



# WAVE - A NEW HOME USE DEVICE BY Silk'n®

## THAT IMPROVES MULTIPLE ORAL CONDITIONS

Over time, various impurities such as stains and calculus (tartar), attach to the teeth's surface by strong electrochemical bonds.

Calculus is a form of hardened dental plaque, caused by precipitation of minerals from the saliva on the teeth. Calculus can form both along the gum line, and within the narrow sulcus that exists between the teeth and the gingiva. Calculus buildup along the gum line is the most common cause of Gingivitis (gum disease).

Discoloration occurs when pigmented residue from certain foods, drinks, or tobacco attach to the film of protein that covers the tooth enamel. The accumulation of this residue forms extrinsic stains. As these impurities are held in place by strong molecular bonds, they are impossible to remove using regular means of daily dental hygiene. While the removal of calculus demands the equipment of a dental hygienist, discoloration and teeth stains can be tackled only by chemicals which are either ineffective or commercially banned for safety reasons.

Home Skinovations Ltd. has developed a safe and effective toothbrush for daily home use, which utilizes low power RF energy (DentalRF™), that in addition to plaque removal (similar to other power toothbrushes), is capable of removing discoloration, extrinsic teeth stains and even tartar, with the intention to effectively prevent gingival inflammation and to improve the user's aesthetic appearance. ToothWave emits RF energy that streams between two electrodes and over a silicon barrier (Figure 1).

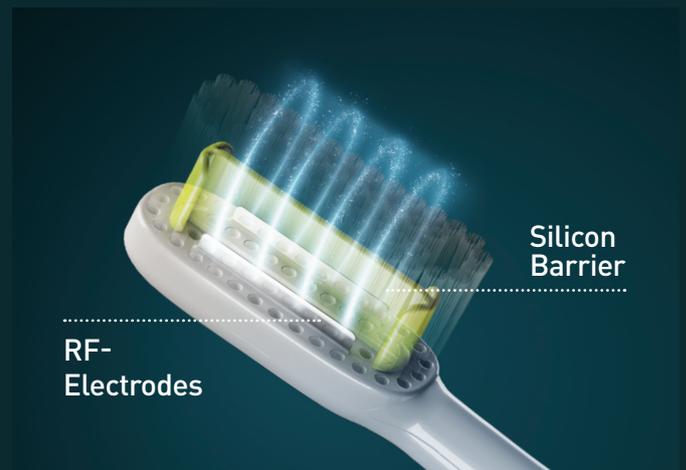


Figure 1:  
Schematic representation of the toothbrush head

Two clinical studies were performed by Salus Research Inc., located in Indiana, US. The studies were conducted according to Good Clinical Practice (GCP) guidelines as required by the regulatory authorities.

These single-blind controlled studies included a treatment group using ToothWave™, and a control group using an ordinary electric toothbrush (without DentalRF), accepted by the ADA. The first study (N=85) measured the effect of each brush on plaque,

gingivitis and calculus reduction, whilst the second study (N=84) measured the effect on whitening and stain reduction. The studies included 84 treatment sessions and 4 clinic visits over a period of 6 weeks. Treatment was defined as a timed 2 minutes of teeth brushing in a regular manner, twice a day (morning and evening) using standard fluoride toothpaste. For each patient, assessment data was collected at baseline, at 4 weeks, and at 6 weeks. Results are presented in figures 2-7.

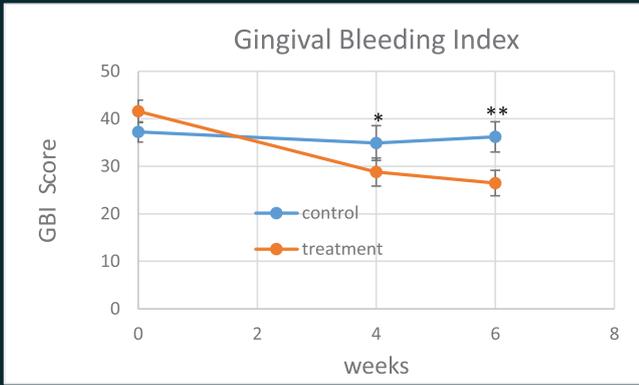


Figure 2: Gingival Bleeding Index (GBI) is significantly lower in the treatment group as compared to the control group following 6 weeks of brushing (\*p=0.023).

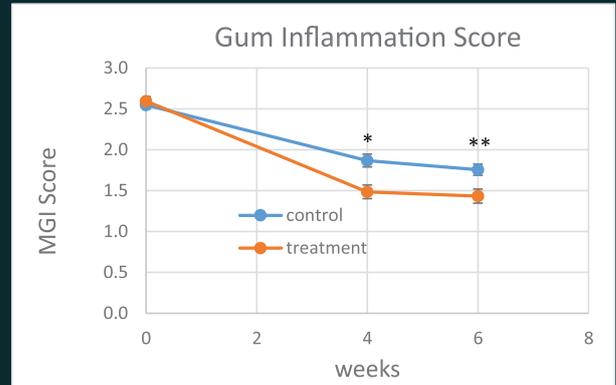


Figure 3: Gum Inflammation (MGI) is significantly lower in the treatment group as compared to the control group following 4 and 6 weeks of brushing (\*p=0.001, \*\*p=0.003).

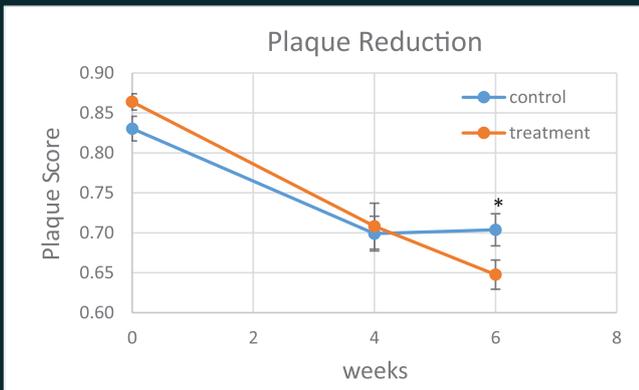


Figure 4: Plaque Score (RMNPI) in the treatment group is significantly lower as compared to the control group following 6 weeks of brushing (\*p=0.051).

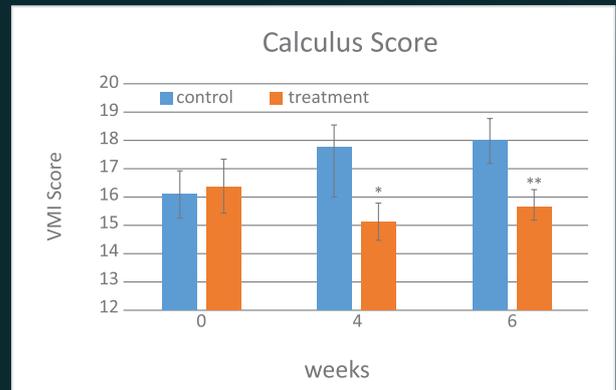


Figure 5: Calculus Score (VMI) is reduced in the treatment group and was increased in the control group during the test phase of the study. (\*p=0.009; \*\*p=0.028).

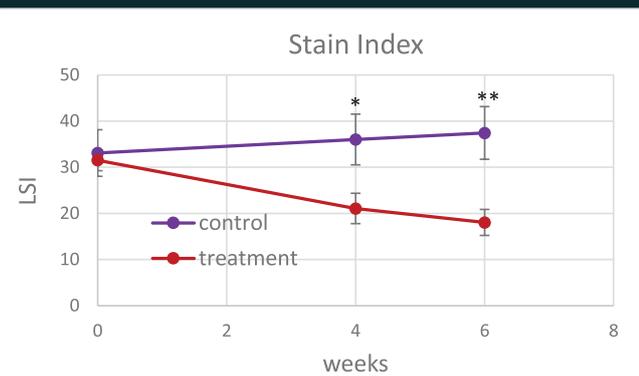


Figure 6: Stain Index (LSI) is significantly lower in the treatment group as compared to the control group following 4 and 6 weeks of brushing (\*p<0.001).



Figure 7: Teeth Shade Index (VITA Bleachguide 3D Master) in the treatment group is significantly lower as compared to the control group following 6 weeks of brushing (\*p=0.024).

## CONCLUSION

The results from the clinical studies show that when compared to an ordinary electric toothbrush (without DentalRF), accepted by the American Dental Association (ADA), ToothWave not only performs far better, in all tested parameters, but also removes tartar while the ordinary electric toothbrush doesn't. For more information, contact: Home Skinovations Ltd.