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Ease of opening of blistered solid dosage forms in a senior citizens target group

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ABSTRACT

Blisters differing in design and handling are established as packaging material for solid dosage forms. The ease of opening of blisters influences application and patient's compliance. In this study the influence of visibility and movability of solid dosage forms in blister packaging on both, easy opening and patient's satisfaction, were investigated by target group testing according to ONR CEN/TS 15945.

For each testing 20 participants in the age of 65–80 years were recruited randomly. They opened the blisters on realistic terms without any auxiliary devices. Video documentation of the hands' movements was recorded to analyze the opening procedure.

To show the influence of visibility of the dosage form in the blister, capsules size 1 were packed in transparent and opaque blisters. A moderate influence of the visibility on both, the ease of opening and patient satisfaction, was observed. A second study dealt with the movability of solid dosage forms in blisters. Therefore, three different sizes of tablets with similar shapes were packed in identical cavities. Limited movability was found as major criterion on effectiveness and effectivity of opening as well as on satisfaction with the opening procedure.

1. Introduction

Various types of standardized blisters are mainstream packaging models for solid dosage forms. They differ in design and the ease of opening. The packaging's influence on both, application and compliance, has previously not been researched. A recent study dealt with the comparability of target group testing and instrumental measurement methods concerning easy opening of blister packages (Wrogemann et al., 2015), analyzing the handling of similar tablet shapes in aluminum foil and transparent film blisters. The cavities differed in transparency and fitting accuracy. The study target was to determine the influence of push-through force on handling and manageability. Surprisingly the push-through force was not the determining factor for patient's satisfaction. Against expectation, the blister packaging requiring higher push-through forces was rated as easier to handle.

Further analysis led to the hypothesis that not only opening force but also movability and/or visibility of blistered tablets were key parameters for easy handling and patient's satisfaction. In follow-up studies the influence of both parameters were investigated. In one study the influence of transparency was evaluated by testing placebo capsules size 1 in clear and white opaque PVC-Aclar® blisters. In a second study, the geometrical factors of tablets and cavity were researched by packing tablets of different sizes in identical aluminum blister cavities.

2. Material and methods

2.1. Material

2.1.1. Placebo gelatin capsules in thermoformed clear and white opaque PVC-Aclar®

- Blister material PVC-Aclar® (PCTFE; poly-chloro-tri-fluoro-ethylene), transparent and opaque (Fig. 1).
- Cavity size suited for capsules size 1; 2 × 5 cavities per blister, blister size 92 × 70 mm.
- Hard gelatin capsules, white opaque, size 1, PhEur.; placebo-filling.

2.1.2. Placebo tablets in aluminum blisters

- Cold formable foil, Constantia Flexibles Ref. No. 1422-5-e (Fig. 2).
- Lidding foil, Constantia Flexibles Ref. No. 1131-7-e.
- Placebo tablets (For clarity reasons the tablet types are named in the text after their length and depth in mm, e.g., tablet 20 × 8 for tablet with length 20 mm, depth 8 mm and width 8 mm).

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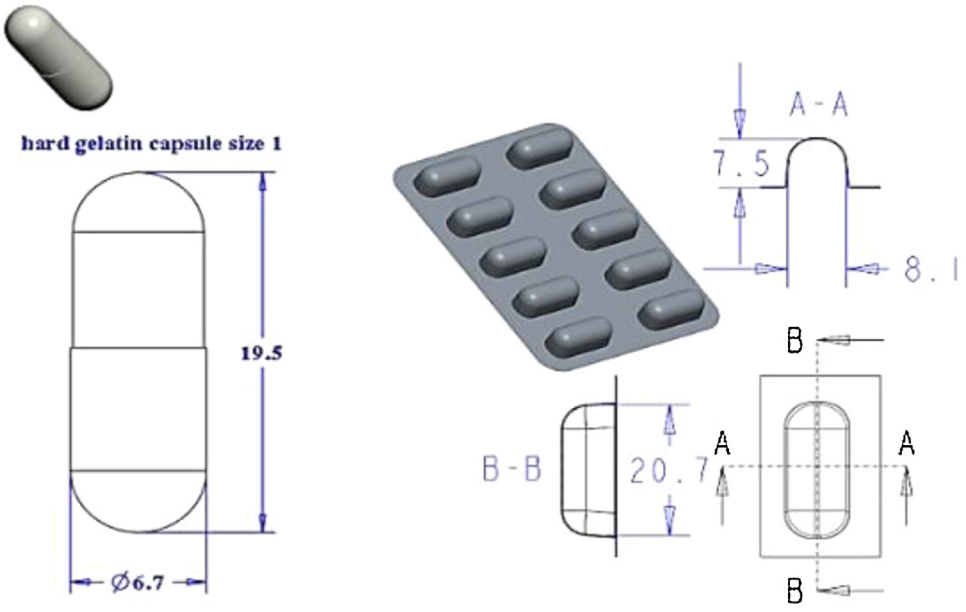

Fig. 1. Placebo capsules and blister—dimensions.

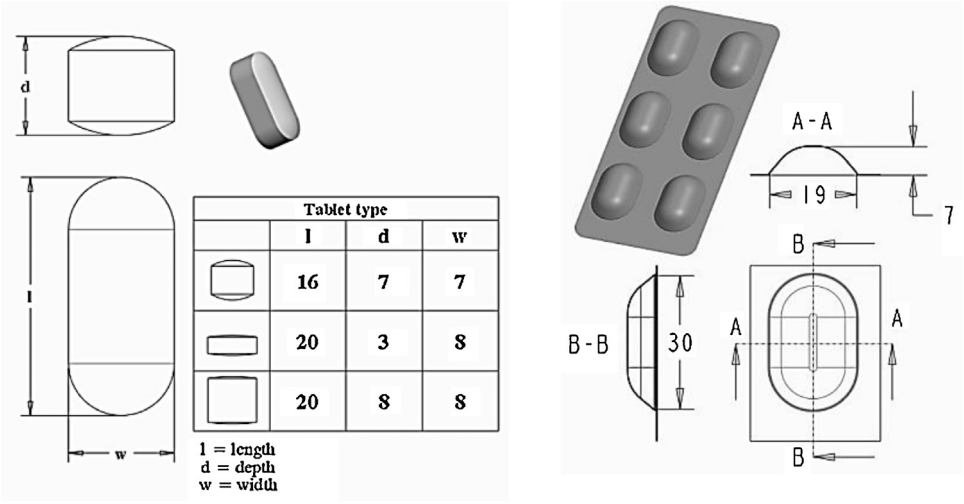

Fig. 2. Placebo tablets and blister—dimensions.

2.2. Methods

The target group test was conducted according to CEN/TS 15945. No opening aid was admitted. CEN/TS 15945 is a three step test, analyzing efficiency, effectiveness and patient's satisfaction of the opening procedure.

1. Efficiency: within 5 min the patient should acquaint himself with the packaging and its opening mechanism and subsequently open it.
2. Effectiveness: a second, identical packaging should be opened within 1 min.
3. Satisfaction: the patient's satisfaction was determined on a five step scale ranging from +2 (very good) to −2 (very poor).

The evaluation of retrieving a single dose and relocking of packaging was not relevant due to blister design. Test participants were randomly recruited according to the age and gender groups as described in CEN/TS 15945 (Table 1). Based on our previous experience, 20 participants are sufficient to indicate the handling properties of packaging, if no certification according to CEN/TS 15945 is required.

To simulate the testing under everyday conditions, our standard kitchen-table setting was applied. Therefore, minimum requirements on testing room design, work space, table size and lighting were defined, based on work space regulations (DIN 8589, 2014; DIN 12464-1, 2011). Documentation was CEN/TS 15945 compliant, recording additional optional data, if applicable. Furthermore

Table 1
Target group composition corresponding to ONR CEN/TS 15945:2011-06.

Age cohort (years)	Male (%)/number	Female (%)/number	Total (%)/number
65–69	10/2	25/5	35/7
70–74	10/2	25/5	35/7
75–80	10/2	20/4	30/6
Total	30/6	70/14	100/20