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Purpose

As evidenced by the issuance of recent industry guidance: 2013 Guidance on Safety Considerations for Product Design to Minimize Medication Errors¹ and the New Guidance for Industry: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules², the FDA continues to look at oral solid dosage formulation (OSDF) design to reduce medication errors and aid in patient compliance and adherence. The purpose of this study was to investigate consumer preferences for oral dosage form designs. In addition, the perceptions of specific tablet physical characteristics mentioned in the FDA guidance were studied. The information collected in this pilot study can be used to assist pharmaceutical companies during the design and development of OSDF.

Methods

A survey style questionnaire was used to interview males (n=132) and females (n=122) of working age +18 years. The questionnaire contained open and rank order questions used together with 3D tablet models.

The main focus of this pilot study was on OSDF and therefore, the characteristics investigated included:

- Preference of dosage type: liquid, tablet or capsule
- Perceptions of ease of swallowing and handling for tablets:
 - Shape and size: oval, round, and caplet, ranging from 150-900 mg (Figure 1)
 - Dimension: thick, standard, and thin (Figure 2)
 - Gloss finish: high, medium, and low gloss (Figure 3)
- Shape memorability: square, triangle, oval, shield, caplet, half moon, kidney, and double-arrow (Figure 4)
- Color shade preference: light, medium, and dark (Figure 5)

Figure 1. Tablet Shape and Size



Figure 2. Tablet Dimension



Figure 3. Tablet Finish

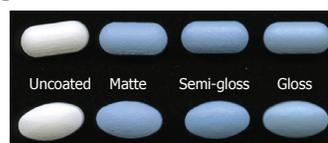


Figure 4. Tablet Shape for Distinction and Memorability



Figure 5. Tablet Color and Shade

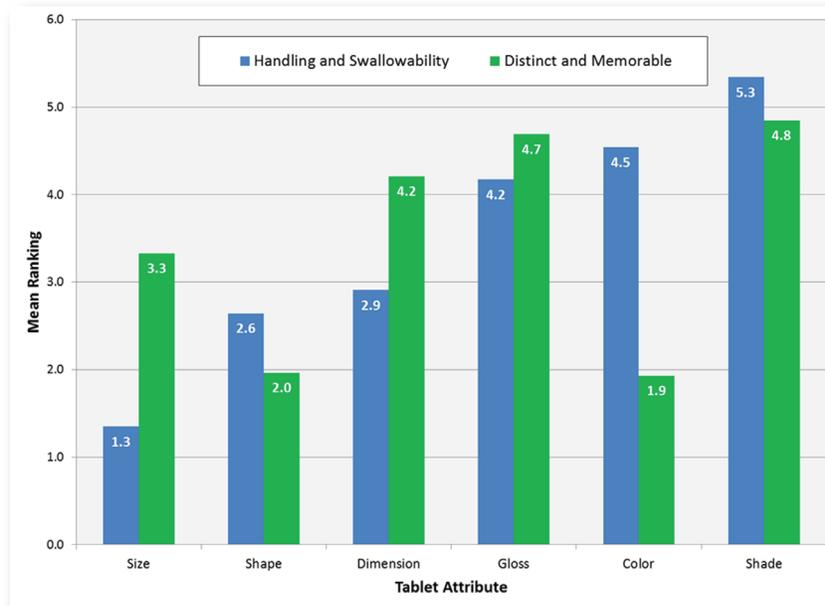


Responses were collected and assigned scores based on the ranking of preference, with lower values indicating higher levels of preference. The Wilcoxon signed-rank test was utilized to measure statistical significance of the responses at a 0.05 significance level.

Results

Of the participants surveyed 65% preferred SODF, 5% preferred liquid dosage form and 30% had no dosage form preference. As shown in Figure 6, the tablet size, shape and dimension (thickness) were considered the most important attributes for ease of handling and swallowing; while shape and color were determined as the most distinctive and memorable attribute of a tablet.

Figure 6. Patient Preference for Tablet Attributes Related to Ease of Handling / Swallowing or Distinctive and Memorable



Each attribute was further investigated, by preference, for ease of handling and swallowability. Figure 7 show tablets less than or equal to 450mg are more preferred than larger tablets. Interestingly the 150mg tablet, the smallest evaluated, was not the most preferred. This is theorized to be related to the difficulty of handling smaller tablets and therefore a 300 to 450 mg tablet is an ideal balance between ease of handling and swallowing.

Figure 7. Consumer Preference for Tablet Size as Related to Ease of Handling and Swallowing

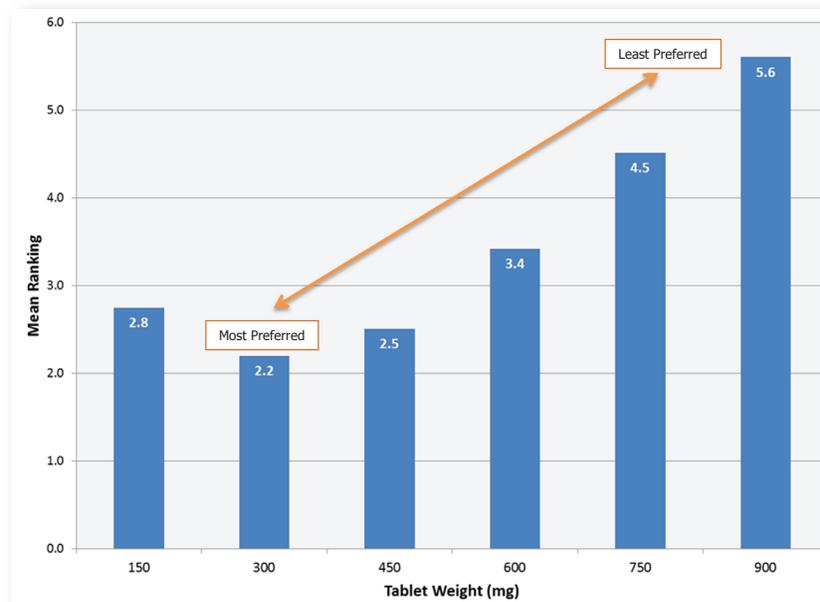


Figure 8 shows tablet shapes with oblong and round edges, like the caplet and oval, are most preferred. With more unique tablet shapes this trend is also seen, as the double-arrow, kidney and shield were preferred over the triangle, square and half-moon, which have broader and sharper corners.

As shown in Figure 9, high gloss was most preferred for ease of swallowing and handling. Film coated tablets in general are easier to swallow.³

Figure 8. Consumer Preference for Tablet Shape as Related to Ease of Handling and Swallowing

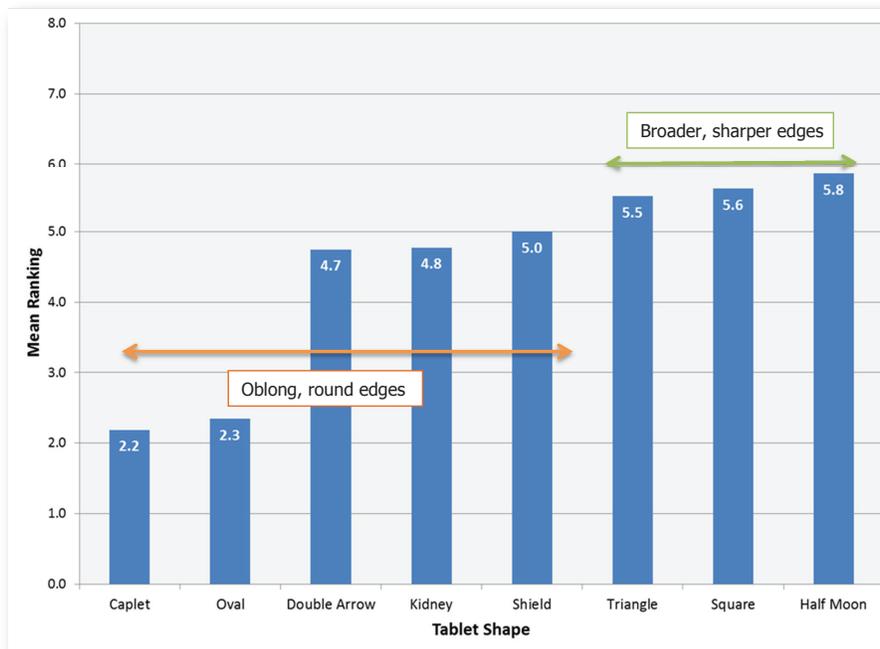
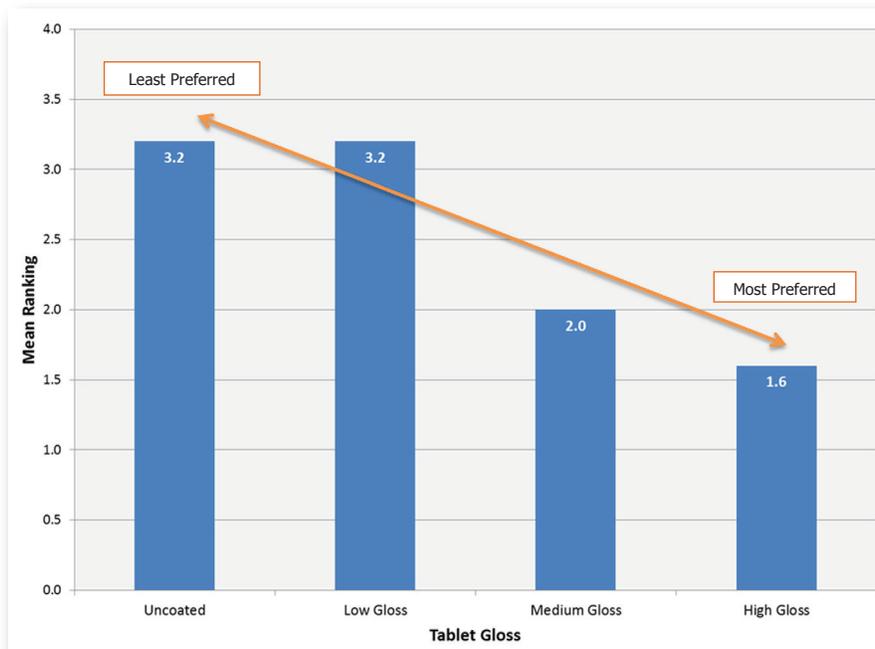
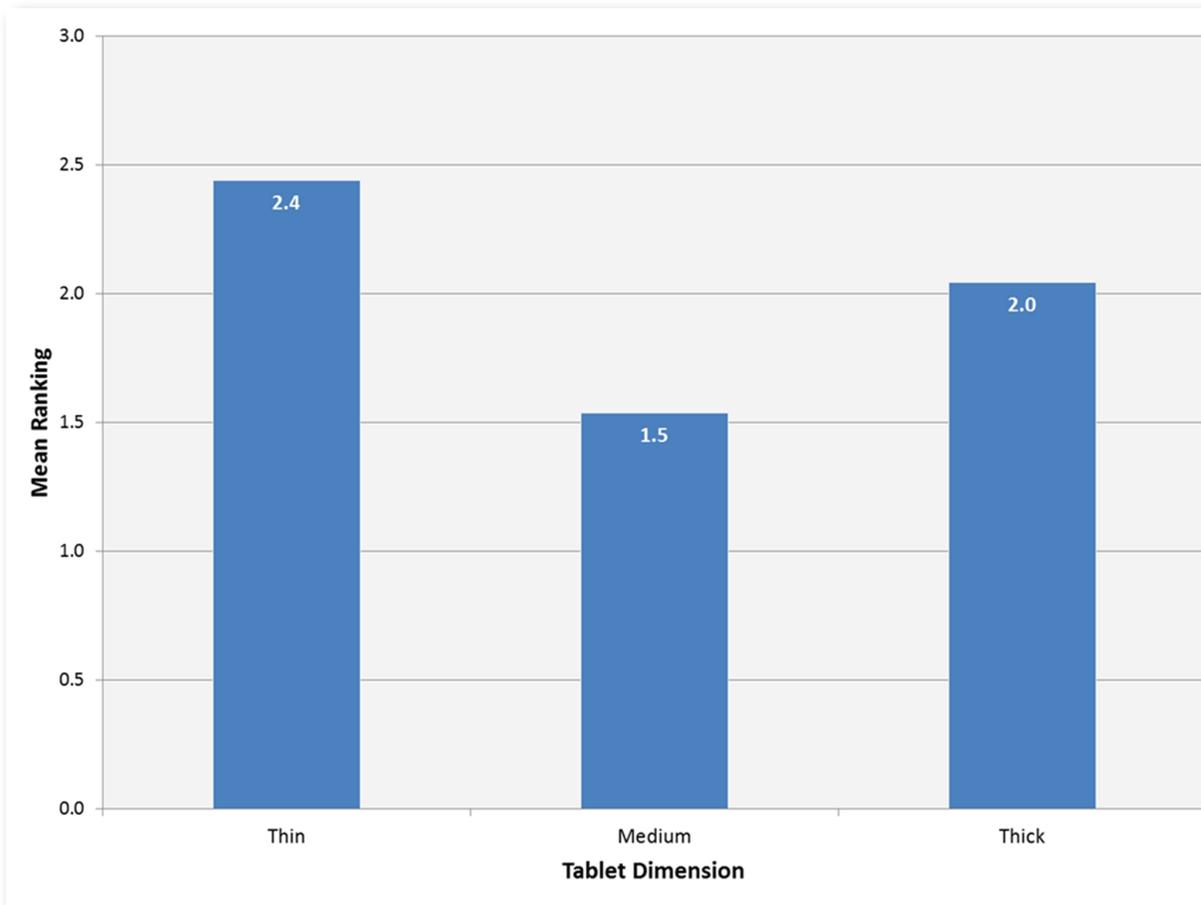


Figure 9. Consumer Preference for Tablet Gloss as Related to Ease of Handling and Swallowing



More specific learnings can be extracted from the survey results. An example, shown in Figure 10, reveals a thicker oval tablet is preferred to a thinner version. This information is critical when designing the final dosage form as the tablet shape, size and dimensions will need to accommodate a specific tablet weight and therefore target API dose.

Figure 10. Consumer Preference for an Oval Tablet, Related to Dimension for Ease of Handling and Swallowing



Conclusions

The results of this study suggest that OSDF characteristics, in particular shape, size, and dimension, significantly influence the perceived acceptability of tablets in the general population. While color and shape were recognized as the key attributes for making a tablet distinctive, memorable, or easy to identify. These are the main attributes or variables to consider to aid in patient compliance and to help reduce medication errors when designing a new drug or OSDF. Designing medication that is easy for the patient to handle and easy to swallow is as important as making it memorable and differentiating it from other medication.

References

1. FDA. Safety Considerations for Product Design to Minimize Medication Errors, 2013;7-9
2. FDA. New Guidance for Industry: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules, 2014
3. Wilson C. & O'Mahony B., (Bio-Images Research, Ltd.); Farrell T, Friend B & Taylor, D (Colorcon Inc.) Modern Tablet Film Coatings and Influence on Ease of Swallowing, AAPS Poster 2006

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