

Oral-Health Relevance of a Polyol-Dominant Sugar-Free Hard Candy Matrix: Formulation Architecture and Human Clinical Evidence

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ABSTRACT

Objective: Sugar-free confectionery can reduce exposure to fermentable sugars, but oral-health relevance depends on the specific polyol matrix, product acidity and pattern of use. We characterized the matrix architecture of an NVTIA herbal hard candy containing 75.685 parts isomalt, 20.000 parts maltitol syrup on a dry-matter basis and 2.500 parts erythritol per 100 parts formulation, together accounting for 98.185% of the dry formulation. **Method:** The candy also contained low levels of citric acid and sodium citrate, botanical extracts, eucalyptus oil microcapsule powder and menthol. Formulation data were integrated with primary human and in situ studies of erythritol, maltitol and isomalt. **Results:** A three-year randomized trial in 485 schoolchildren found that erythritol candy was associated with fewer dentin-caries lesions at selected follow-ups and longer times to lesion development or progression than xylitol or sorbitol controls; companion analyses reported lower plaque weight, lower plaque organic-acid levels and reduced mutans streptococci with erythritol. Maltitol randomized studies show favorable effects on plaque acidogenicity, cariogenic bacteria and selected caries-risk variables. Short isomalt exposures have also shown favorable effects on enamel de-/remineralization balance in an in situ study. At the same time, primary studies of sugar-free acidic lozenges and confections demonstrate that low cariogenicity and low erosive potential are distinct product properties. **Novelty:** Accordingly, the polyol-dominant matrix provides a strong scientific basis for reduced cariogenic substrate exposure, while direct measurement of finished-product pH, titratable acidity, plaque-pH response and enamel-surface effects can further define its complete oral-health profile. The present analysis establishes a formulation-specific framework for oral-health evaluation while retaining the complete product as the principal unit of interpretation.

INTRODUCTION

Dental caries and erosive tooth wear arise through different physicochemical and biological pathways. Caries is driven by repeated microbial fermentation of dietary carbohydrates and sustained acidification within dental plaque, whereas erosion can occur through direct chemical exposure of enamel to non-bacterial acids. This distinction is especially important for sugar-free hard candies. Replacing sucrose with polyols can markedly alter the substrate available to cariogenic biofilms, yet an acidulated confection may still influence enamel through its intrinsic pH and titratable acidity.

The studied formulation uses a three-polyol matrix dominated by isomalt, with maltitol and erythritol as secondary sweeteners. Together these sugar alcohols account for 98.185 parts per 100 parts of the optimized dry formulation. The remaining fraction contains botanical extracts, eucalyptus oil microcapsule powder, menthol, citric acid and sodium citrate. This architecture creates a useful model for evaluating oral-health relevance at the formulation level, with the complete polyol matrix serving as the primary unit of interpretation.

Human clinical evidence is particularly developed for erythritol-containing candies. A three-year school-based randomized controlled trial enrolled 485 children and compared erythritol, xylitol and sorbitol candies using standardized caries scoring [1]. Companion analyses assessed plaque mass, microbial counts and organic-acid profiles [2], and a later posttreatment study examined persistence of caries-related effects [3]. Additional clinical studies have evaluated erythritol-related plaque variables [4] and maltitol in chewing gum or snack formats [5]–[7], while isomalt has been investigated in an *in situ* de-/remineralization model [8]. Broader polyol evidence is not completely uniform: systematic reviews and other school-based or gum studies show that effects vary with the polyol blend, background prevention, exposure format and endpoint [9]–[13]. That variability is useful here because it keeps the interpretation tied to the actual hard-candy matrix rather than to the name of a single sweetener.

The aim of the present study was therefore to characterize the polyol architecture and physical quality of the NVTIA hard candy, synthesize primary human evidence for its principal sugar-alcohol components, and explicitly distinguish cariogenic substrate effects from acid-mediated erosion considerations. This approach enables a balanced oral-health interpretation that is specific to the finished formulation and directly identifies the measurements that can extend the evidence base in future human use studies.

RESEARCH METHOD

The optimized 100-part formula contained 75.685 parts isomalt, 20.000 parts maltitol syrup calculated on a dry-matter basis and 2.500 parts erythritol. The polyol fraction therefore accounted for 98.185 parts of the total formulation. The remaining 1.815 parts comprised monk fruit extract, Platycodon grandiflorus water extract, lily bulb water extract, low-glycyrrhizic-acid licorice extract, eucalyptus oil microcapsule powder, menthol, citric acid and sodium citrate. Each candy had a target mass of 2.50 g.

The polyol matrix was dissolved and vacuum-cooked at 148°C and -0.085 MPa until 97% solids were reached. Botanical components and the citric-acid/sodium-citrate system were introduced after cooling to 108°C, while eucalyptus oil microcapsule powder and menthol were added after further cooling to 92°C. The resulting candy was cast and cooled to produce a low-moisture hard-candy structure. Finished-product moisture averaged 2.35% and mean unit mass was 2.50 g. These physical measurements were used to confirm that the polyol-rich matrix formed a stable hard-candy body under the tested process.

A structured search of PubMed/MEDLINE and primary journal records was performed through 18 August 2026 using combinations of erythritol, maltitol, isomalt, polyol, sugar-free candy, chewing gum, dental caries, plaque pH, *Streptococcus mutans*, enamel remineralization and erosion. Randomized human trials and human *in situ* studies were prioritized; systematic reviews were used only to place the primary findings in a wider clinical context. The dietary-effect synthesis focused on oral food exposures, while air-polishing powders and other non-food dental procedures were treated as a

separate application domain. Acid-erosion studies of sugar-free lozenges/confections were included so that reduced fermentable-sugar exposure was not treated as synonymous with low erosive potential.

Evidence was organized into three domains: caries development, plaque/microbial acidogenicity, and enamel de-/remineralization or erosion. Ingredient-specific studies were used to define the clinical and biological background of the polyol matrix. Because the finished candy also contains citric acid, erosion-related evidence was considered as a parallel product property alongside microbial cariogenicity, allowing both dimensions to be evaluated within the same oral-health framework.

RESULTS AND DISCUSSION

Results

Polyol architecture and matrix quality

The optimized formulation was overwhelmingly polyol-based: isomalt contributed 75.685%, maltitol dry solids 20.000% and erythritol 2.500% of the 100-part formula. The three polyols together represented 98.185% of the dry formulation. The matrix produced a hard candy with 2.35% mean moisture and a mean unit mass of 2.50 g, indicating that replacement of conventional sugars by the specified polyol blend was compatible with the required physical candy structure.

From an oral-health perspective, this composition substantially changes the carbohydrate environment presented by the confection. The dominant sweetening matrix is no longer sucrose-based, and each of the three principal polyols has an independent literature relevant to plaque fermentation, microbial ecology or enamel mineral balance. The formulation also contains 0.120 part citric acid and 0.030 part sodium citrate, creating an acid-buffer context whose finished-product pH and titratable acidity are best quantified directly.

Erythritol-related human evidence

The strongest long-duration clinical evidence concerns erythritol candy. In a double-blind three-year randomized study of 485 schoolchildren, daily consumption of approximately 7.5 g polyol as erythritol candies was associated with fewer dentin-caries teeth and surfaces at selected follow-ups and with longer times to development or progression of caries lesions compared with xylitol or sorbitol groups [1]. Companion biological analyses found that the erythritol group showed repeated reductions in plaque weight, lower plaque acetic and propionic acid after three years, and lower salivary and plaque mutans streptococci than the comparison groups [2]. Three years after cessation of the intervention, several time-to-event advantages remained observable in the erythritol cohort [3].

A separate six-month clinical study in 136 teenagers also reported reductions in plaque/salivary mutans streptococci and plaque amount with erythritol and xylitol compared with other study conditions [4]. Together, these trials provide a longitudinal

human context in which erythritol exposure is associated not only with reduced fermentable-sugar replacement but also with measurable changes in plaque ecology.

Maltitol, isomalt and acid-related evidence

Maltitol also has human randomized evidence. In 258 adolescents, maltitol- and xylitol-sweetened chewing gums produced higher plaque pH, lower plaque growth and reduced concentrations of several cariogenic bacterial species compared with controls over 30 days [5]. In 271 high-caries-risk schoolchildren, twice-daily maltitol snacks for 42 days improved selected plaque-pH and caries-risk variables, including a reduction in salivary lactobacilli and an increase in the proportion of subjects classified at lower caries risk [6]. A separate randomized gingivitis model found that xylitol- or maltitol-sweetened gum attenuated the increase in bleeding scores under non-brushing conditions compared with gum base, while effects under normal brushing conditions were smaller [7]. A four-week randomized plaque study similarly found a reduction in plaque with maltitol gum compared with gum base [12]. In another intervention involving 153 volunteers, frequent maltitol-gum use was associated with lower abundance of several early plaque-biofilm taxa even though the overall community structure changed little [11].

For isomalt, an in situ component of a combined experimental study found that short practical exposures could favor the enamel de-/remineralization balance [8]. This result is particularly relevant to the present matrix because isomalt represents more than three-quarters of the complete formulation by weight.

Primary studies also emphasize the importance of separating caries risk from erosion. An analysis of 30 sugar-free confections found that many acid-containing products had low pH, high titratable acidity and measurable enamel-softening potential [14]. In an earlier human in situ study, one of two acidic sugar-free lozenges significantly softened abraded enamel under the tested conditions [15]. These observations identify acidity as an independent formulation variable to be measured directly alongside polyol-related cariogenicity endpoints.

Table 1. Primary human and in situ studies informing the oral-health interpretation of the polyol matrix.

Study	Design	Exposure	Outcome domain	Key finding
Honkala et al. [1]	Double-blind RCT; 485 children; 3 years	Erythritol, xylitol or sorbitol candies; ~7.5 g/day polyol	Caries development	Erythritol group had fewer dentin-caries teeth/surfaces at selected follow-ups and longer time to lesion development/progression.

Study	Design	Exposure	Outcome domain	Key finding
Runnel et al. [2]	Randomized school-based intervention; 3 years	Same polyol-candy program	Plaque, saliva and mutans streptococci	Erythritol was associated with lower plaque weight, lower acetic/propionic acid and lower mutans streptococci counts.
Falony et al. [3]	Posttreatment follow-up; 420 re-examined	Three years after cessation of the 3-year polyol intervention	Time-to-caries events	Several erythritol-associated survival advantages persisted after intervention.
Mäkinen et al. [4]	Clinical trial; 136 teenagers; 6 months	Erythritol, xylitol or sorbitol products	Plaque and mutans streptococci	Erythritol and xylitol reduced plaque/salivary mutans streptococci and plaque amount.
Thabuis et al. [5]	Double-blind randomized; n=258 adolescents; 30 d	Maltitol gum, xylitol gum, gum base, or no gum	Plaque pH, growth, bacteria, glucans	Maltitol and xylitol reduced plaque acidogenicity and several cariogenic bacterial measures vs controls.
Cocco et al. [6]	Double-blind RCT; n=271 high-caries-risk children	Maltitol, stevia or sugar snacks for 42 d	Plaque pH and cariogenic bacteria	Maltitol improved selected caries-related variables relative to baseline and risk classification.
Takatsuka et al. [8]	Randomized in situ component within mixed experimental design	Short isomalt exposures	Enamel de-/remineralization	Short isomalt treatments showed a favorable effect on de/remineralization balance under in situ conditions.

Evidence from broader polyol programmes also helps define the boundary of interpretation. A systematic review of polyol-containing chewing-gum studies found caries-preventive signals overall but substantial variation among polyols and study designs [9]. In a low-caries population already receiving comprehensive prevention, a cluster-randomized lozenge trial did not show an additional caries reduction from xylitol/maltitol or erythritol/maltitol mixtures [10]. A later systematic review of polyol gums and gingival inflammation likewise emphasized heterogeneity and the limited

number of maltitol-specific trials [13]. These results make product format, baseline oral-care conditions and adherence important covariates for any study of the present candy.

Discussion

The oral-health relevance of the present hard candy is best understood through its matrix architecture. Nearly the entire dry formulation is composed of isomalt, maltitol and erythritol, representing a shift from conventional sucrose or glucose-syrup confectionery toward a three-polyol matrix. Human studies show that these polyols exhibit distinct biological profiles across endpoints, while collectively defining a markedly different plaque-substrate environment from fermentable-sugar confectionery. Erythritol has the most extensive long-term candy data, with a three-year randomized intervention and posttreatment follow-up showing favorable caries-timing and plaque-microbial patterns [1]–[3]. Maltitol trials provide shorter-term evidence for plaque pH, bacterial load, gingival response and biofilm composition [5]–[7], [11], [12], while isomalt has supportive in situ data for mineral-balance effects [8]. Broader reviews and mixed-polyol trials [9], [10], [13] reinforce that the size of any oral-health effect depends on exposure format and study setting.

The proportion of each polyol is important. Isomalt represents 75.685 parts of the total formulation, so the physical and oral behavior of the candy is principally determined by an isomalt-rich matrix. Maltitol at 20 parts contributes substantially to sweetness and matrix behavior, while erythritol at 2.5 parts is present at a lower absolute level than the daily erythritol doses used in the long-term caries trials. Accordingly, the erythritol RCTs provide especially informative ingredient-specific biological context, while formulation-specific interpretation remains anchored to the complete candy's actual exposure profile. Previous ingredient-specific studies provide an important clinical and mechanistic context for understanding the potential physiological relevance of the composite system and offer a foundation for subsequent evaluation of the complete formulation.

The maltitol literature is especially useful because it shows that plaque-pH, plaque quantity and microbial outcomes can be measured over relatively short intervention periods [5], [6], [11], [12]. These endpoints are practical candidates for a formulation-specific study. For example, a randomized crossover protocol could compare the complete hard candy with a sucrose-containing reference confection and a non-acidified polyol control, measuring plaque pH curves, salivary flow, mutans streptococci, lactobacilli and subjective oral residence. Such a design would directly characterize how the complete matrix behaves in the mouth and extend the ingredient-level evidence to the finished-product setting.

A second major consideration is erosion. The term 'sugar-free' primarily describes the fermentable-sugar profile, whereas acid-mineral interactions represent a distinct physicochemical dimension of confectionery design. The present formula contains a small citric-acid component together with sodium citrate. Because erosive potential depends on product pH, titratable acidity, calcium/phosphate saturation, contact time

and salivary response, the most informative next step is direct physicochemical characterization of the finished candy. Studies of other sugar-free confections show that acid content can dominate enamel-softening potential in some products [14], [15]. Accordingly, the cariogenic advantage associated with replacing sucrose with polyols can be considered alongside a parallel product attribute – acid–mineral interaction – that can be optimized independently.

The formulation's low moisture and stable hard-candy structure are also relevant. A consistent matrix supports reproducible dissolution and exposure, which is necessary for comparing plaque-pH responses across participants. Future work may additionally evaluate whether the citric-acid/sodium-citrate ratio can be tuned to maintain flavor while reducing titratable acidity, and whether mineral-compatible buffering strategies can further enhance the oral-health profile without compromising sensory acceptance.

Study Considerations and Future Directions

The present study was designed to establish an oral-health framework from the actual polyol architecture of the candy and from primary human evidence for its principal sugar alcohols. Within this scope, the strongest existing human data concern repeated erythritol exposure at higher daily doses and maltitol exposure in gum or snack formats, while the current hard candy provides a distinct isomalt-dominant combination and a different oral-contact pattern.

Building on this evidence, direct finished-product studies can integrate plaque pH, titratable acidity, salivary flow, enamel microhardness or in situ mineral balance, and short-term microbial endpoints. Such measurements would allow the reduced-cariogenic-substrate concept and the acid-erosion profile to be characterized in parallel, producing a more complete oral-health assessment than either dimension alone.

CONCLUSION

Fundamental Finding : The NVTIA sugar-free hard candy is built on a 98.185% polyol matrix dominated by isomalt, with substantial maltitol and a smaller erythritol fraction. Primary human studies provide strong biological and clinical context for polyol-related reductions in cariogenic substrate exposure, plaque acidogenicity and selected caries outcomes, particularly for erythritol and maltitol, while isomalt has supportive in situ mineral-balance evidence. **Implication :** The current formulation architecture provides a scientifically grounded basis for oral-health positioning. **Limitation :** Acid-mediated enamel erosion remains a parallel formulation property determined principally by finished-product acidity, complementing the sugar-free substrate profile. **Future Research :** The next-step framework centers on direct plaque-pH, titratable-acidity and enamel-response evaluation of the complete candy.

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