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Measuring Mechanical Properties of Medicated Chewing Gum and Evaluating Chewing Efficiency for Different Shape Teeth

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Abstract: Medicinal chewing gum (MCG) is a relatively new drug delivery platform that offers significant advantages over traditional tablets. However, the lack of suitable testing methods has slowed its adoption by the pharmaceutical industry. The official pharmacopoeia does not recommend a formal test method to determine the mechanical properties of MCGs. This project uses a two-bite test method to assess the mechanical and textural properties of MCG to investigate the effect of experimental parameters on the results.

Keywords: Medicated chewing gum (MCG); Two-bite test; Texture profile analysis; Teeth shape

1. Introduction

1.1 Background

Medicated chewing gums (MCGs) represent a unique platform for drug delivery. They have been defined as solid single-dose preparations. which may contain more than one active pharmaceutical ingredient (API) with a base consisting primarily of gum that has to be chewed for a certain period [1]. Despite their advantages in drug delivery, MCGs remain a niche product due to the scarcity of studies concerning the evaluation of the mechanical properties of MCGs and the lack of suitable testing methods.

1.2 Project Aim and Process

The focus of this project was on the analysis of the textural profile of the MCG and the effect of tooth shape on masticatory efficiency. Because an official test method to determine the mechanical properties of MCG has not been recommended by official pharmacopoeias, Texture Profile Analysis (two-bite test), which is already widely used [2], is used to test the mechanical and structural properties of chewing gum. The mechanical analysis of human teeth occlusion and masticatory shows that a chewing sequence: shearing, crushing, and grinding [3] is required to take place to allow effective processing of food including chewing gums. Moreover, molars have a major role in the crushing, grinding, and chewing of food to dimensions suitable for swallowing. Therefore, Molars are good for testing chewing gum [4]. A replica of human teeth used in clinical study provided by the supervisor, Kazem Alemzadeh,

The general approach is listed below:

1. Conduct a literature survey and analyse the two-bite test for chewing gums, specifically medicated.

2. Design and fabricate three sets of different shapes of maxillary and mandibular teeth to be in-house to the fabricated set of adaptors. And then design review for the Instron machine's set of adaptors to in-house a set of maxillary and mandibular teeth and submit the engineering drawings for fabrication to the workshop.

3. Design and Experiments (DOE) for a two-bite test using an Instron machine based on Al Hagbani [5] and co-workers (2017-2021), and the view of other researchers.

2. Literature Review

2.1 Medicated Chewing Gum

The drug components in MCG need to be mechanically processed to be released, they need to be chewed until the active ingredient is fully released and then the remaining gum is discarded. The MCG delivery method has significant advantages over conventional tablets [6]. First, the drug is absorbed through the oral mucosa rather than the gut, thus the risk of gastrointestinal problems is reduced and the susceptible drugs contained are protected from chemical or enzymatic attack in the gastrointestinal (GI) tract. Second, it has a low risk of overdose because chewing is required to release the drug. Third, it is more accessible to children, adolescents, and other patients who have difficulty swallowing pills.

2.2 Texture Profile Analysis (Two-bite test)

2.2.1 Introduction

Two-bite test (a form of texture profile analysis, TPA) is used to quantify the mechanical and textural characteristics of the food. The purpose is to simulate two bites of the food by a human through two consecutive uniaxial compression cycles with a probe. Dr Szczesniak developed the original TPA parameters as part of her sensory work at the General Foods Technical Centre in the early 1960s and created an instrument (the General Foods Texturizer) that could enhance their sensory work and objectively quantify texture. The immediate predecessor, the Strain Gauge Denture Tenderometer of MIT[7].

2.2.2 Properties

Mechanical properties, textural properties and work done in compression were calculated by extracting information from two-bite test deformation curves. Three distinguishable textural parameters for cohesiveness, springiness, and chewiness were extracted from the TPA as reported by Al-Muhtaseb.

Cohesiveness is the ability of a product to withstand a second deformation relative to the resistance under the first deformation.

$$Cohesiveness = \frac{A_2}{A_1} \tag{1}$$

Springiness is the physical rebound of a product after it has deformed during the first compression, allowing for a target waiting time between compressions.

$$Springiness = \frac{t_{B-C}}{t_{A-D}} \tag{2}$$

Chewiness is considered a secondary textural characteristic when force is applied to food products.

$$Chewiness = F_D \frac{A_2}{A_1} * \frac{t_{B-C}}{t_{A-D}} \tag{3}$$

where F_D (N)is the peak force that occurs during the first compression (Hardness).

$$Compressibility = \frac{(d_{A-D} + d_{B-C})}{\text{Original thickness}} \tag{4}$$

where d_{A-D} and d_{B-C} are the distances between A and D, and between B and C, respectively. Collectively, d_{A-D} + d_{B-C} represents the total reduction in CGT thickness after the two compression cycles.

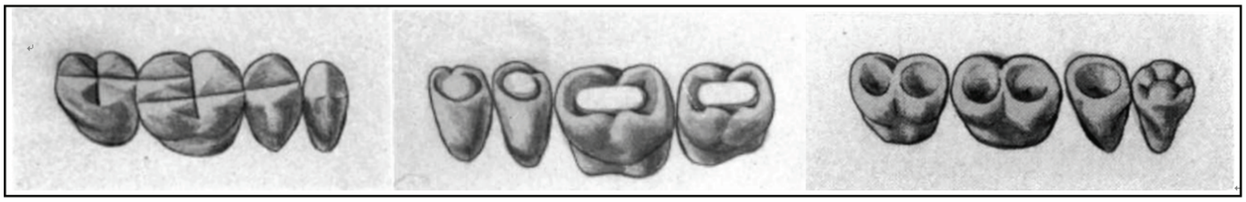
The work done in compression was calculated using Equation 5:

$$\text{Work done} = D_1 + D_2 \tag{5}$$

where D_1 and D_2 are the areas under the curve in Figure 1.

3. Teeth Design

Hardy mentioned some types of famous artificial teeth. McGrane's teeth (Fig. 1a) have a high cutting efficiency and are suitable for simulating the chewing process of shearing. Geometric" teeth, designed by LaDue and Saffir (Fig. 1b) and Hall's teeth (Fig. 1c) have better crushing efficiency which is appropriate to simulate the crushing process.



a McGrane's teeth **b LaDue and Saffir teeth** **c Hall's teeth**

Fig.1 Types of artificial teeth

This experiment focused on simulating the two phases of mastication separately: shearing and crushing, rather than focusing on the precise shape of the tooth.

3.1 Knife-edge shape (shearing)

The optimal design to break a strong or stiff food (shearing) item would concentrate forces onto a small area of initial contacts, such as a sharp cusp tip. Therefore, the knife-edge shape is suitable for shearing, which was also used by Setiady. Through the bigger contact area, the lower efficiency shearing, the sharp cusp is prone to fracture and suppresses crack propagation, which causes MCGs to not be chewed sufficiently.

3.2 Mortar and pestle shape (crushing)

For molars, the Pattern of cusps and grooves is similar to a mortar and pestle for crushing food. Therefore, a combination of a mortar and a pestle should be used as the shape of teeth for crushing. However, it was found that because of the low strength of the 3d printed material, this flat shape could not withstand the required force and broke. This design strengthens the wall to base joint and allows it to complete the entire experiment.

3.3 Semi-circle (crushing)

The hemi-circle is another tooth shape that has been used to simulate the crushing process and the diameter is 11.3 mm. It is more like the shape of a mortar and pestle and has a complex force during mastication, which is used in comparison to the second design to test which shape has higher chewing efficiency.

4. Methodology for Two-bite test

For humans, only the lower jaw moves during chewing, but the machine only moves the upper adaptor. Therefore, the maxilla teeth are mounted on the lower adapter and the mandible teeth on the upper adaptor, opposite to a normal human jaw.

4.1 Sensitivity Analysis

A type of flat plate teeth is used to evaluate the effects of changing different test parameters on experimental results.It excluded the effect of tooth shape and the angle between the upper and lower jaws on masticatory efficiency. A comparison of the image of the flat plate teeth with the image of the designed teeth allows the characteristics of each tooth to be observed quite easily.

4.2 Parameter Settings

Two-bite tests are performed on MCG specimens by the Instron 50 KN 2580 series Static Load Cell machine (Instron, Massachusetts, USA), and the software Bluehill Universal (Instron, Massachusetts, USA) is used to analyse the data.

4.2.1 Compression Speed and Compression Ratio

According to Rosenthal's results, the speed of compression is more than about 2 mm/s increases in the speed of compression make little difference to the hardness. Therefore, the speed of compression needs to be at least greater than or equal to 2 mm/s. The flat plate teeth are used to test speeds from 2 mm/s to 10 mm/s (the maximum speed of the Instron machine used) to see if the speed affected mastication efficiency in this experiment.

4.2.2 Chewing interval

A typical interval of 1-2 seconds is recommended by Burt. Therefore, about a 1.5 s interval is used in this experiment, which gives a stroke length of 13.78 mm. The distance between mandible teeth and MCGs is 2 mm.

5. Result

The shape of MCGs after chewing by different teeth. Each type of teeth is tested ten times and the average value is calculated and used in Table 1. The results of the ten tests fluctuate within an acceptable range. The flat plate teeth are used as the base tooth shape for the control group to see the effect of the change in tooth shape.

For artificial teeth, the different materials do give an effect on the experimental results, which is discussed in Section 6. Artificial teeth have the highest chewing efficiency, and the highest damage to the internal structure of the MCGs and require the least amount of force to chew MCGs. Which makes it suitable for crushing while having a high shearing capacity. For mortar and pestle teeth, a large force is required to complete the mastication process and a high sample rebound happens.

6. Conclusion

Two-bite tests were carried out with different test parameters to calculate the textural and mechanical properties of the MCG. The project found that, apart from the elasticity of the textural properties, the replica tooth output had much lower mechanical and textural properties as well as the highest masticatory efficiency than the other designs. The test parameters are found to influence the results, supporting Peleg's assertion that textural properties are not intensive MCG material properties and therefore cannot be used in isolation, but rather as a comparison to see the effect of varying the test parameters. In future performance analyses of MCGs, the two-bite test could be used and the artificial teeth with a FMA angle of 29.1 degrees is a better choice for experiment, but experimental parameters other than the part to be studied would need to be fixed to reduce their impact on the experimental results.

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