

XyliMelts time-release adhering discs for night time oral dryness

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Introduction. Xerostomia (dry mouth or cotton mouth) is caused by many medications, by radiation treatment, by Sjogren's syndrome, and by airway pressure machines for sleep apnea, with the prevalence increasing with age. In most individuals, daytime dryness can be managed via a number of simple strategies. However, at present there are no products designed to be used at night to reduce the oral dryness perceived upon awakening during the night or in the morning. The purpose of this study was to assess whether a self-adhering, slowly-dissolving disc that time releases 500mg xylitol, cellulose gum (lubricant and humectant), and mild peppermint flavor (Xylimelts for Dry Mouth, OraHealth Corp.) could reduce perceived oral dryness and discomfort while sleeping.

Methods and Materials. Subjects between the ages of 19 and 66 who self identified as having morning oral dryness were evaluated twice in late afternoon seven days apart. For seven days after a baseline evaluation, each subject adhered one XyliMelts disc to the buccal side of a maxillary first molar or adjoining gingiva after each meal (3 discs per day) and two discs (one each side) at bed time. At each evaluation, each subject used a 100 mm visual analogue scale (VAS) to report perceived level of mouth moisture and level of oral discomfort upon awakening from nighttime sleeping.

Results. Fifteen subjects were evaluated. Their mean age was 46.21. Mean initial morning oral wetness without using XyliMelts discs while sleeping was rated at 22.2 (SD 15.2) and with use of XyliMelts while sleeping at 67.8 (SD 14.9) ($t = -8.79, p < .001$). The mean for initial discomfort without the discs was rated as 65.2 (SD 21.8) and with use of XyliMelts while sleeping as 27.6 (SD 17.5) ($t = 6.43, p < .001$). These findings indicate that there was significant improvement in subjective wetness

and a significant decrease in perceived morning discomfort when XyliMelts were used while sleeping. When used during the day, the mean duration before a disc was perceived to be fully dissolved was 69 minutes (range - one-half to two hours). All subjects reported that the disks were easily placed. One subject reported mild nausea after initial placement which dissipated with further use. No other adverse reactions were reported by any subject during use of the product.

These findings show that there is a significant improvement in subjective wetness and a significant decrease in perceived morning discomfort when XyliMelts for Dry Mouth adhering discs are used while sleeping. Use of XyliMelts for Dry Mouth while sleeping caused perceived morning oral wetness scores to increase more than three fold.

Conclusion: For xerostomia, use of XyliMelts for Dry Mouth time-release adhering discs while sleeping significantly improves perceived oral wetness and significantly improves perceived discomfort.

Morning Oral Wetness

