

A new occlusive patch test system comparable to IQ and Finn chambers

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ABSTRACT

Background: A good patch test system should have good adhesion and contact, and minimal leakage; Finn and IQ patch test system have these properties but are expensive. **Aims:** To develop a new cost-effective occlusive patch test system that had good contact with the skin and was non-irritant. **Methods:** The system (designated Chamber X) was fabricated using a semi-permeable tape and a flexible virgin plastic chamber. Chamber X was developed by (i) selecting adhesive tape based on its non irritancy and adhesive potential (ii) testing plastic chamber material for its skin irritancy (iii) testing the assembled system against Finn, IQ and locally available chambers for irritancy, contact, leakage and occlusivity. **Results:** Chamber X showed better occlusion than IQ, Finn and locally available chambers and was comparable to, ($P > 0.05$) IQ and Finn in terms of irritancy, contact and leakage. **Conclusions:** The results demonstrate that the Chamber X offers a cost effective patch test system comparable to IQ and Finn chambers in terms of safety, adhesion, leakage and occlusivity.

Key words: Allergy testing, Chamber X, clinical trial, Finn chambers, human patch test, IQ chambers

INTRODUCTION

Patch testing has, for many years, been used to make a diagnosis of and predict the potential for primary irritation and/or allergenicity of materials that come in contact with the skin.^[1] Initially, an absorbent material containing the test product was attached to a variety of adhesive tapes and applied directly on the skin for testing. Many systems with better occlusivity and contact have since been developed.

We present data on safety, adhesion, leakage and occlusivity of a new system (designated Chamber X fabricated by C.L.A.I.M.S. Pvt. Ltd.) based on flexible virgin plastic chamber material in combination with

an adhesive tape. Chamber X was developed by (i) selecting a non-irritant adhesive tape with good adhesion^[1] (ii) testing the plastic chamber material for its skin irritancy, and (iii) testing the assembled system against Finn, IQ and locally available chambers for skin irritancy, contact, leakage and occlusivity.

METHODS

The study was monocentric, randomized and comparative. It was approved by an independent ethics committee after a review of the study documents and was registered under the CTRI (Clinical Trial Registry of India) prior to initiation. Statistical analysis was done using SPSS software version 10.0. The Students “t” test and Mann–Whitney U test were used for statistical analysis of data to prove significance.

Materials

The Chamber X is made from two components:

1. The adhesive tape
2. The chamber material

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The adhesive tape used was the semi-occlusive Micropore™ (3M) because of its good adhesion and low irritation potential. The chamber was made from grade 1070 LA 17 low density polyethylene (LDPE) supplied by Reliance Industries. This grade is virgin plastic without any plasticizer and has been approved by the Food and Drug Administration (India) for use in contact with food and beverages; it is quite flexible and can maintain good contact with the skin surface (<http://plastics.ides.com/datasheet/e117557/relene-1070la17>).

Adhesive tapes assessed during these experiments included Micropore (latex free hypoallergenic paper tape); Durapore (latex free silk like hypoallergenic tape), Transpore (clear, porous, latex free hypoallergenic plastic tape) and Surgical Paper tape (hypoallergenic paper tape) which were all obtained from 3M India Limited.

The Chamber X was compared with commercially available patch testing systems: Finn chambers (obtained from Smart Practice, Phoenix, Arizona, USA), IQ chambers (from Chemotechnique Diagnostics, Sweden) and locally available aluminium chambers (purchased from Systopic Laboratories, New Delhi, India).

A Spectrophotometer (CM 2600 D, Konica Minolta) was used to assess erythema and a Moisturemeter SC, (Delfin Technologies) was used to measure the occlusive properties of the chambers during the study.

Methods

Testing of adhesive tape

Adhesion and irritancy of the following tapes were assessed in order to select the appropriate tape for making Chamber X: Micropore, Durapore, Transpore, Surgical Paper tape and tapes of IQ chambers.

Bare patches of different tapes were applied on the upper inner forearm of 32 volunteers (this site was preferred over the back as pressure on the back during rest or sleep could alter evaluation of adhesion giving false positive results). Six test sites ($3 \times 3 \text{ cm}^2$) were marked on the upper arms of the volunteers for application of five different tapes and one site (without any application) was the control. The patches were applied in 3 layers: adhesive surgical tape (Micropore/Durapore/Transpore/ $1 \times 1 \text{ cm}^2$) patches was first applied and covered by $2 \times 2 \text{ cm}^2$ gauze sheet, and followed by $3 \times 3 \text{ cm}^2$ patches of Micropore/Durapore/Transpore.

Scoring for adhesiveness was performed at 24 hours after removing the tapes, and irritancy scoring was done at 48 hours.

Patches were analysed for irritancy and adhesion (using irritancy and adhesion scales described below). The innermost 1×1 tape was a measure for irritancy and the outermost 3×3 tape was a measure of adhesion and irritancy.

Draize scale for irritancy

Score for erythema

0=No reaction

1=Very slight erythema/glaze/wrinkles

2=Slight erythema/glaze/wrinkles

3=Moderate erythema/glaze/wrinkles

4=Severe erythema/glaze/wrinkles

Score for oedema (O)

0=No reaction

1=Very slight oedema

2=Slight oedema

3=Moderate oedema

4=Severe oedema

As per Bureau of Indian Standards (BIS) guidelines for safety evaluation of cosmetics, with reference to IS 4011:1997 Amendment No. 2, September 2004, the product is classified as non-irritant if the mean score is 2; mildly irritant if score is up to 4 and irritant if it scores above 4.^[2]

Adhesion scale^[3]

0 = \geq 90% adhered (essentially no lift off of the skin)

1 = \geq 75% to $<$ 90% adhered (some edges only lifting off of the skin)

2 = \geq 50% to $<$ 75% adhered (less than half of the system lifting off of the skin)

3 = $<$ 50% adhered but not detached (more than half the system lifting off of the skin without falling off)

4 = patch detached (patch completely off the skin).

Testing Chamber X material

An empty Chamber X in the reversed position was applied on the back in order to maximize skin contact and to check safety of Chamber X material. The results were evaluated using the Draize scale and spectrophotometric “a” value readings (erythema).

Method for testing chamber irritancy and contact

Patches were applied on the back of 30 healthy

volunteers using Chamber X, Finn chambers, IQ chambers and local aluminium chambers.

For the irritancy test, each patch contained two chambers: One filled with 1% sodium lauryl sulfate (SLS) and the other filled with 0.9% saline (negative control). The Chamber X material was stuck on the tape selected from study 1, while the other chambers were on their original tape. Thus, four patches were randomly applied on the back, each containing 2 chambers. The SLS bearing test area should give a definite reaction so as to prove proper contact of the chambers with the skin.

Evaluation of irritancy

The results for irritancy were evaluated using:

1. Draize scale and
2. Spectrophotometric “a” value readings (erythema).

The Draize scale SLS scores of Chamber X were compared to those of the other three types of chambers. The score of Chamber X should be equal/greater than the scores of the IQ/Finn/local aluminium chambers so as to prove efficient contact of the chambers.

The saline patch (negative control) was also assessed by the Draize scale.

Method for testing chamber leakage:

1. One drop of ink was filled into each of the four types of patch test systems and applied onto a glass slide to visually observe leakage (*in vitro*).
2. One patch of each of the 4 types of patch test systems containing filter paper dipped in a food grade colour dye was applied on the back of 30 volunteers (*in vivo*).

In vitro testing was done prior to testing *in vivo*.

Evaluation of leakage

Visual observation and photographic evidence of the food grade color patch and the slides was done to evaluate the chambers' resistance to leakage.

Table 1: Empty inverted chamber X-draize scores

Draize scores	0 hr	24 hr	48 hr
AVG	0.00	0.53	0.31
Standard deviation	0.00	0.30	0.10

Method for testing occlusivity

Each of the four different types of patch systems was applied in duplicate for one hour, on the skin of the inner forearm of ten volunteers. Moisturemeter SC readings were taken on the occluded skin before and after application of the chambers to check the moisture build up and hence occlusive property of the chambers.

RESULTS

Statistical analysis was done using Students “t” test or Mann–Whitney U test using SPSS software version 10.0

Tape selection

All the tapes tested showed average irritancy scores below 2 and hence were classified as non-irritant. All the tapes tested also had good adhesivity with average adhesion scores below 1.

Micropore tape was selected as most appropriate for Chamber X as it showed no irritation, good adhesion and was cost effective.

Skin irritancy testing of Chamber X material

There was no significant difference in “a” scores from baseline ($P = 0.5$), and the average score at 48 h was 0.31 demonstrating that the empty inverted Chamber X was non-irritant [Table 1].

Contact, irritancy and leakage test

Evaluation of contact of chambers using Spectrophotometer (Tables 2 and 3) showed a significant increase in “a” value (erythema) from baseline [Figure 1] indicating good contact of skin with

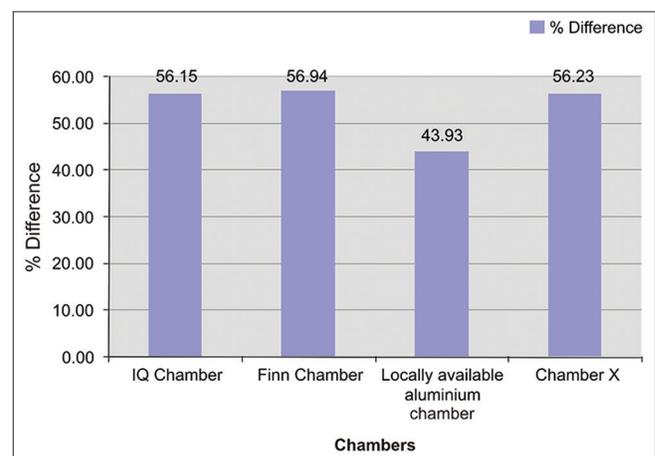


Figure 1: Percentage difference between baseline and 48 hour spectrophotometer scores

Table 2: Comparison of mean SLS scores of spectrophotometric readings “a” value between the chambers

Duration in hours	Mean SLS ($\bar{x}\pm SD$) (N=30)			
	Finn chamber	IQ chamber	Local Al chamber	Chamber X
0	7.32±1.48	7.13±1.29	7.17±1.33	7.22±1.33
24	10.71±1.81	10.85±1.38	9.54±1.87	10.63±1.62
48	11.43±1.73	11.19±1.69	10.32±1.53	11.29±1.62
Difference (0-48 hr)	*4.11±1.79	*4.06±1.74	*3.15±1.55	*4.06±2.06
(P value)	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)
Comparison at 48 hrs				
Chamber X v/s others (P value)	0.9205 (NS)	1.0000 (NS)	0.0581 (NS)	

*P value<0.05. SD: Standard deviation, SLS: Sodium lauryl sulphate, NS: Not significant, IQ: Not an abbreviation, Al: Aluminium

Table 3: Comparison of mean total SLS score based on Draize scale between the chambers

Duration in hours	Mean total SLS score ($\bar{x}\pm SD$) (N=30)			
	Finn chamber	IQ chamber	Local Al chamber	Chamber X
24	2.63±1.07	2.43±1.01	2.20±1.03	2.60±1.04
48	2.93±0.91	3.03±0.93	2.83±0.91	3.07±0.83
Comparison at 48 hrs				
Chamber X v/s others (P value)	0.5360 (NS)	0.8611 (NS)	0.25903 (NS)	

*P<0.05. SD: Standard deviation, SLS: Sodium lauryl sulphate, NS: Not significant, IQ: Not an abbreviation, Al: Aluminium

Table 4: Comparison of mean total saline score between the chambers

Duration in hours	Mean total saline score ($\bar{x}\pm SD$) (N=30)			
	Finn chamber	IQ chamber	Local Al chamber	Chamber X
24	0.07±0.25	0.07±0.25	0.07±0.25	0.23±0.50
48	0.00±0.00	0.00±0.00	0.03±0.18	0.00±0.00
Comparison at 48 hrs				
Claim chamber VS others (P value)	NS	NS	0.3651 (NS)	

*P value<0.05. SD: Standard deviation, SLS: Sodium lauryl sulphate, IQ: Not an abbreviation, Al: Aluminium

Table 5: Evaluation of occlusive property of the different chambers using Moisturemeter SC

Readings	Local chambers		Finn chambers		IQ chambers		Chamber X	
	Baseline	1 Hr	Baseline	1 Hr	Baseline	1 Hr	Baseline	1 Hr
Average	31.33	55.61	27.77	60.24	31.14	77.55	28.67	75.67
Difference		24.27		32.47		46.41		47.00
% difference		77.46		116.92		149.03		163.93

SLS: Sodium lauryl sulphate, IQ: Not an abbreviation

SLS for all the chambers tested. There is no significant difference in the “a” value between the chambers and the IQ chamber, Chamber X and Finn chamber had similar average “a” value scores.

All the chambers also showed a significant increase in Draize scores from the baseline [Figure 2] indicating good contact of skin with SLS. However, there was no significant difference in the Draize score between the chambers.

There was no significant change from baseline in Draize scores in chambers filled with filterpaper dipped in 0.9% saline indicating that all the chambers tested including Chamber X were not irritant. There was also no significant difference in the Draize score between the chambers [Table 4].

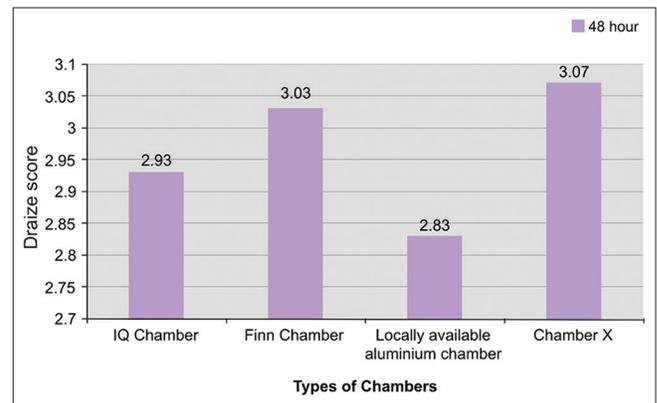


Figure 2: Draize score of 30 volunteers at 48 hour against baseline score of “0”

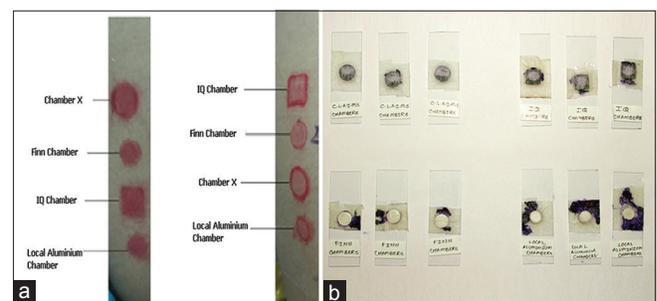


Figure 3: Photographic Representation of leakage, (a) in vivo; (b) in vitro

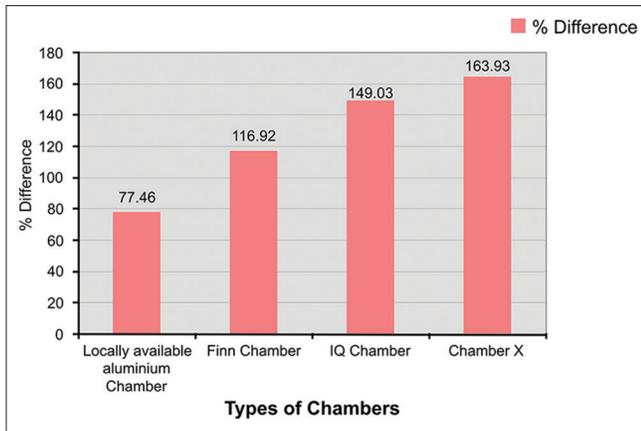


Figure 4: Percentage difference between baseline and 1 h MMSC values

Evaluation of leakage

Visual observation of the leakage from the different chambers, as seen in Figure 3a and b, indicated that Chamber X, IQ chamber and Finn chamber showed minimal leakage as compared to local aluminium chambers. Thus, the Chamber X, IQ chamber and Finn chamber are comparable in terms of leakage.

Evaluation of occlusive property of chambers

Chamber X showed the best occlusive property followed by IQ chamber and Finn chamber [Table 5 and Figure 4].

DISCUSSION

A new patch test system, based on a flexible virgin plastic chamber was tested for its safety, adhesiveness and occlusive properties. It was demonstrated that Chamber X was non-irritant and had good

adhesiveness. No significant outward migration of the dye occurred during use as determined by the dye marker. This eliminates problems arising from interaction between samples and adhesive tape. The occlusive properties are related to the chamber design and the selection of plastic from which the chamber was fabricated. The chamber is flexible which allows it to follow the contours of the body and hence maximizes contact between skin and test product. There were also no adverse reactions or discomfort experienced by the volunteers in the experiments detailed.

The results demonstrate that Chamber X is comparable to IQ and Finn chambers in terms of safety, adhesion, leakage and occlusive property. It has been designed to be available at a substantially lower cost.

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Announcement

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