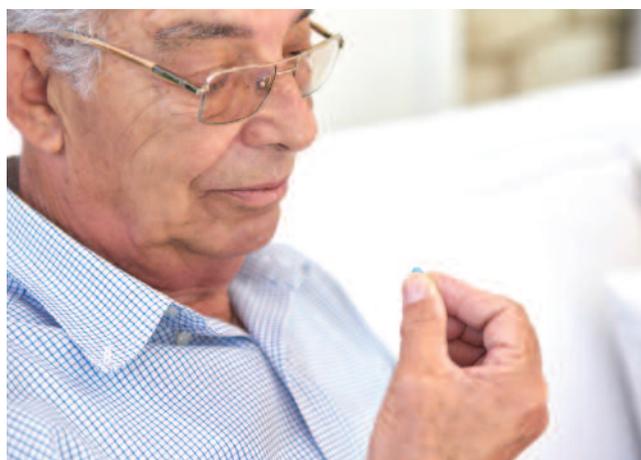


swallowability

THE QUEST FOR EASIER-TO-SWALLOW TABLETS

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This article summarizes a study that enlisted volunteers to assess how easily they could swallow a 1,075-milligram tablet presented in three shapes: almond, round, and elongated.

In a previous article, one of the authors argued that—until recently—the people who formulate and design tablets focused on engineering factors, and that the organoleptic aspects were given little if any consideration [1]. Yet organoleptic factors are the key to obtain a positive answer when the patient or consumer looks at the tablet and asks, “Do I want to swallow this?”

Orkla Health, a company that manufactures food supplements, herbals, vitamins, and minerals—most as tablets—originated and sponsored the work summarized here because many of the tablets it produces are large (more than 600 milligrams), and many consumers find them difficult to swallow. While little can be done to reduce the mass, the company wanted to learn whether its tablets could be made more “swallowable.” The same issue has been raised regarding pharmaceuticals [2].

In a more recent study, researchers described a multicenter, intercultural study that examined which of people’s sensory, hedonic, and efficacy expectations are associated with pharmaceutical pills of different color and shape [3]. Their

conclusion: Different colors and shapes—coupled with the expectations about their effect—probably play an important role in terms of people’s subsequent experience:

“The diamond shape was also expected to be more alerting and more effective for headaches as compared to the oval-shaped tablets, but also harder to swallow and more bitter. Perhaps unsurprisingly, this would suggest there is no one colour or shape that is best for pills in general; the colour/shape of a pill should presumably therefore be chosen depending upon what needs to be emphasised (and the identified concerns of the target consumers). Fleshing this point out, if the patients/consumers had reported difficulty in swallowing, it would perhaps be inadvisable to use diamond-shaped tablets in order to enhance expected efficacy, as this shape may also promote an expectation that such shaped tablets would be difficult to swallow.”

The study that we conducted for and in collaboration with Orkla Health, which we summarize here, did not address the needs of people unable or reluctant to swallow tablets, a condition known as dysphagia. Furthermore, the tablets were vitamins and minerals, not pharmaceuticals. Still, the tablets had to be swallowable and should convey “perceived efficiency” to the consumer.

How well people accept foods—or in this case tablets—depends on their integrating numerous sensory factors, including color, flavor, texture, density, consistency, size, and shape. All are important, but their impact varies with the context. Peanuts, for example, are chewed before they’re swallowed while watermelon seeds are not. Indeed, over the ages, many seeds evolved in a way that allowed animals, including humans, to swallow them without qualms. It was this difference, drawn from nature, that inspired the earlier article [1].

In the present work, the target mass was 1,075 milligrams to compare with an existing product. With an almond as inspiration and in close dialogue with a tablet tooling manufacturer (Elizabeth, McKeesport, PA), the tablet’s shape was finalized (Figure 1). Dubbed the “almond

tablet," it resembles a Cialis tablet, but at 1,075 milligrams it dwarfs the 365-milligram Cialis tablet. Almond, round, and elongated tablets were made of identical blends of calcium carbonate, cabrboxymethyl cellulose, and magnesium stearate. Next, they were coated with an aqueous suspension comprising hydroxypropyl methylcellulose, titanium dioxide, polyfructose, acacia gum, and talc and then polished using carnauba wax.

There are many ways to evaluate tablet swallowability. The most sophisticated and the ones used most often to study dysphagia are surface electromyography [4] and esophageal impedance (barium esophogram) coupled with videofluoroscopy [5]. But those methods require voluminous equipment and specialized personnel, so the present study used volunteer panels. In one study, the panels evaluated the almond tablet against a round tablet (Figure 2). In another, they evaluated the almond tablet against an elongated tablet (Figure 3).

Each study followed the same procedure: The volunteers were told about the test's objective, coached about how to conduct the tests, and shown how to complete the questionnaires.

The test

The evaluation began with a central location test (CLT) in which subjects were told at random which of two tablets—round versus almond or elongated versus almond—to swallow first. They were then asked to assess the difficulty of swallowing it and the degree to which the tablet could be felt in the throat on a scale of 1 to 10. One indicated that it was "very easy" and 10 that it was "very difficult" to swallow. For noticing in the throat, 1 indicated "did not notice" and 10 "could clearly feel." With each tablet, the subjects were supplied a carefully weighed glass of water to help them swallow it, but they were not told how much to drink. After the subjects swallowed the tablet, the glass of water was again weighed. The purpose here was to see whether there was a correlation between the reported ease of swallowing and the amount of water consumed.

After they had swallowed and evaluated each of the two tablets individually, the subjects received two tablets (one of each type) and were asked to evaluate whether one was easier to swallow than the other and, if there was a difference, the subjects' comments were recorded. They were allowed to answer "as easy" or "as difficult" to swallow. After they completed those tasks, the subjects were asked a number of questions about how they experienced swallowing the tablets in general (Table 1) and some demographic questions.

Following the CLTs, the subjects were supplied with five tablets of each type and a questionnaire to take home. They were instructed to swallow one tablet of each type every day for 5 days and to evaluate the ease or the difficulty of swallowing the samples using the same scale as the CLTs. They were again allowed to make comments, too.

Partial conclusions

Round versus almond. Of the 105 panelists who compared the round and almond tablets, males and females

FIGURE 1

Almond-shaped comparator tablet

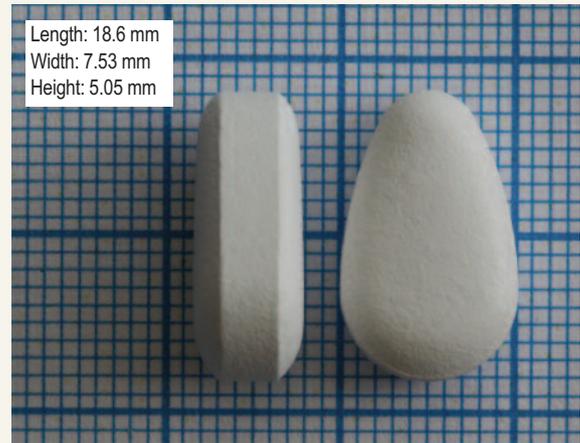


FIGURE 2

Round comparator tablet

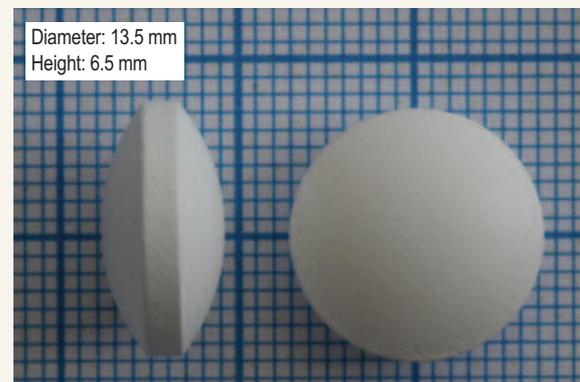
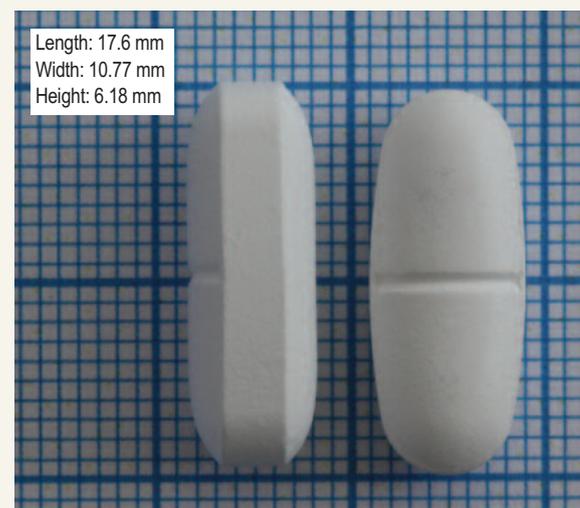


FIGURE 3

Elongated comparator tablet



were nearly equally represented. There was a statistically significant difference between the two tablets regarding swallowability and how noticeable they were in the throat. The almond tablet was deemed easier to swallow and was less noticed in the throat (Figure 4). A good correlation was found between the CLT and the at-home results. No correlation was found between the difficulty of swallowing and the amount of water consumed while swallowing the tablets.

Elongated versus almond. Of the 109 panelists who assessed the almond and elongated tablets males and females were nearly equally represented. No statistically significant difference was found regarding swallowability and how noticeable they were in the throat (Figure 5). Nor was there a correlation found between the difficulty of swallowing and the amount of water consumed while swallowing the tablets.

Additional investigation

To visualize how the subjects responded to the round, elongated, and almond tablets, six volunteers were scanned using ultrasound imaging. The equipment included a 9L linear probe (frequency 8.4 to 9 megahertz) connected to a GE Logiq E9 ultrasound machine. The probe was applied to the proximal esophagus on the left side of the throat. Once a good longitudinal view of the proximal esophagus was obtained, the volunteer was asked to swallow one tablet. Each volunteer rested until the others had swallowed a tablet, and the procedure was then repeated with another tablet. The sequence for each volunteer was randomized.

All volunteers were “normal swallows” and did not express having had any problem in swallowing tablets. Three of them said they found the round tablet the most difficult, two the elongated, and one did not feel any difference. From the ultrasound images, it’s apparent that most of the tablets passed easily through the throat. Yet some were seen to return to the throat and then disappear again (second gulp). This was seen four times when the round tablet was swallowed and twice when the elongated tablet was swallowed. Interestingly, it appeared that the larger-radius end of the almond tablet entered the esophagus first.

Discussion

Of the three different shapes of tablets compared, almond, round, and elongated, the almond tablet was significantly easier to swallow than the round one, while the difference between the elongated and almond tablets was insignificant.

In terms of noticing the tablet in the throat, the almond shape was least noticed compared with the round, and the difference between the elongated and the almond tablets was insignificant. That said, the insignificant difference in favor of the almond is interesting because it indicates that the smallest dimension is not the most important parameter in this context. If it were, the preferences would be ranked as elongated -> almond -> round from “could not feel” to “could clearly feel.” In fact, the ranking from the study was almond -> elongated -> round, indicating that the “seed shape” is the decisive parameter because the the almond tablet is wider than the elongated one.

TABLE 1

How easy is it for you to swallow tablets?

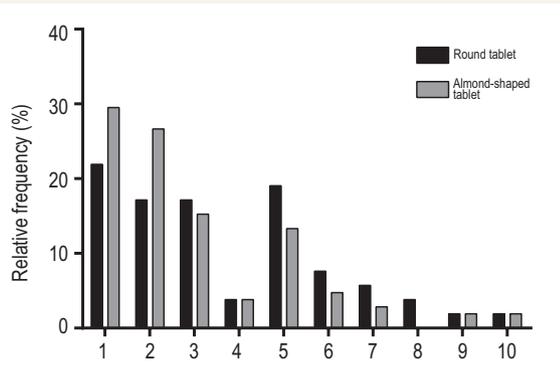
	Always (%)	Often (%)	Occasionally (%)	Rarely (%)	Never (%)
How often do you experience difficulty in swallowing tablets?	1	7	13	65	14
How often do you feel that the tablet sticks in the throat?	0	7	25	50	18
When ingesting tablets, how often do you swallow a few simultaneously?	33	24	10	10	23
How often do you crush tablets to ingest them?	1	1	1	7	90

	Daily (%)	Often (%)	Few days a week (%)	Few times a month (%)	Few times a year (%)
How often do you ingest tablets?	66	2	2	13	17

	Water (%)	Milk (%)	Juice (%)	Other (%)
What do you drink to swallow the tablets?	91	3	3	3

FIGURE 4

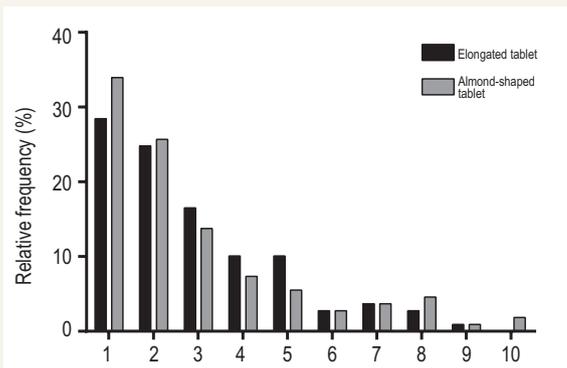
Round tablet versus almond-shaped tablet: How easy was it to swallow?



Note: On a scale of 1 to 10, with 1 indicating "easy to swallow" and 10 "difficult to swallow"

FIGURE 5

Elongated tablet versus almond-shaped tablet: How easy was it to swallow?



Note: On a scale of 1 to 10, with 1 indicating "easy to swallow" and 10 "difficult to swallow"

It would be nice to have an objective, easy-to-use parameter to evaluate swallowability, but how much water is ingested doesn't seem to be the answer. The ultrasound might have furnished some interesting information, since people seem to orient the almond tablet while swallowing it. That insight could help in designing easier-to-swallow tablets.

One more comment about the amount of water consumed: In clinical trials it is customary to ask volunteers and patients to swallow solid oral dosage forms with 240 milliliters of water. In our study, however, the volunteers were provided with a glass containing only 100 milliliters of water. On average, the volunteers ingested just 39.6 milliliters (standard deviation 23.5). And, of the study's 428 participants, only 22 consumed all 100 milliliters of the water, and 16 didn't drink any. This might support criticism of prescribing 240 milliliters of water in clinical trials. But it might also indicate that the study's results would have been more relevant if we had offered the volunteers a full 240-milliliter glass of water.

Most investigations into swallowing have concentrated on dysphagia patients, which is a relatively small group. In the study described here, a normal population was examined. In the future, it might be more productive to examine the "middle ground," i.e., people who are able to swallow tablets and capsules but dislike doing so. Finally, as described by Wan et al., the expectations of the target population must be taken into account, too.

T&C

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