Polymer Testing 59 (2017) 38–45

Contents lists available at ScienceDirect

Polymer Testing

journal homepage: www.elsevier.com/locate/polytest

Product Performance

Comparison of condom deterioration in different pack shapes

John Gerofi [a, *], Morten Sorensen [b]

[a] Enersol Pty Ltd, 235 Nelson St, Annandale, NSW, 2038, Australia
[b] United Nations Population Fund, UN City, Marmorvej 51, 2100 Copenhagen, Denmark

ARTICLE INFO

Article history:
Received 2 December 2016
Accepted 5 January 2017
Available online 6 January 2017

Keywords:
Condom
Shelf-life
Packaging
Shape
Deterioration
Physical properties

ABSTRACT

Most condoms, especially those purchased by international aid agencies, are packed in square aluminium foil packs. The alternative rectangular packs use less packing material, and are more compact to ship and store. In this article, we describe a trial where condoms in square packs and in simulated rectangular packs were tested for physical properties after oven-conditioning for 3 months at 50 °C. We concluded that some products' inflation properties were unaffected by the pack shape. All products' tensile properties were adversely affected by a rectangular pack when a ring sample was used, but when more conventional dumbbell samples were used, the effect was quite small.

1. Introduction

Since the inception of the WHO Specification for Condoms in 1989 [1], condoms purchased by UN agencies and by many other public sector purchasers have been required to be packed in square packs, made of an aluminium foil laminate. This was done to give the condoms the best possible protection as the type of packaging was believed to be necessary to offer adequate shelf life in tropical countries.

In the commercial market, several manufacturers [2,3] still produce condoms in rectangular packs, although square packs have become dominant.

In this study, we report on an experiment to determine the effect of package shape on condom physical properties. It was based on using storage at 50 °C to simulate accelerated aging of the condoms. While aging at elevated temperatures does not exactly mimic real time behaviour at ambient temperatures, it has been shown to give a reasonable approximation [4]. The constraints of the smaller packages were also simulated, by folding the square packs. This ensured that the condoms themselves and the packing materials were all identical in design.

2. Raw material impact of pack shape

Current UNFPA requirements are for square packs, approximately 55 mm by 55 mm. Thus each side of the pack has an area of about 30.25 cm^2. There are also some circular packs, resulting in an area of 23.75 cm^2. While there is an apparent saving of 22% in materials, the actual method of packaging generally involves starting with a roll of foil, which is passed through the packing machine, and excess material is trimmed off. Thus the trimmings from the laminated foil would need to be recycled. This includes separation of the plastic and aluminium.

The smallest rectangular pack which comfortably contains the condom is 27 × 65 mm, giving a surface area of 17.55 cm^2 per side. This is the most economical pack in terms of foil usage, and uses about 58% of what is needed for a square pack.

On the other hand, the smallest rectangular packs are usually associated with more waste during foiling, since the machines used must distort the condom during packing, and often it is difficult to achieve a perfect seal along the edges, because of the tight fit of the condom. For square packing, there are some foiling machines available that are inherently more gentle than the types generally used for rectangular packing. Such machines typically need less maintenance than the older style machines, and should generate less product wastage, although that has not been documented.

Some manufacturers use a compromise between the square and "smallest" rectangular pack, for example saving, say, 25% of the foil instead of 42%. Such a pack could, for example, be 60 mm by 38 mm, and would involve considerably less distortion of the condom

* Corresponding author.
E-mail addresses: jgerofi@enersol.com.au (J. Gerofi), sorensen@unfpa.org (M. Sorensen).

http://dx.doi.org/10.1016/j.polymertesting.2017.01.005
0142-9418/

during packing than a 27 by 65 mm pack.

Anecdotal information quoted in the early 1990s suggested that the distortion of the condom in a rectangular pack introduced stresses which weakened the product. Some supporting data were given for tensile tests, but not for inflation. Results described later in this article will show this in detail. The ISO technical committee charged with writing standards for condoms (TC 157) set up a working group (WG13) to consider various aspects of condom shelf life. The only published document (below) we were able to find suggests that condoms packed in rectangular packs fared no worse than those in square packs.

The potential saving in packing materials and shipping volume suggests the need to review whatever information is available, and to do testing to establish the effect of pack shape on the condoms.

3. Previous reports on pack shape

LIG [5] presented a poster at the 1998 AIDS conference. Nine different combinations of packaging material and format, condom batch and spermicide dose were compared. The study lasted 5 years and three temperatures were used, 25C, 30C and 40C. In this article, they compared 3 spermicidal products, 2 in rectangular packs and one in square packs.

A detailed discussion of this article is given in Ref. [6]. The result of this study suggests that the rectangular pack shape does not cause more deterioration than the square pack, although the pack materials were not specified in each case.

4. Manufacturer survey

In 2014, a survey [7] was conducted on behalf of UNFPA, of 10 cooperating manufacturers.

Seven of the manufacturers use rectangular as well as square packs. One also produces a circular pack, which is a cut-down version of a square pack.

The rectangular packs ranged from 68 × 27 mm to 70 × 30 mm. Thus none of these manufacturers provide the intermediate size of pack [8] that is found in Europe.

The materials used in the foils are basically similar to those used for the square packs, with the exception that one manufacturer uses rectangular foils with cellophane and paper outside layers.

The demand for rectangular packing is very restricted, with the notable exception of the Scandinavian and Indian markets. Manufacturers reported that between 1% and 8% of their production was in rectangular packs.

Five manufacturers reported that they had packed essentially identical condoms in different packs - both different foil combinations of the same shape, and also different pack shapes. Thus it should be possible to obtain both new and naturally aged condoms packed in different packs for further research.

Three manufacturers have formal shelf life studies on condoms in different shaped packs, and they may be willing to make these available for further study. One further manufacturer has retained samples of condoms of the same type being packed in two different shapes of pack.

5. Method

Products supplied from UNFPA emergency stocks and others supplied directly by manufacturers were used. A total of 6 products was used.

The samples received were divided into 3 groups as follows:

1 Unmodified samples
2 Samples folded and held so that the effective area available to the condom was 75% of the full area available in the pack.
3 Samples folded and held so that the effective area available to the condom was 50% of the full area in the pack.

These are shown in Fig. 1, on a typical pack. The packs were held in shape with the aid of soft flat rubber bands, cut from medical gloves.

The resultant pack sizes were not exactly the same as those commonly used in the industry. The 50% size is actually slightly smaller than the common rectangular pack, which is usually longer than the long side of the folded pack. Typically, the “square” packs have sides in the range 55–60 mm, and they are not always exactly equal. The smallest size rectangular packs are usually 68–70 mm long by 28–31 mm wide.

The samples for testing were put into an oven held at 50 °C for 3 months, and they were subsequently tested for leaks, inflation and tensile properties, according to ISO 4074. The test method for leaks was the ISO 4074:2014 conductivity method.

Sample sizes were as follows:

Leaks: 200
Inflation: 200
Tensile (ring sample): 10
Tensile (dumbbell): 10

The leaks test was only conducted on the square samples and the 50% folded samples. For some products, there was test information available on the new product, from pre-shipment tests. In these cases, the sample size was 315 condoms for both inflation and leaks testing.

6. Results

6.1. Compliance

Because of funding and time constraints, the sample sizes used were not as large as those that would have been used for pre-shipment testing of condoms for UNFPA. Nonetheless, the sample sizes were large enough to draw conclusions with reasonable confidence with regard to lot compliance.

The compliance results after 3 months at 50 °C are shown in Table 1, with more information about the individual tests below:

According to the AQLs specified in ISO 4074, the number of non-compliers allowed for a sample of 200 is 1 for holes and 7 for inflation. For those new products where 315 samples were tested, the number of non-compliers allowed is 2 for holes and 10 for inflation. The numbers allowed apply for single sampling, normal inspection in ISO 2859-1 [9].

No holes were found in any samples. The highest number of inflation non-compliers found in any sample was 4 out of 200. Thus, it can be concluded that after exposure to 50 °C for 3 months, all products passed the ISO 4074 requirements quite comfortably.

6.2. Burst volume and pressure

The mean results for inflation are shown in Figs. 2 and 3. The error bars shown represent 95% confidence intervals for the mean values.

There is a visually obvious decrease in mean burst volume and pressure for 3 of the samples (Fox, Emu and Dingo) as the pack size is reduced. For the other three samples, the results appear very similar, independent of pack size. The overlapping of the confidence intervals suggests that the difference between the corresponding results is not statistically significant.