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Effectiveness of Biotene in Treatment of Xerostomia – A Systematic Review



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ABSTRACT

BACKGROUND: Biotene is an artificial salivary substitute formulated to manage the symptoms of dry mouth caused due to various systemic conditions and diseases, including common medications, autoimmune diseases, and exposure to radiation of the head and neck region. **AIM:** To assess the effectiveness of Biotene in the treatment of xerostomia. **METHODS:** A literature search was performed using PubMed, Ovid Medline, Elsevier science direct, Wiley online library, Cochrane Library, Lilacs, and Google scholar using the MeSH terms- xerostomia, Biotene, salivary substitute. Of 58 articles, 9 were full-text articles assessed for eligibility, and five were taken for the qualitative analysis. This review was reported according to the PRISMA guidelines. Five randomized control trials were selected for the review process. **RESULTS:** Biotene showed statistically significant results compared to other salivary substitutes in all the studies. Biotene was equally effective in providing symptomatic relief for xerostomia patients. **CONCLUSION:** Biotene was found to be effective in treating the symptoms of xerostomia when compared to other salivary substitutes.



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INTRODUCTION:

Saliva is an extracellular fluid secreted by the mouth's salivary glands, a fluid essential for the patient's oral health. It functions as a lubricant and antimicrobial, preventing tooth decay, improving digestion, and helping taste perception^[1]. When the salivary secretion is less or absent, the condition is known as xerostomia[oral dryness].in addition to impairing oral health, this may also increase the risk of dental caries, periodontal disease, and oral opportunistic infections^[2]. Xerostomia patients experience a burning sensation, abnormal taste, halitosis, dysphagia, and inability to retain dentures^[3].Many older adults suffer from xerostomia, which adversely affects their well-being^[4]. Approximately 14-16% of adults suffer from xerostomia, a condition affecting the general population^[5].It is common to develop dry mouth due to various serious systemic conditions and diseases, including common medications, autoimmune diseases, and exposure to radiation of the head and neck region ^[6].There are several long-term causes of xerostomia, including chronic diseases such as diabetes, Sjogren's syndrome, Parkinson's disease, rheumatoid arthritis, parotid gland disorders, malignancies of the head and neck, and their treatment, head and neck surgery, an anamnestic radiation^[7,8,9], and systemic lupus erythematosus^[10].It may be preferable to administer artificial saliva to alleviate the symptoms and suppress infections caused by microorganisms such as candida. Biotene is one of the over-the-counter products available for this purpose^[11].Biotene is a dental hygiene product intended to relieve dry mouth symptoms^[12]. It contains an active ingredient called sodium monofluorophosphate and enzymes like lactoperoxidase, lysozyme, and lactoferrin, which mimic the properties of human saliva, which is why it is also referred to as artificial saliva^[13].In addition to providing moisture, it also cleans the oral cavity. Biotene is available as an alcohol-free mouthwash, sugar-free chewing gum, toothpaste, and Oral balance gel is available as a moisturizing gel. Upon contact with plaque-forming bacteria, Biotene produces an antibacterial enzyme system that penetrates the cell walls and destroys them just below the gum line in the oral cavity. Oral balance moisturizing gel is felt to prevent moisture loss, thereby soothes and protecting the dry oral tissues^[14]. This allows Biotene to be the preferable choice in the treatment of xerostomia. In a report given by Riley and Kairalla, Biotene Oral balance gel has been found to significantly reduce microorganisms growth rate compared to controls after 24 hours of in vitro culture^[15].In light of the insufficient evidence in Biotene's effects in the treatment of xerostomia, this study is intended to systematically review the related articles to present some scientific evidence.

OBJECTIVE:

To assess the effectiveness of Biotene in the treatment of xerostomia.

MATERIALS AND METHODS

Study Design:

A Systematic review of randomized control trials that evaluated Biotene's efficacy during the treatment of xerostomia. A total number of 58 articles were referred in which five articles were selected based on inclusion and exclusion criteria using PRISMA guidelines.

Search Strategy:

The following databases were used to find published articles on randomized control trials for the effectiveness of Biotene in the treatment of xerostomia: PubMed, Ovid Medline, Elsevier science direct, Wiley online library, Cochrane Library, Lilacs, and Google scholar. Each database was searched to obtain the articles using specific MeSH terms- xerostomia, Biotene, salivary substitutes. Cochrane database was used to collect articles using PRISMA guidelines and bias assessment.

INCLUSION CRITERIA:

- Articles related to the topic
- Articles focusing on Biotene
- Articles that are only Randomized control trials
- Articles in English
- Full-text articles

EXCLUSION CRITERIA:

- Articles not related to the topic
- Articles focusing on other properties of Biotene
- Studies focusing on other treatment options
- Studies other than randomized control trials.

- Articles in other languages

Figure 1: Flow diagram showing the number of studies identified, screened, assessed for eligibility, excluded, and included in the systematic review.

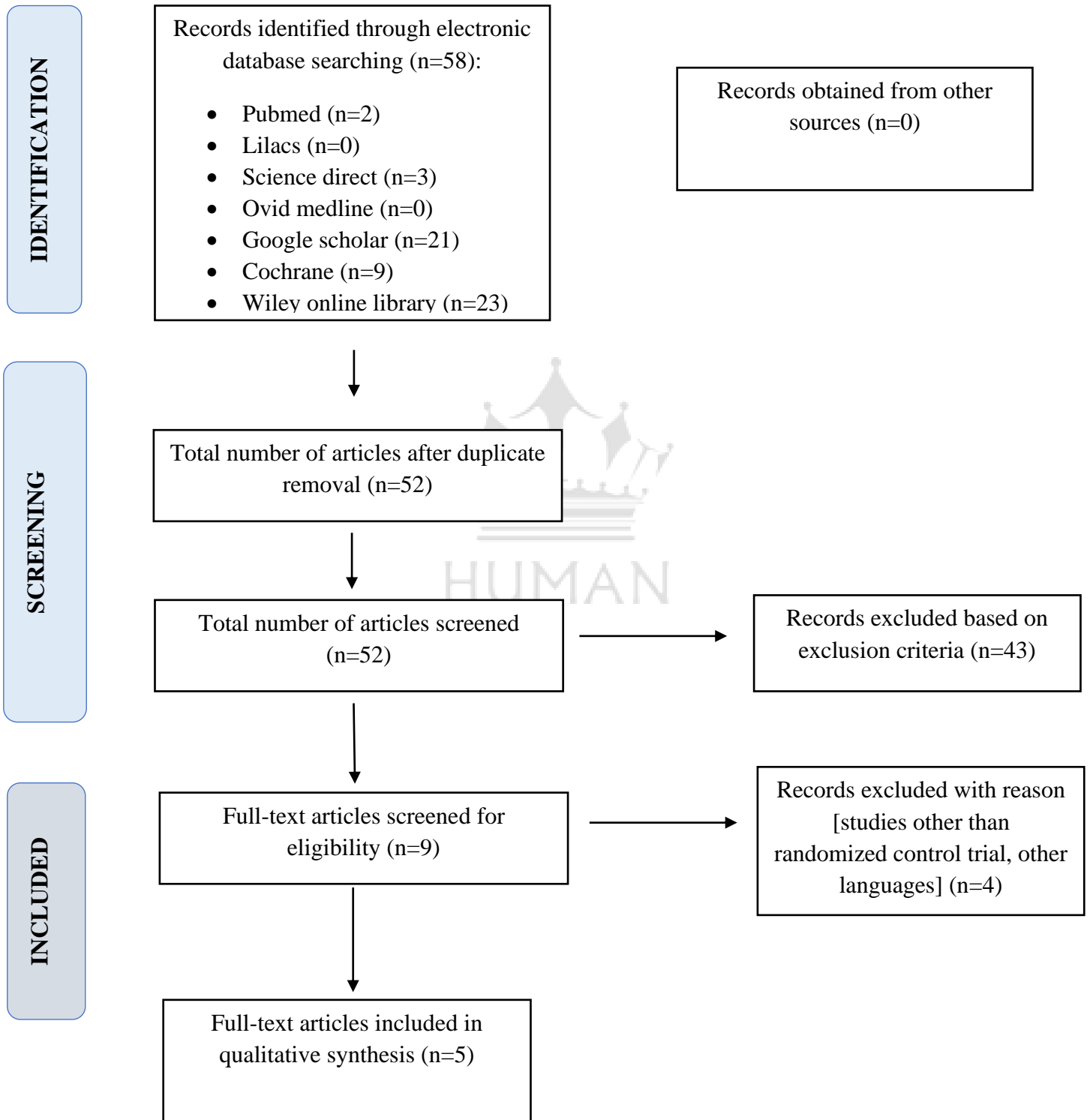


TABLE 1: CHARACTERISTICS OF THE INTERVENTIONS IN THE INCLUDED STUDIES

S.NO	AUTHOR NAME	YEAR OF PUBLICATION	SAMPLE SIZE	PATIENT CHARACTERISTICS	DURATION	INTERVENTION
1.	Shahad S.A. et al. ^[15]	2005	20 [18 male, 2 female]	Patients were aged 18 years or older, with previous radiotherapy treatment for head and neck cancer	2 weeks	Group 1: use of OB for 2 weeks followed by 1 week of no salivary substitute use followed by 2 weeks of using BX. Group 2: use of BX followed by 1 week of no salivary substitute use followed by 2 weeks of using OB.
2.	Michel Salomet al. ^[16]	2015	180	Patient 18 years or older with a clinical diagnosis of xerostomia or any medical condition associated with xerostomia	2 weeks each separated by a 3-7 day washout period.	Patients were randomized into two groups with crossover after 2 weeks of treatment on each period to assess Novasial [5ml single-dose stick] and Aequasal or Biotene oral spray.
3.	Anna Greta Barbe et al. ^[17]	2017	40	Minimal age of the patient - 18 years Daily intake of at least one drug by patients with medication-induced xerostomia is listed as a declared side effect in product inserts or subjective xerostomia	28 days followed by a 21 days washout period followed by another 28 days.	Patients were randomized with crossover after 28 days to treatment with GUM Hydral or Biotene oral balance gel.

4.	J.B. Epstein et al. ^[18]	1998	19[14 male,5 female]	Patients with persisting xerostomia following radiation therapy to the head and neck	First period-2 weeks followed by a 1 week washout second period-3 weeks.	Patients were randomized into two groups with crossover after 2 weeks of treatment on each period of the trial to assess Oral Balance gel and Biotene toothpaste compared to a placebo.
5.	Anna Greta Barbe et al. ^[2]	2019	32	Patients had xerostomia independent of the reasons of dry mouth symptoms	Phase 1-7 days followed by a 7- day washout phase, then Phase 2- 7 days.	Patients were randomized to investigate the efficacy of test gel[Dr.Wolff Gel] versus control [biotene]

INTERPRETATION: Based on the characteristics of the articles chosen for the study, it is interpreted that Biotene effectively alleviates symptoms of xerostomia.

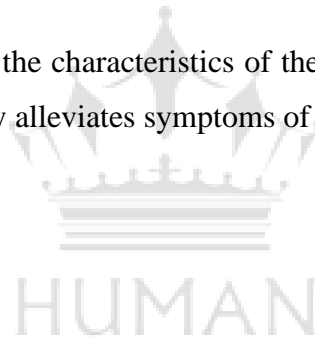


TABLE 2: OUTCOME OF THE STUDY

S.NO	AUTHOR NAME	YEAR OF PUBLICATION	OUTCOME	RESULT
1.	Shahad S.A. et al. ^[15]	2005	Both treatments effectively treated the symptoms, but BX was better in some outcomes.	BX was rated as more pleasant than OB[p<0.05] and was statistically significant.
2.	Michel Salomet al. ^[16]	2015	Novasial was a safe and well acceptable treatment compared to Aequasyl and Biotene.	Novasial reduced oral mouth dryness by 19.5%, (12.5 +/- 22.6 mm, P < .0001 versus baseline), versus 10% (6.6 +/-17.9 mm with Aequasyl, P < .0001 versus Baseline; and P < .0156 versus Novasial) and 13% (8.6 +/- 18.9 mm) with Biotene (P < .0001 versus baseline).
3.	Anna Greta Barbe et al. ^[17]	2017	Both products were effective in improving oral health.	Gum Hydral and Biotene Oral Balance significantly reduced VAS [p<0.05] GUM Hydral significantly reduced the XQ Part 1 dysphagia score. Biotene Oral balance significantly reduced the halitosis organoleptic score and plaque index.
4.	J.B. Epstein et al. ^[18]	1998	Oral balance gel and Biotene toothpaste showed greater improvement in symptoms of xerostomia.	Oral Balance Gel and Biotene toothpaste showed statistically significant improvements.
5.	Anna Greta Barbe et al. ^[21]	2019	No mouth gel alleviated the overall xerostomic burden, and overall perceived symptomatic relief lasted 2 hours.	Differences favoured the test gel for symptom-relieving effects between test gel and water (p<0.001) and were statistically significant.

TABLE 3: BIAS ASSESSMENT AS INCLUDED IN THE STUDIES

AUTHOR NAME, YEAR	RANDOM SEQUENCE GENERATION	ALLOCATION CONCEALMENT	BLINDING OF OUTCOME	INCOMPLETE OUTCOME DATA	BLINDING OF PARTICIPANTS AND PERSONNEL	SELECTIVE REPORTING
Shahad S.A. et al. ^[15] [2005]	+	+	+	+	+	+
Michel Salomet al. ^[16] [2015]	+	-	+	+	?	+
Anna Greta Barbe et al. ^[17] [2017]	?	+	+	+	+	+
J.B. Epstein et al. ^[18] [1998]	?	+	+	?	+	+
Anna Greta Barbe et al. ^[2] [2019]	+	+	+	+	+	+

+ = low risk; - = high risk; ? = unclear risk of bias

DISCUSSION:

The most effective way to treat xerostomia is to treat the symptoms of dry mouth. Biotene is a salivary substitute that can provide relief and suppress infections caused by microorganisms in the mouth. In addition, since it mimics the properties of saliva, it can also be used as a tool in dental hygiene. This systematic review found results that favoured the effectiveness of Biotene. Shahad S.A. et al.^[15] Reported on the efficacy of Bioxtra [BX] and Biotene Oral balance systems. Both the products were effective; thereby, there is a reduction in the visual analog scale scores from day0-14. When both the groups were compared based on the perception of dry mouth and improvements in speech, it was identified that BX achieved significantly better results when compared to OB. It was also more pleasant than OB [p<0.05] and had a long-lasting lubricating effect. As a result, both

treatments eased symptoms of post-radiotherapy xerostomia, though BX achieved superior outcomes in some assessments compared to OB. The effect of Novasial, Aequasyl, and Biotene on treating xerostomia caused by various causes has been reported by Michel Salom et al. [16]. As there was a 10-19.5% decrease in VAS scores, all three medications effectively reduced mouth dryness, chewing difficulties, and taste alteration. Furthermore, in patients with xerostomia caused by head and neck radiation, Novasial was effective because it was well tolerated, and the patients were willing to continue treatment. Therefore, it was concluded that Novasial had better outcomes than the others. Anna Greta Barbe et al. [17] reported that both GUM Hydral and Biotene oral balance significantly [$p < 0.05$] reduced VAS, OHIPG-14 total score and single items, and XQ Part 1 [oral dryness, oral pain, taste loss] and Part 2 items. Biotene Oral balance significantly reduced the halitosis organoleptic score and plaque index. GUM Hydral significantly reduced the XQ Part 1 dysphagia score. Both the products effectively improved oral health and alleviated symptoms of dry mouth. The double-blind crossover trial of Oral Balance gel and Biotene toothpaste versus placebo done by J.B. Epstein et al. [18] reported that Biotene toothpaste [Laclede products] were more effective than the control products. Patients who used this product reported reduced dry mouth symptoms. The trial conducted by Anna Greta Barbe et al. [2] [2019] reported that neither the test gel nor Biotene reduced the symptoms. It provided a short-term symptomatic relief and improved tastes and gum health. Based on the study results, Biotene is effective in addressing xerostomia symptoms to provide comfort and relief to patients suffering from xerostomia.

CONCLUSION:

Regardless of the underlying cause, Biotene was found to treat the symptoms of xerostomia. It was found to provide symptomatic relief for a short duration, but long-term results were questionable. Further clinical studies involving longer time and larger samples are advised to be initiated to acknowledge the full extent of its efficacy as a salivary substitute.

LIMITATION OF THE STUDY:

The articles didn't mention the ability of Biotene to instigate salivary secretion.

CONFLICT OF INTEREST: Nil

ACKNOWLEDGEMENT: Nil

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