orthodontic tooth movement and reduction in root resorption.
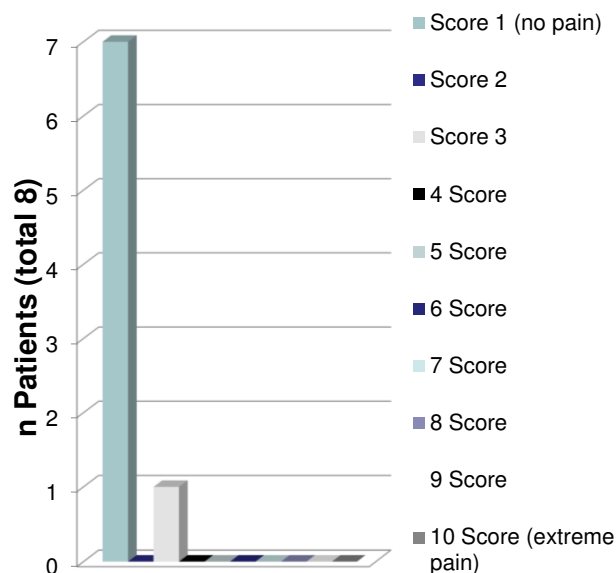
OBJECTIVES

To clinically assess patient compliance and pain perception with the Aevo System.

MATERIALS & METHODS

Eight subjects (12 to 23 y.o.) from a university-based (4) and private orthodontic office site (4) with full fixed braces and 1st premolar extractions, used the Aevo System on a requested daily basis for 20 minutes, until extraction space closure was accomplished employing a split-mouth design.

Compliance was ascertained from the Aevo System in-clinic software and a pain perception questionnaire was completed by the subjects.

Patient Pain Perception

- Score 1 (no pain)
- Score 2
- Score 3
- 4 Score
- 5 Score
- 6 Score
- 7 Score
- 8 Score
- 9 Score
- 10 Score (extreme pain)

n Patients (total 8)

Pain Perceprion Score form 1 to 10

Patients	Patient Compliance
For all patients	38.8% to 99.3%
University-based patients	54.3% average
Private office patients	74.8% average

RESULTS

Preliminary data are presented in this research report.

Patient compliance varied from 38.8% - 99.3%. On average patients from the private office were more compliant (74.8%) than university-based patients (54.3%).

On a pain perception scale from 1 to 10 (1= no pain and 10 = extreme pain), 7 of 8 patients recorded a score of 1, and 1 patient, a score of 3, which was also the only patient with a pain score in the control group.

Generally, from the five multi-site centers across Canada, results show that the Aevo System provides a statistically significant increase in tooth movement rate ($p<0.05$), with an average percentage increase of 29.0% in tooth movement, compared to the controls.

It was also shown that the Aevo System had a statistically significant decrease in root resorption rate ($p<0.05$), with the control having a root resorption rate on average 220.8% higher than Aevo System.

Finally, there was no increase in adverse events or pain reported for the Aevo System as compared to the control ($p< 0.05$).

CONCLUSIONS

There exists a wide range in patient compliance in system usage. Patients do not perceive any increase in pain when using this device. Tooth movement is accelerated.

Manufactured by SmileSonica Inc. in Canada, ISO 13485 certified.

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