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Comparison of the Quintest™ to the Lancet in Allergic Skin Testing

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SUMMARY **Many skin testing devices have been commercially available over recent years, but use has been limited because of significantly greater costs of such devices. Therefore, the lancet continues to be the most widely used skin testing device in Australia. This study compared performance of another multitest device, the Bayer Quintest™ to the Becton Dickinson Microlance. Nineteen atopic volunteers were skin tested using histamine dihydrochloride 10mg/ml, glycerosaline and eight allergens. In 190 tests, 6 discrepancies between the Quintest and Microlance occurred. The Microlance produced slightly larger wheals than the Quintest, reaching statistical significance in 3 allergens. We found the Quintest comparable to the Microlance in concordance of positive and negative allergen responses and in wheal size. The Quintest had higher acceptability to both participants and staff for comfort, ease of use and safety. The Quintest's major advantage is the ability to rapidly screen large numbers of subjects, especially during clinical trials. The major limitation is it's cost.**

In recent years many different skin prick testing devices have been commercially available.[1-6] However, no one device has proven to be more acceptable in terms of patient comfort, ease of use and economic viability. For these reasons in Australia today, most skin prick testing continues to be performed with lancets, which have proven to provide reasonable reproducibility and precision in overseas studies.[1,2]

In large scale epidemiological and other research studies a device which allows for the rapid application of allergens and decreases the overall infection risk resulting from needle stick injury would be of great advantage.

This study compared the lancet currently used in this hospital, the Becton Dickinson Microlance (Rutherford, New Jersey, USA) to the Bayer Quintest™ (Spokane, Washington, USA). The specific aims of the study were to compare agreement of false positive and false negative reactions, agreement of positive and negative reactions to a number of allergens, resultant wheal sizes and the acceptability of each device to both participants and to staff using the device.

SUBJECTS AND METHODS

Devices

The Bayer Quintest™ is a disposable skin testing device which has a safety handle from which five linear columns extend (Fig. 1). Each column is spaced 3 cm apart and contains a 1.2 mm steel tip. The device is supplied with a ten well allergen tray, which is re-useable for one week. The Quintest is dipped into the preloaded allergen tray, applied to the patient and then discarded.

The Becton Dickinson Microlance (Fig. 2) is a 32 mm stainless steel device with a 2 mm

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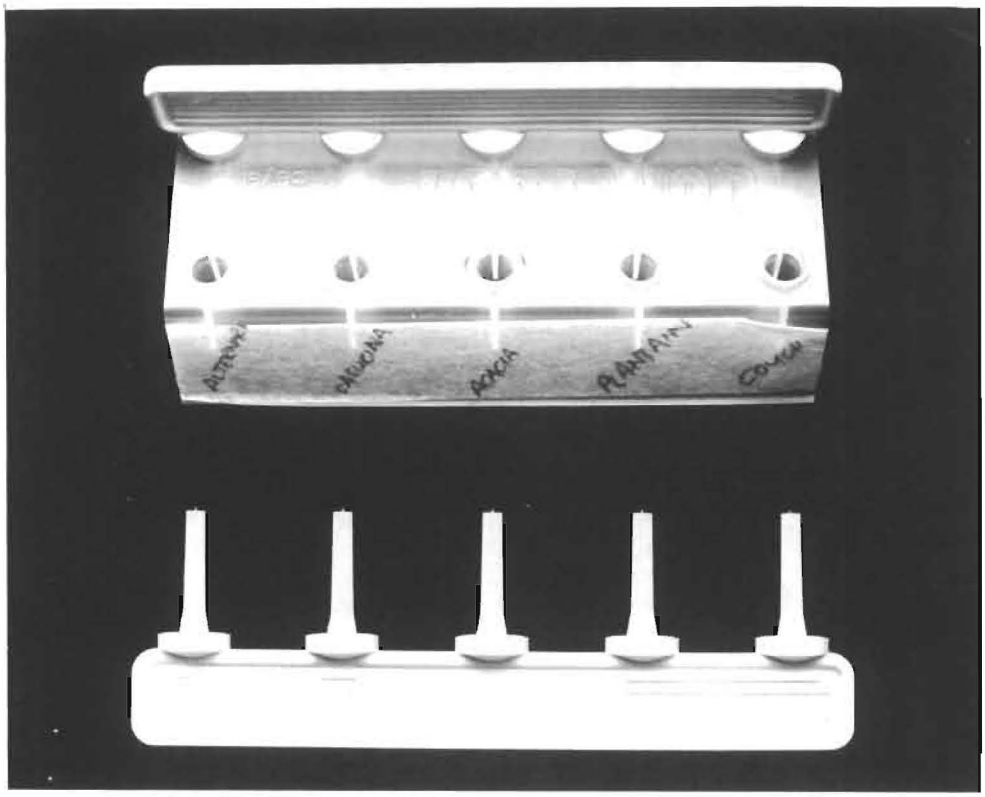

Fig. 1 Bayer Quintest skin prick testing device.

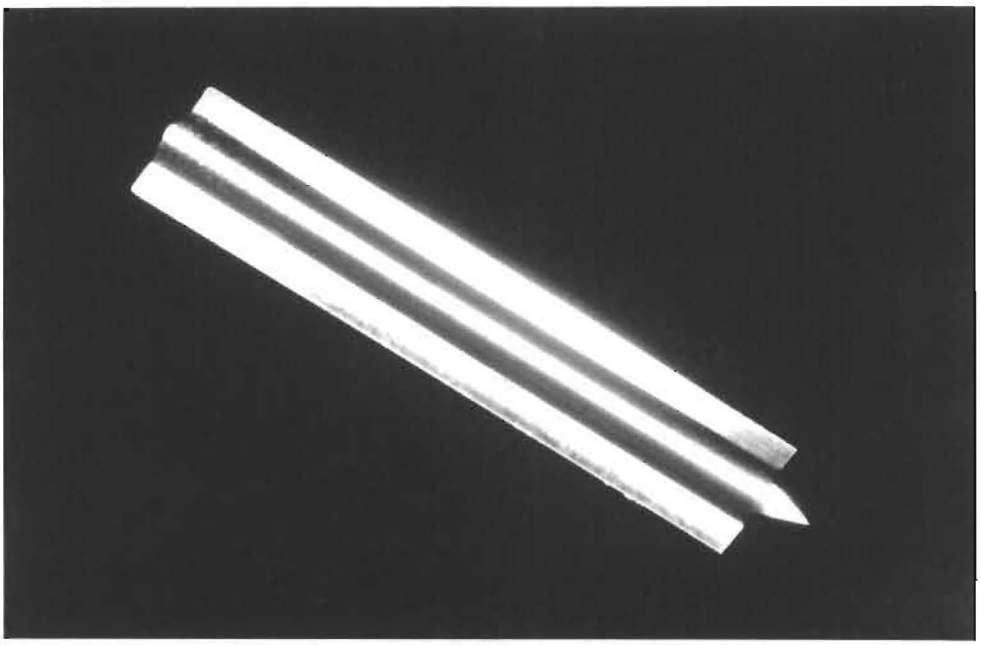

Fig. 2 Becton Dickinson Microlance.

point. A drop of allergen is placed on the skin, the Microlance is then passed through this at a 45 degree angle and the skin is gently lifted to create a break in the epidermis. The Microlance is discarded after each single allergen test.

Subjects

Nineteen known atopic volunteers participated in this study. Each participant gave informed consent prior to their commencement in the study. No anti-histamines were permitted for one week prior to testing.

Skin testing materials

Each patient was tested with eight allergens (Hollister-Stier, Spokane, Washington, USA), histamine dihydrochloride 10 mg/ml (Hollister-Stier, Spokane) and glycerosaline (Hollister-Stier, Spokane). Fifteen patients were tested with the same panel of allergens, while the other four were tested with a slightly different panel (Table 1).

Study plan

The panel of 10 allergens were applied to the dorsal surface of both forearms, using one method on each arm. The allergens were applied in identical order on each arm and a random order schedule was used to determine which device was used first, so that the order of the device used first was switched continuously between patients.

Skin testing was performed by two research nurses experienced in allergy testing. After application the test was read 15 minutes later by the same nurse. The longest and mid-point orthagonal diameters were measured for both the wheal and flare responses. The average diameters of each was then calculated. A reaction was considered positive if the average diameter was $\geq$ 3 mm. Each skin test was outlined with a texta pen and transferred onto transparent tape for permanent recording.

A false positive test was identified if the wheal produced from the glycerosaline skin test was an average diameter of $\geq$ 3 mm and a false negative skin test if the wheal size of a histamine skin test was $\leq$ 3 mm average diameter.

Participants were also asked to rate the level of discomfort caused by each device on a visual analogue scale, where 1 = no discomfort, 3 = moderate discomfort and 5 = severe discomfort. They also rated whether the Quintest was the same, better; or worse than the Microlance for skin prick testing and which device they would prefer if they had to have a skin prick test again.

Research staff who used the device were also asked to rate which device they preferred in terms of speed and ease of application.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Scientists (SPSS) version 6.1 for Windows (Chicago, Illinois). The wheal sizes produced by each device were compared within subjects for each allergen using paired *t* tests. Discomfort ratings were compared within patients in the same way. Wilcoxon tests were used to assess preferences for a particular device. All tests were two-sided and a 5% significance level was used.

RESULTS

Nineteen atopic volunteers participated in the study. The mean age being 35 ± 11 years with 84% being female and 12% male.

Of the 190 individual skin prick tests performed (19 volunteers x 8 allergens plus histamine and glycerosaline) there were only 6 discrepancies between the Microlance and the Quintest in terms of whether a positive or negative result was obtained. Table 2 shows these differences. In three instances the Quintest was negative and the

Table 1 Allergens used in skin prick testing

Allergen panel	Number tested
Histamine, glycerosaline, *D. pteronyssinus*, perennial rye, couch (bermuda), plantain, alternaria	19
Additional allergen	
Paspalum, acacia, casuarina	15
Cat, dog, cockroach	4

Microlance positive, whilst in three other cases the opposite occurred.

There was good agreement between devices in wheal size. Although the Microlance produced larger wheal sizes than the Quintest in most cases, this was only statistically significant for three allergens, which are highlighted in Table 3. In all other allergen comparisons, the Quintest and Microlance were not significantly different.

There were no false negative responses to histamine or any false positive reactions to glycerosaline with either device. The Microlance produced an average wheal diameter of 6.2 ± 1.9 mm when histamine was used compared to 5.5 ± 1.3 mm with the Quintest, however, there was no statistically significant difference within subjects.

Fig. 3 shows the frequency distribution of the participants discomfort ratings for each device. This figure shows the majority of participants rated each device as causing a small amount of discomfort. However, a larger percentage rated the Quintest as less painful than the Microlance. The Quintest mean rating for discomfort was 1.4 ± 1.0 compared to 2.2 ± 1.1 for the Microlance and this difference was statistically significant p = 0.01 within subjects. The Quintest method was preferred by 94.7% of participants for future skin prick testing if required and 89.5% rated the Quintest method as being better than the Microlance method.

Both research nurses preferred the Quintest to the Microlance in terms of ease of use and speed of allergen application (p = 0.001).

Table 2 Disagreement in positive and negative test results between devices (six individual subjects)

Allergen	Quintest wheal (mm)*	Microlance wheal (mm)*
D. pteronyssinus	2.5	4
D. pteronyssinus	0	3
Casuarina	0	4
Alternaria	5	2
Alternaria	3.5	0
Cockroach	8	0

* < 3 mm = negative skin test
≥ 3 mm = positive skin test

Table 3 Comparison of mean Quintest and Microlance wheal sizes

Allergen	Mean wheal size (mm)		Mean difference of wheal size (± SD)	p value
	Quintest	Microlance		
Histamine	5.5	6.2	-0.6 (±1.8)	0.2
Glycerosaline	0	0	0	-
D. pteronyssinus	**4.8**	**6.4**	**-1.5 (±2.4)**	**0.01***
Perennial rye	6.5	7.9	-1.5 (±3.4)	0.08
Paspalum	5.6	4.3	0.8 (±3.6)	0.4
Couch	**4.0**	**5.3**	**-1.3 (±2.3)**	**0.02***
Plantain	3.8	3.9	-0.1 (±1.4)	0.8
Acacia	1.8	2.1	-0.2 (±0.9)	0.4
Casuarina	1.1	1.4	-0.3 (±1.2)	0.4
Alternaria	1.1	0.9	0.1 (±1.9)	0.8
Cat	0	0	0	-
Dog	0	0	0	-
Cockroach	4.3	3.3	1.0 (±4.8)	0.7

* denotes statistically significant difference

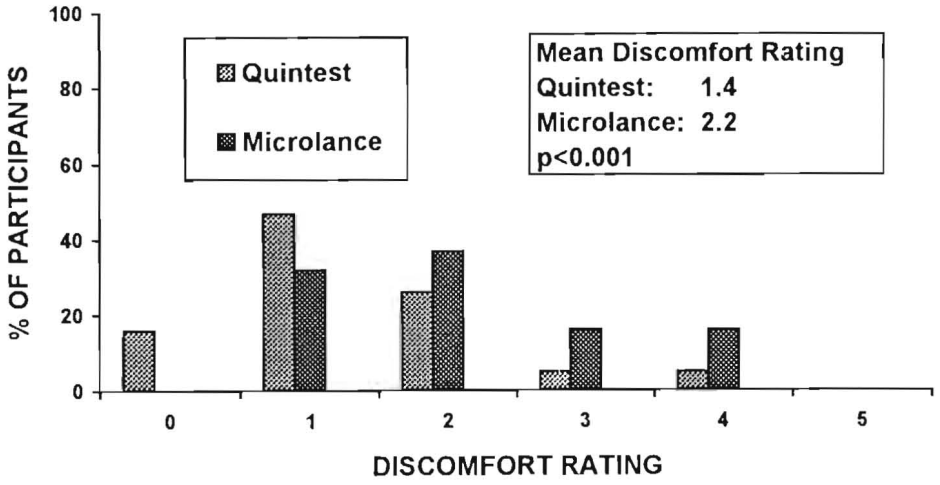

Fig. 3 Discomfort ratings for Quintest and Microlance.

DISCUSSION

This study aimed to compare the Quintest device to the Microlance for concordance of positive and negative responses to a number of allergens, the similarity of wheal size, the number of false positive and false negative results and the acceptability of the devices to the subjects participating in the study.

We found the Quintest to be comparable to the Microlance for concordance of positive and negative allergen responses and wheal size. Neither device produced false positive or false negative results. The Quintest was more acceptable than the Microlance to participants in the study as it caused less discomfort and it was preferred by the majority of participants to be used for future skin prick testing if required. Both research nurses preferred the Quintest to the Microlance in terms of speed of application and ease of use.

There were some differences found between devices. In six of 190 individual skin prick tests performed there were an equal number of discordant results between devices (Table 2). In two cases, the Microlance produced a positive responses to an allergen (casuarina and *D. pteronyssinus*) while the Quintest produced no wheal response. The average wheal size produced by the Microlance in these two cases were casuarina (4 mm) and *D. pteryonyssinus* (3 mm). These responses were in two separate patients and neither patient produced any other discordant responses despite having positive skin prick tests to a number of other allergens. In the other positive skin tests for these patients the average wheal size produced by the two devices did differ. There were also two skin tests where the Quintest produced a positive result and the Microlance a negative result. The average wheal produced by the Quintest for the discordant result to alternaria was 3.5 mm and this subject also had a number of other positive skin prick tests, however, the wheal sizes produced for these allergens were very similar for both devices. In the second of these two cases the Quintest produced an 8 mm wheal while the Microlance produced no wheal. This may have been an operator error, where the skin was not broken by the lancet. This subject was also allergic to other allergens and there was a small difference in the wheal size produced in one of the other positive allergen tests. In the final 2 cases of discordant responses, both the Quintest and the Microlance produced a response which was < 3 mm in size, where the other device produced a response > 3 mm.

When the mean average wheal size for each device (Table 3) was examined, 6 of the 10 comparable allergens (glycerosaline, cat and dog dander were excluded as there were no positive tests), the lancet produced a larger average wheal sizes than the Quintest. Of these only two were statistically

significantly larger, *D. pteronyssinus* ($p = 0.01$) and couch (bermuda) ($p = 0.02$). This may be related to a slightly larger point on the Microlance 2 mm, compared to a 1.2 mm tip on the Quintest. Nelson *et al.*[1] suggest in their study that devices producing greater skin trauma produce a greater wheal size. Adinoff *et al.*[2] found that the Microlance caused more bleeding than the other four devices they compared, which suggests more skin trauma. The Quintest has a fixed collar containing the steel tip, therefore allowing better control of the depth and force of skin penetration. The lancet relies upon operator control, which may lead to a greater skin trauma.

The major limitation of the Quintest is the economic cost of the device. One Quintest device costs $AUD 2.53 with an additional cost of $AUD 3.40 for the 10 well allergen tray, which is re-useable for one week. The total cost for an 8 allergen test plus histamine and glycerosaline is $AUD 5.06 per patient, plus a percentage of the re-useable allergen tray. This compares to $AUD 0.09 for one Microlance and $AUD 0.90 for a 10 allergen test. However, the Quintest is more cost effective in terms of a more rapid application of allergens. It takes 10 seconds to apply a 10 allergen Quintest skin prick test, this includes opening of the packaging and application of the allergens. To do the same 10 allergen test with the Microlance it takes 5 to 10 minutes depending on the skill of the person performing the test. This time span includes opening individual lancets, applying each allergen to the dorsal arm surface and then performing the skin prick manoeuvre. This may not be a very important feature of day to day clinical practice but it is a major issue when conducting large scale screening with skin prick testing, as in a clinical trial, or in a very busy allergy clinic. The Quintest increases patient turnover, allowing a greater number of patients to be tested in a shorter time and it also has a lower discomfort level and greater acceptance by patients.

The Quintest device has proven to be a safe, efficient and well accepted device for performing skin prick tests. It allows rapid screening of a large number of subjects with ease and with a high safety level.

ACKNOWLEDGMENT

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