

Refereed papers

Evaluation of the MoleMate™ training program for assessment of suspicious pigmented lesions in primary care

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ABSTRACT

Background Pigmented skin lesions or ‘moles’ are a common presenting problem in general practice consultations: while the majority are benign, a minority are malignant melanomas. The MoleMate™ system is a novel diagnostic tool which incorporates spectrophotometric intracutaneous analysis (SIAscopy) within a non-invasive scanning technique and utilises a diagnostic algorithm specifically developed for use in primary care. The MoleMate™ training program is a short, computer-based course developed to train primary care practitioners to operate the MoleMate™ diagnostic tool.

Objectives This pre-trial study used mixed methods to assess the effectiveness and acceptability of a computer-based training program CD-ROM, developed to teach primary care practitioners to identify the seven features of suspicious pigmented lesions (SPLs) seen with the MoleMate™ system.

Method Twenty-five practitioners worked through the MoleMate™ training program: data on feature recognition and time taken to conduct the assessment of each lesion were collected. Acceptability of the training program and the MoleMate™ system in general was assessed by questionnaire.

Results The MoleMate™ training program improved users’ feature recognition by 10% (pre-test median 73.8%, $p < 0.001$), and reduced the time taken to complete assessment of 30 SPLs (pre-test median 21 minutes 53 seconds, median improvement 3 minutes 17 seconds, $p < 0.001$). All practitioners’ feature recognition improved (21/21), with most also improving their time (18/21). Practitioners rated the training program as effective and easy to use.

Conclusion The MoleMate™ training program is a potentially effective and acceptable informatics tool to teach practitioners to recognise the features

of SPLs identified by the MoleMate™ system. It will be used as part of the intervention in a randomised controlled trial to compare the diagnostic accuracy and appropriate referral rates of practitioners using the MoleMate™ system with best practice in primary care.

Keywords: computer-aided diagnosis, primary care, suspicious pigmented lesion.

Introduction

In the UK malignant melanoma is the eighth most common cancer, with 8100 new cases and 1800 deaths annually;¹ the incidence has doubled over the last 20 years.² Patients often present to their general practitioners (GPs) with concerns about pigmented skin lesions, but GPs rarely see malignant melanomas. The earlier a melanoma is detected and the 'thinner' the lesion, the better the prognosis.³ Therefore the management of suspicious pigmented skin lesions, and in particular the recognition of potential malignant melanomas, is an essential skill in general practice.

GPs are less accurate than dermatologists in the diagnosis of skin cancers,^{4,5} and there is conflicting,^{6,7} and probably insufficient,⁸ evidence about the confidence and ability of GPs to manage pigmented skin lesions. GPs are able to improve their diagnostic and management skills in dermatology through a variety of training methods,⁹ sometimes to the level of specialists.¹⁰ However, training may not improve management decisions in the longer term,¹¹ and current practice has been shown to influence diagnostic ability more than previous dermatology training.¹²

Primary care practitioners are currently able to use a variety of checklists to assist their management of pigmented skin lesions, including the seven-point checklist (as recommended in the NICE skin cancer guidelines),^{13,14} and the 'ABCD(E)' checklist (as recommended in the SIGN guidelines).^{15,16} These checklists are sensitive for the diagnosis of malignant melanoma, but are low on specificity.¹⁷ Technology such as dermoscopy, photography and teledermatology may also assist pigmented skin lesion management decisions. Although there is a consensus on the use of dermoscopy in secondary care,¹⁸ there is less evidence that using the dermatoscope in primary care increases the accuracy of diagnosis.¹⁹ Photographs may be useful in the referral and follow-up of patients with pigmented skin lesions.²⁰ Teledermatology has been assessed in secondary care for the remote diagnosis of pigmented skin lesions,²¹ and has recently been successfully piloted in a primary care setting.²²

Despite the wide availability of guidelines and newer technologies to aid the management of pigmented skin lesions in primary care, only 10–12% of

referrals made under the UK 'two-week wait' skin cancer referral criteria are malignant.²³ This places dermatology departments under considerable pressure, highlighting the need for increased specificity for the diagnosis of pigmented skin lesions, combined with the continued need for high sensitivity in order not to miss an early malignant melanoma diagnosis.

The MoleMate™ system is a novel diagnostic tool for the management of pigmented skin lesions by primary care practitioners. The system uses SIAscropy, a technology that examines the haemoglobin, melanin and collagen levels in the epidermis and dermis. There is increasing evidence to show that SIAscropy improves accuracy of diagnosis in secondary care,²⁴ although a recent study with equivocal results used an outdated version of the technology.^{25,26} As the prevalence of pigmented skin lesions in the general population is very different from that in secondary care, a diagnostic algorithm has been specifically developed and verified for use in primary care (Figure 1).²⁷ The MoleMate™ system consists of a hand-held scanner, which transmits images (SIAscans) to computer software incorporating the algorithm. The primary care practitioner looks for the presence or absence of certain features on the computer screen images and, by following the algorithm, ascertains whether the lesion is suspicious and needs further investigation. A CD-ROM has been developed in order to train primary care practitioners to identify the features seen with the MoleMate™ system. The aim of this study was to evaluate the effectiveness and acceptability of the MoleMate™ training program among primary care practitioners.

Method

The MoleMate™ system as a diagnostic tool

A dermatoscopic image of the pigmented skin lesion is viewed first, followed by the SIAscans in the order of the MoleMate™ algorithm (bright dots, melanin brain, blood lacunes, dermal melanin, blood vessels and blood displacement). Finally, the lesion is measured using an on-screen measuring tool. The

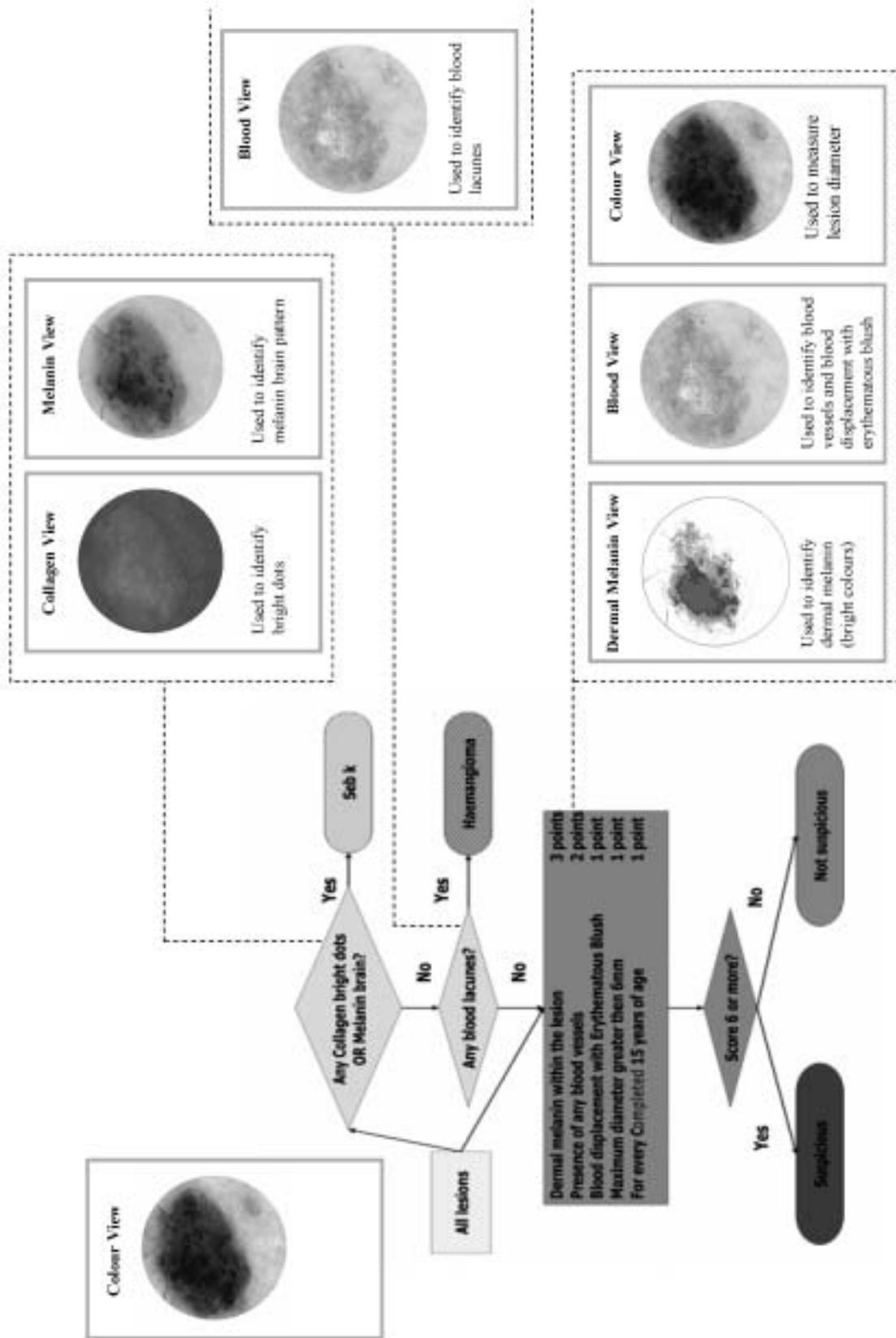


Figure 1

primary care practitioner must indicate whether or not each feature is present, and whether the lesion is greater or less than 6 mm diameter. By following the algorithm, the practitioner is able to identify whether a lesion is benign (such as a seborrhoeic keratose or haemangioma), or whether the lesion is suspicious and needs further investigation.

The MoleMate™ training program CD-ROM

The training program consists of four sections:

- 1 **Demonstration** Introduction and illustration of features seen with the MoleMate™ system, using SIAscans of 13 pigmented skin lesions.
- 2 **Pre-test** Baseline assessment of SIAscans of 30 pigmented skin lesions.
- 3 **Feedback** Review of pre-test responses with mistakes highlighted and examples of the SIAscan features given. Practitioners must review every incorrect answer.
- 4 **Post-test** Assessment of SIAscans of a further set of 30 pigmented skin lesions, including nine from the pre-test set and 21 new lesions.

The practitioner's assessments of the SIAscan images for each lesion, plus the time taken to assess each lesion, are recorded automatically as a binary variable by the software and are 'scored' against the 'gold standard' assessment of whether each feature is present or absent (reached by consensus between scientists and clinicians involved in the development of the MoleMate™ system).

The 'pre-test/post-test design' has been widely used across many disciplines to evaluate and quantify learning, especially of change over a short period of time. It has previously been used to assess interventions to increase GPs' knowledge of malignant melanoma and skin cancer and to assess computer-aided instruction for other clinical situations such as cardio-pulmonary resuscitation and surgery.^{9,11,28,29}

Development of the MoleMate™ training program

The MoleMate™ training program was developed by Astron Clinica in collaboration with primary care researchers. Images were selected to reflect the case mix generally observed in UK primary care, from cases which were relatively straightforward to assess. Initial piloting by four primary care practitioners and three scientists led to small modifications to the program. These included making minor alterations to nomenclature and abbreviations throughout, clarifying the

features seen in the demonstration section by adding arrows pointing to the features and increasing the annotation and highlighting of features in the feedback section. A short break was introduced into the training session after the pre-test section to reduce fatigue.

Pigmented skin lesion workshops

Primary care practitioners were recruited by flyer and email to attend one of two Pigmented Skin Lesion workshops during March and April 2007. At each workshop the participants completed the MoleMate™ training program, then a consultant plastic surgeon (PH) talked about the management and referral of pigmented skin lesions. Participants were given ninety minutes to work through the training program, which included a refreshment break. These workshops were held in the evening and vouchers to cover travel costs were provided.

Analysis

Effectiveness of the MoleMate™ training program

Differences between the average pre- and post-test scores and times taken to conduct each assessment were summarised using the median and the interquartile range, as the data had outliers and were therefore not consistent with a normal distribution. The start time and the time at which each question was completed were recorded by the program, but the time at the end of the last question was not recorded: the time taken to complete the last question was approximated by using the mean for the previous nine questions.

Data were analysed in SPSS (12.0.1), using non-parametric statistical methods, and any *p* value <0.05 was regarded as statistically significant. The pre- and post-test data were compared using a Wilcoxon matched pairs signed rank sum test. Differences between the pre- and post-test data for groups of practitioners (GPs, GP Registrars (GPRs) practice nurses (PNs) and a physician's assistant (PA)) were compared using a Mann Whitney U test with exact test option. As there were less than five practitioners in the PN/PA group, the results were summarised but not analysed further due to the impossibility of declaring statistical significance. Pre- and post-test scores for each feature seen with the MoleMate™ system were compared using a Wilcoxon matched pairs signed rank sum test to identify any change in participants' ability to correctly identify each feature. Pre-test scores and times for participants who did not complete the training program

were compared to those who did using the Mann Whitney U test with exact test option.

Acceptability of the MoleMate™ training program

Participants were asked for their views on the MoleMate™ training program using a specifically designed questionnaire. This included a series of statements with which participants were asked to rate their agreement or disagreement on a 7-point Likert scale, with '1' being strongly agree, '7' being strongly disagree and '4' being neutral. The questionnaire asked practitioners to rate the ease of identifying each of the features seen with the MoleMate™ system. Descriptive statistics were used to analyse the questionnaire responses and comparisons were made between different groups of practitioners. Also, the views of any participants who did not complete the training program were compared to the views of those who did (see Appendix 1, the questionnaire).

Results

Twenty-five primary care practitioners attended two Pigmented Skin Lesion workshops, with 21 completing the MoleMate™ training program. The program completer group consisted of eight GPs (average age 41 (range 34–60); 50% female; average of 17 (range 9–30) years general practice experience) and ten GPRs (average age 31 (range 26–40); 70% female; average of 0.75 (range 0.5–1) years general practice experience). There were also two PNs and one PA in general practice who were considered as one group in the summary

analysis but formed too small a cohort for further group analysis (average age 45 (range 30–56); 100% female; average of 18 (range 17–19) years general practice experience). Four GPs failed to complete the program due to time pressure (average age 49 (range 46–55); 50% female; average of 18 (range 9–26) years general practice experience).

Effectiveness of the MoleMate™ training program

Feature recognition

The median pre-test score was 73.8% (inter-quartile range (IQR) 67.9%–78.3%), the median post-test score was 86.2% (IQR 81.0%–88.3%) and all participants improved after completing the feedback session. There was a highly significant improvement between median pre- and post-test scores (10.0%, IQR 7.6%–15.0%, $p<0.001$). All three groups of primary care practitioners had higher scores in the post-test than the pre-test. The improvement was significant for GPs and GPRs (median improvement 10.4%, $p=0.012$ and 11.6%, $p=0.005$, respectively) and was in the same direction for the small PN/PA group (median 15.7%), see Figure 2.

Differences between pre- and post-test scores were evaluated for each of the individual features seen with the MoleMate™ system: more participants correctly identified each feature in the post-test. The most significant improvement was in the identification of blood lacunes (median=25%, $p<0.001$) and blood displacement (median=20%, $p<0.001$), see Figure 3.

Differences between scores for lesions in both pre- and post-test sets ($n=9$) were compared with pre- and post-test scores for the unique lesions ($n=21$). For the

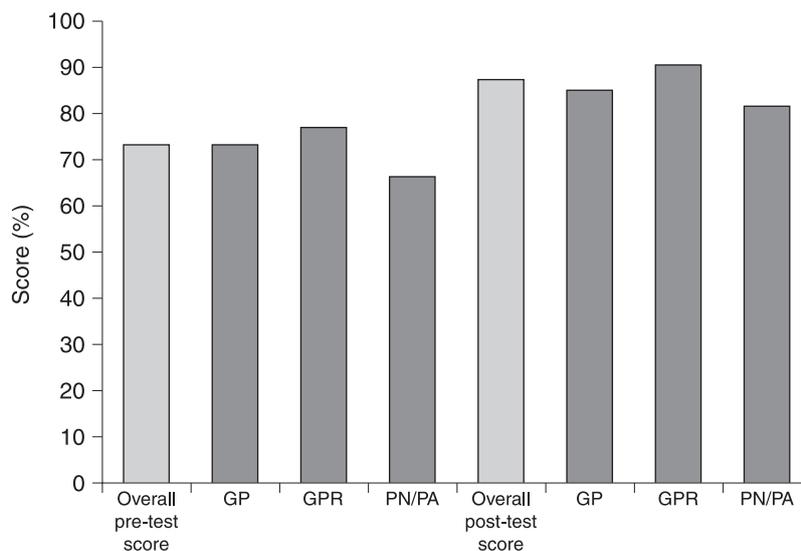


Figure 2 Comparing median pre- and post-test scores between GPs ($n=8$), GPRs ($n=10$) and PN/PAs ($n=3$)

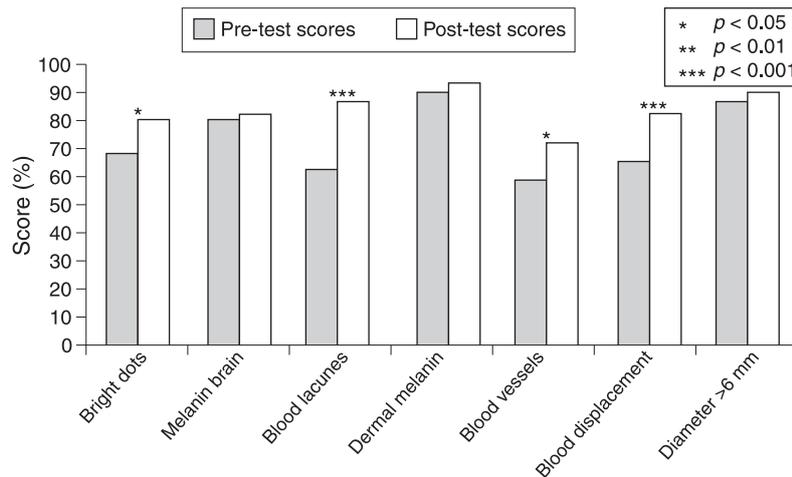


Figure 3 Comparing pre- and post-test scores for individual features of lesions ($n=21$)

unique lesions, the median pre-test score was 74.8% (IQR 67.3%–80.0%) and the median post-test score was 85.7% (IQR 82.0%–89.1%), giving a median improvement in accuracy of 8.8% (IQR 6.5%–11.7%, $p<0.001$). For the repeated lesions, the median pre-test score was 69.8% (IQR 64.3%–76.2%) and the median post-test score was 84.1% (IQR 80.2%–87.3%), giving a median improvement in accuracy of 11.1% (IQR 9.5%–17.5%, $p<0.001$).

Time taken to complete the MoleMate™ training program

The median time taken to complete the pre-test was 21 minutes and 53 seconds (21:53), (IQR 17:41–26:41) and the post-test was 17:51 (IQR 15:45–20:04). Eighteen participants completed the post-test more quickly than the pre-test: three participants were slower (by 7 seconds, 22 seconds and 2 minutes, respectively). The participants who were quicker were significantly

faster at completing the post-test than the pre-test (median 3:17, IQR 1:16 to 7:09, $p<0.001$). All three groups of practitioners were quicker on average at completing the post-test than the pre-test: for both GPs and GPRs this difference was significant ($p=0.017$ and $p=0.028$, respectively) but not for the PN/PA group ($p=0.109$), see Figure 4.

Participants who did not complete the MoleMate™ training program

The pre-test scores and times of the four non-completers were compared to those of participants who did complete the training program. The median pre-test score for non-completers was 61.2% (51.4%, 56.7%, 65.7%, 71.0%), significantly lower than the pre-test scores of participants who did complete the training program ($p=0.029$). The median time taken for non-completers to finish the pre-test was 27:37 seconds (20:54, 21:42, 33:33, 35:29), not significantly

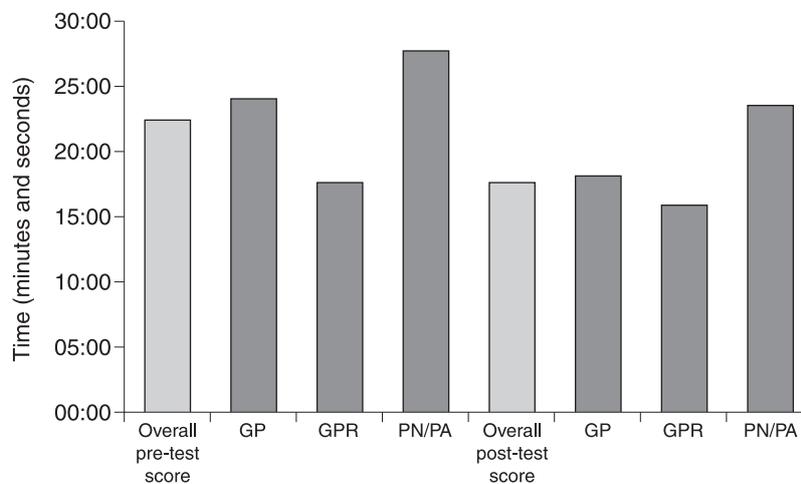


Figure 4 Comparing median pre- and post-test times between GPs ($n=8$), GPRs ($n=10$) and PN/PAs ($n=3$)

longer than participants who did complete the training program ($p=0.231$).

Practitioners' views on the MoleMate™ Training Program

The majority of participants found the MoleMate™ training program easy to use (86%, $n=21$). Most agreed that it was easy to understand the demonstration and that the feedback session was useful (81% and 90% ($n=19$ and $n=22$)[AU3], respectively). Participants were asked about the ease of identifying each individual feature seen with the MoleMate™ system. The median Likert scale answer was compared with the total score for each individual feature. This reveals a negative association, demonstrating that features scoring highly were easier to identify (see Figure 5).

Despite these views, only half of the participants felt confident in their management of a patient with a suspicious pigmented skin lesion after the session (overall 52%, $n=11$; GPs 62%, $n=5$; GPRs 60%, $n=6$; PN/PAs 0%, $n=0$). The remainder were 'unsure' (overall 29%, $n=6$; GPs 25%, $n=2$; GPRs 20%, $n=2$; PN/PAs 67%, $n=2$) or 'not confident' (overall 19%, $n=4$; GPs 12%, $n=1$; GPRs 20%, $n=2$; and PN/PAs 33%, $n=1$).

Discussion

This study has shown that the MoleMate™ training program is a potentially effective tool for teaching primary care practitioners to recognise the features of pigmented skin lesions seen with the MoleMate™ system. Comparing pre- and post-education scores, there was an overall improvement in feature recognition

and time taken, with a significant improvement among the GPs and GPRs. The MoleMate™ training program was developed through collaboration between industry and academia and iterative steps were taken during the piloting phase to improve the educational content and ease of use. This was reflected in the participants' very positive views about the MoleMate™ training program.

The improvements in feature recognition were seen for both the repeated lesions and the unique lesions, suggesting that the learning of features could be generalised to new lesions. The study showed a significant improvement in participant recognition of some features (blood lacunes, blood displacement, bright dots and blood vessels). Recognition of the remaining features showed less improvement, but the pre-test accuracy level for these was much higher (melanin brain 79%, dermal melanin 92%, diameter of lesion 85%) suggesting a ceiling effect. In support of this, when completing the questionnaire, the participants were able to correctly identify which features were more difficult to recognise and accurately score. Similar improvements in diagnostic decisions about possible skin malignancies were found in a recent study using dermoscopy after a short educational intervention.³⁰

The four non-completers were all GPs. Their primary care and postgraduate dermatology experience was similar to that of the GPs who did complete the training program, but on average they were older. They all completed the pre-test, and although their median score was significantly lower than those who did complete the MoleMate™ training program, they did not take significantly longer. Despite not completing the post-test due to time restrictions, the non-completers had similar views to the other participants on the effectiveness and acceptability of the MoleMate™ training program and the usefulness of the MoleMate™ system in general practice consultations.

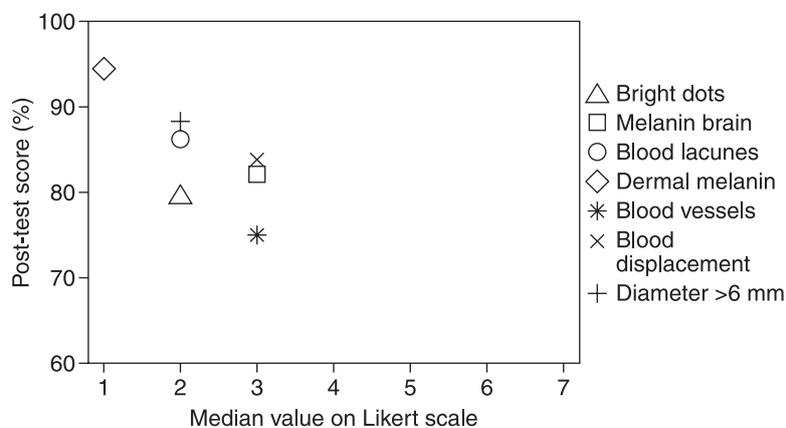


Figure 5 Comparing median post-test scores and median Likert Scale answers for each individual feature seen with MoleMate™

The small number of participants limits the generalisability of the findings from this study. Furthermore, there may have been selection bias due to the fact that, although the Pigmented Skin Lesion workshops were advertised to all GP practices in Hertfordshire and Bedfordshire, the response was small and we therefore extended the invitation to the local GP vocational training scheme members. Attending practitioners may therefore have had a greater interest in skin cancer or an above-average interest in dermatology. They were also more likely to be early adopters, although only two practitioners indicated prior exposure to the MoleMate™ system.

Despite the small number of participants, the study is well powered because the training program design includes thirty lesions for each test, with seven features per lesion. The GP registrars may be more familiar with informatics and computer-aided diagnostic programs, although there were no significant differences between GPs and GPRs in feature recognition and time taken to complete the training program. There were only two practice nurses and one physician's assistant among the participants, making a very small group for comparison with the GPs and GPRs. Finally, this pre-test/post-test design only evaluates practitioners' immediate recall of the learning intervention, and we need further evaluations of practitioner performance over time, from randomised settings and after use in the clinical situation.

We recognise that this pre-trial evaluation of the MoleMate™ training program is theoretical and, as such, the results have no immediate clinical value. It will now be used as part of the intervention in a randomised controlled trial to evaluate the effectiveness of using the MoleMate™ system compared with normal best practice in UK primary care consultations. The trial will report on the ability of practitioners to evaluate individual pigmented skin lesions to determine whether the lesion is benign or suspicious and if further specialist opinion is required.

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MoleMate™, Astron Clinica, SIAscopy, SIAscan and SIAscope are trademarks of Astron Clinica Limited.

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CONFLICTS OF INTEREST

None.[AU3]

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Appendix 1: Questionnaire

Use of the MoleMate™ Training Program*

- 1.1 It is easy to understand the demonstration
- 1.2 It is easy to see the bright dots on the collagen view
- 1.3 It is easy to see the melanin brain on the melanin view
- 1.4 It is easy to see the blood lacunes on the blood view
- 1.5 It is easy to see the bright colours on the dermal melanin view
- 1.6 It is easy to see the blood vessels on the blood view
- 1.7 It is easy to see the blood displacement with erythematous blush on the blood view
- 1.8 It is easy to measure the diameter of the lesion
- 1.9 How useful did you find the feedback section[AU4]
- 1.10 It is easy to use the MoleMate™ Training Program

Information about you

- 3.1 Name
- 3.2 Year of birth
- 3.3 Gender Male/Female
- 3.4 Years as a GP or Practice Nurse
- 3.5 Have you ever had any dermatological training? If yes, please describe
- 3.6 Have you every seen MoleMate™ before?
- 3.7 Have you any further comments that would help us with the further development of the MoleMate™ training program?

* 1.1–1.10 all assessed using a 7 point Likert scale, 1 = strongly agree, 4 = neither agree nor disagree, 7 = strongly disagree.