Canadian Agency for Drugs and Technologies in Health

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Optical Scanners for Melanoma Detection

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Summary

- ✓ **The key to a melanoma cure is early detection before the cancer has spread beyond the epidermal skin layer.**
- ✓ **Several novel, hand-held, automated optical scanning devices have been developed to aid care providers in early diagnosis. These technologies quickly and non-invasively permit visualization deeper into the skin to detect evidence of malignant change.**
- ✓ **Approved for marketing in Canada and/or the United States (US) are the devices Aura, MelaFind, and the SIMSYS-MoleMate Skin Imaging System.**
- ✓ **The reference standard is visual examination of skin lesions, followed by biopsy and histopathologic analysis, although inter-rater agreement among dermatopathologists varies. Dermoscopy provides additional visual information, increasing diagnostic accuracy, but is not widely used and is time-consuming.**
- ✓ **Optical scanners have favourable sensitivity rates (i.e., they identify most melanomas) but show low specificity, meaning that many skin lesions are mislabelled as suspicious and proceed to unnecessary biopsy.**

The Technology

Melanoma is a cancer that begins in melanocytes, which are deep epidermal cells that produce the pigment melanin. In Canada, melanoma is the seventh most common cancer, with about 6,000 new cases estimated in 2013 (3,300 men and 2,700 women) and an age-standardized incidence rate of 13.4 per 100,000 people (15.1 for men and 12.2 for women).[1] Based on 2007 estimates, the lifetime probability of dying from the disease is 1 in 287 men and 1 in 420 women.[1] If melanoma is detected at an early stage (less than 1 mm deep), the 5-year survival rate is 93 to 97%; however, the survival rate drops to 10% to 20% with advanced disease.[2,3] To enable early detection while avoiding unnecessary biopsies, there is a need for accurate diagnostic devices that can differentiate benign skin lesions from malignant ones.[4] Several non-invasive, automated, hand-held optical scanners have been developed to help dermatologists determine whether a skin biopsy is indicated. Three devices that have been approved in Canada and the US are discussed here.

- Aura (Verisante Technology, Inc., Vancouver, British Columbia, Canada) uses near-infrared laser light (Raman spectroscopy) to measure vibrational modes of biomolecules and distinguish malignant from benign skin lesions. The hardware includes a diode laser, a fibre and fibre-bundle delivery system, a hand-held Raman probe, a spectrograph, a camera detector, and a computer. A 785 nm laser beam is delivered to the probe, and the signal from the skin is transmitted to the spectrometer for spectral analysis.[5-7]
- MelaFind (MELA Sciences, Inc., Irvington, New York, US) uses an illuminator that shines light of 10 wavelengths, a lens system that creates images of the light scattered back from the lesions, and a light sensor to assess tissue up to 2.5 mm beneath the skin's surface. Information from the device is transmitted into image analysis algorithms using a skin disorder database. A treatment suggestion is provided; i.e., MelaFind positive (high degree of morphological disorganization) or MelaFind negative (low degree of morphological disorganization).[8-11]
- SIMSYS-MoleMate Skin Imaging System (MedX Health, Inc., Hamilton, Ontario, Canada) uses a hand-held scanner and computer software to provide images that demonstrate a lesion's vascular composition and pigment network. The technology employs spectrophotometric intracutaneous analysis (SIAscopy) — a light-based imaging system capable of producing rapid images of melanin, blood, and collagen to a skin depth of 2 mm.[12,13] The MoleMate proprietary software provides dermatoscopic images; dermal and epidermal pathological characteristics; and the ability to catalogue, monitor, and compare lesions over time.[12]

Regulatory Status

- Aura was approved by Health Canada as a Class II device in October 2011[14] and is marketed in Canada, the European Union, and Australia.[15] The manufacturer is preparing to seek US Food and Drug Administration (FDA) approval soon.[16-18]
- The MelaFind device is not yet approved for use in Canada. Pre-market approval was granted by the US FDA in November 2011 following an expedited review.[19] However, the FDA placed limitations on the device's use and required a five-year post-approval study (NCT01700114) to evaluate whether MelaFind increases the diagnostic sensitivity for melanomas and high-grade lesions without substantially increasing the false-positive rate.[20] To ensure the capture of false-negative results, patients who are not biopsied must be followed for at least two years. The company's website suggests the device is available in about two-thirds of US states.[21] MelaFind received regulatory approval to market the device in Europe in September 2011.[22,23]
- The SIMSYS-MoleMate system received Class II marketing approval from Health Canada in January 2012,[14] was approved by the US FDA in September 2011, and is also approved for marketing in Europe.[12]

Patient Group

The most common form of melanoma, encompassing 65% of melanomas, is superficial spreading melanoma, which often arises in a pre-existing mole and grows horizontally before invading vertically; a further 25% are nodular melanomas that bypass the horizontal growth phase.[24]

Melanoma risk factors include severe blistering sunburn, ultraviolet light exposure (sunlight and tanning lamps or beds), presence of numerous moles (> 50), positive family or personal history, and immune suppression. Risk is higher for people with light- versus dark-coloured skin.[25-28]

Compared to other cancers, a younger population is affected by melanoma, accounting for 22 years of lost life due to invasive disease.[25] Unlike many cancers, the age-standardized incidence rates of melanoma have increased annually from 1998 to 2007 (by 1.4% in men and 1.5% in women)[1] and the lifetime risk of developing invasive melanoma has increased from 1 in 500 people in 1930 to 1 in 74 in 2000.[29]

Current Practice

Tumor depth is the most important prognostic factor for melanoma. Early detection when lesions are more superficial may improve survival; however, early recognition can be a challenge.[2,3,25] Trained dermatologists can recognize advanced melanoma by visual inspection using the ABCDE criteria (Asymmetry, Border irregularity, Colour variegation, Diameter > 6 mm, Evolution), but, in the early stages, melanomas often mimic benign lesions.[4] Hence, most melanomas in North America are > 6 mm in diameter (the size of a pencil eraser) when diagnosed.[25]

For those at increased risk, such as people with many nevi (sharply circumscribed lesions of the skin) or a tendency to develop atypical nevi, early detection relies on thorough yearly examinations by physicians, supplemented by monthly self-exams by patients.[4,30] There is no evidence to support general population screening for melanoma.[28,31]

The reference standard for melanoma diagnosis is visual examination of skin lesions by a dermatologist, followed by biopsy and histopathology analysis,[32] although inter-rater agreement among dermatopathologists is not 100%. For example, a study testing dermatopathologist agreement across 1,250 samples revealed a kappa value of 0.8 for melanoma versus non-melanoma and 0.62 for malignant versus borderline versus benign melanocytic lesions.[33]

About half of all melanomas are first identified by the patient.[2,34] Clinical guidelines suggest that a mole exhibiting a significant change in shape or colour, or causing itching or burning, should undergo complete (not partial) excision. This is possible if the lesion is small. If not — for example, for cosmetic or functional reasons — then incisional or punch biopsies are indicated focusing on areas with pigmentation variation or nodular components. Further, if a patient expresses concern about a particular lesion, it is recommended that reassurance be provided only if a lesion is highly unlikely to be melanoma; otherwise, repeat observation after one to two months is considered essential. Photography (single lesion or total body) may be used to capture baseline images with repeat photography several months later.[35]

A useful dermatologic tool is dermoscopy, which involves 10x microscopy and polarized light and/or a liquid medium to allow for a non-invasive, detailed examination of the structures of a pigmented lesion.[29,36-38] Sequential dermoscopy may be used to track changes in lesions over time and has been shown to decrease rates of excision of benign lesions.[38] However, the utility of dermoscopy varies with experience, many dermatologists are not trained in its use, and it can be time-consuming, particularly when used for multiple lesions.[29,34]

Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 1), the University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and economic studies. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1 2009 and February 14, 2014. Regular alerts were established to update the search until March 6, 2014.

Citations were selected for inclusion if they evaluated the use of optical scanners for the detection of melanoma. Devices currently approved for marketing in Canada or the US were considered.

The Evidence

Aura

One study of Aura was identified from the University of British Columbia and the BC Cancer Agency, where the device was developed.[5] Research funding was provided by a number of sources including the device manufacturer. Adults were enrolled if they had lesions that were of clinical interest or possible skin cancers. Excluded were lesions that were very small (< 1 mm across); inaccessible to the probe; infected; or previously biopsied, excised, or traumatized. For the analysis, Raman spectral measurements were taken from skin lesions that caused concern; i.e., malignancies and premalignancies that required treatment plus benign conditions that can visually mimic skin cancer. The final classification of lesions was established through clinical evaluation by an experienced dermatologist (without dermoscopy) and/or by histopathologic analysis if a skin biopsy was performed after device use. Biopsy was carried out for all possibly malignant lesions; all lesions classified as cancerous at the end of the study were confirmed as such through biopsy, and approximately 30% of premalignant and benign lesions were also biopsied. Included in the analysis were 518 lesions from 453 subjects (sex distribution approximately equal, median age 61 years). Of these, 313 lesions (60%) underwent subsequent treatment, including 44 melanomas.

The system's diagnostic performance was tested according to the ability to discriminate melanoma from benign pigmented skin lesions that are similar in appearance. Results showed that, for melanoma versus benign pigmented lesions, as sensitivity increased from 90% to 99%, specificity fell from 58% to 15%. Across the sensitivity span of 90% to 99%, positive predictive values (PPVs) ranged from 30% to 15%, and negative predictive values (NPVs) from 98% to 99%. The authors concluded that their results supported the use of Raman spectroscopy to guide skin cancer diagnosis, including differentiation of melanoma from benign pigmented skin lesions, and that this technology had the potential to reduce the number of unnecessary skin biopsies.

MelaFind

One published study on the MelaFind device was identified. The industry-funded, multi-centre, prospective, blinded trial (NCT00434057) was conducted at seven US centres in 2007 to 2008.[8,39] Enrolled were 1,383 patients scheduled for the excision of 1,831 pigmented skin lesions. Exclusions included small or large lesions (< 2 mm or > 22 mm); lesions near the eye or on palmar, plantar, or mucosal surfaces; sites that were not device-accessible; and previous biopsy, excision, scarring, or tattoo in the area. Melanoma risk factors, ABCDE, and patient's concern were recorded, as were pre-biopsy diagnoses by examining dermatologists. MelaFind images, standard clinical photographs, and a dermoscopic image were acquired for each lesion. Histologic specimens evaluated by two independent dermatopathologists served as the reference standards (a third served as adjudicator, as needed). As the objective was to see how MelaFind performed in situations of uncertainty, lesions with a pre-biopsy diagnosis of melanoma were excluded. Regarding blinding, clinicians did not receive the results of the MelaFind device, and information from MelaFind was not used in diagnosis or treatment.

Of the evaluable lesions, about 8% were melanomas; most were spreading superficial melanomas, a form that can be difficult to differentiate from benign lesions. Compared with histopathologic evaluation, MelaFind displayed 98% sensitivity (125 of 127 lesions) and 9% specificity, versus 4% specificity for the clinical examination alone (P = 0.02). PPV for MelaFind was 9% and NPV was 99%. Sensitivity for clinicians could not be calculated, as the melanomas they missed would only be identified via long-term follow-up; however, a separate study (39 dermatologists, 50 lesions of which 25 were melanomas) revealed about 78% sensitivity for clinicians.[8,39-42] A similar study from Sweden reported 71% sensitivity for clinicians.[43]

SIMSYS-MoleMate

A randomized controlled trial (RCT) of SIMSYS-MoleMate was conducted at 15 primary care sites in Eastern England, enrolling 1,297 patients with 1,580 lesions. This study was funded by the School for Primary Care Research of the National Institute for Health Research. Patients were assessed by trained clinicians via best practice (clinical history, naked eye examination, seven-point checklist), alone or with the MoleMate system.[44] There was little difference between groups in numbers of histologically confirmed melanomas, appropriateness of referral, proportion of benign lesions appropriately managed in primary care, and percentage agreement with an expert decision (based on clinical examination alone) to biopsy or monitor. The authors stated that adding MoleMate to best practice resulted in lower agreement with expert assessment that the lesion was benign and led to a higher proportion of referrals (30% versus 22%, P = 0.001). Further, they expressed concern that “the novel technology provided false reassurance, as the systematic application of best practice guidelines ultimately proved more accurate.”[44]

Adverse Effects

No adverse effects of device use are described aside from the potential harms which may follow false-negative and false-positive results. False-negatives can lead to delays in diagnosis and treatment, and possibly increased morbidity and mortality, whereas false-positives can lead to unnecessary invasive procedures.

Administration and Cost

Aura

The probe is lightly placed on the lesion for about one second. Spectral measurements are taken in duplicate by separately measuring each lesion and then measuring normal-appearing surrounding skin, usually within 5 cm of the lesion. Larger and non-homogeneous lesions are measured several times. The information is processed by the computer, and separation of benign from malignant lesions is possible according to the Receiver Operating Characteristics (ROC).[5] Proponents list Aura’s advantages over competitors as rapid scan time (1 second), a small probe for hard-to-reach lesions, use for skin cancers aside from melanomas, and less extensive user training.[5,45] The device selling price in Canada will be $65,000 including all necessary software, although it is also available for long-term monthly lease, plus $10 for each disposable tip that touches a patient.[7,16] There are no additional costs for operation. A service contract after the one year warranty period is available for $5,000 per year. (Anna Trinh, Verisante Technology, Inc., Vancouver: personal communication, 2014 Mar 4).

MelaFind

After hair is removed and the skin is prepared with alcohol, the device lightly touches the lesion for several seconds. Findings are analyzed in less than a minute including comparison with 10,000 archived images. Provided are images of the lesion from each of 10 wavelengths plus information about the level of three-dimensional morphological disorganization; i.e., “high disorganization” or “low disorganization.”[26,46] The device may be purchased for US$128,000, which includes operational software packages and upgrades, as well as device training and practice integration support. (Natalie Tucker, MELA Sciences, Irvington, NY: personal communication, 2014 Mar 5). Alternatively, the two-year cost of leasing the device, including training cost, is US$7,500 to $10,000 in the US and Germany. There is a $50 fee for each use to “unlock” the system.[32,34,47-49] Consumables include products to assist in the data capture such as cleaning and coupling agents, and patient data cards. (Natalie Tucker, MELA Sciences, Irvington, NY: personal communication, 2014 Mar 5).

SIMSYS-MoleMate

Detailed descriptions of the SIMSYS-MoleMate administration procedure were not available, although manufacturer information indicates that scans are performed "in seconds," and that the device can be used to detect skin cancers other than melanomas. The cost of SIMSYS-MoleMate is C$4,000 to $5,000 for the scanner alone and $5,000 to $6,000 with mole mapping.[12] An economic evaluation was performed alongside the United Kingdom (UK)-based RCT of SIMSYS-MoleMate.[50] Results showed that over a lifetime horizon, the MoleMate system would cost an extra £18 over best practice alone and yield an extra 0.01 quality-adjusted life-years (QALYs) per patient examined. The incremental cost-effectiveness ratio was £1,896 per QALY gained, with a 66% probability of being below £30,000 per QALY gained; i.e., the upper limit of acceptable QALY value in the UK.

Concurrent Developments

There is great interest in detection of early melanomas, particularly using non-invasive optical technologies.[2,4,51,52] Nevisense (SciBase, Sweden) is marketed to aid in the detection of melanomas and is currently available only in the Nordic countries, Germany, and Australia, although application for FDA approval may be underway.[52,53] VivoSight (Michelson Diagnostics, UK) is an optical scanner with FDA approval and a CE mark,[54] but marketing materials only describe its use for non-melanoma skin lesions.[55] Many additional technologies are being explored such as confocal laser scanning microscopy, epidermal genetic information retrieval, electrical impedance spectroscopy, optical coherence tomography, reflex transmission imaging, high resolution ultrasound, and melanoma-sniffing dogs.[3,29]

Rate of Technology Diffusion

Uptake and diffusion of optical scanning devices may be slow for several reasons: multiple types of devices based on different technologies are available, which may lead to a lack of clinical agreement as to which specific device to adopt; marketing approval is not universal; purchase or leasing costs are high compared to other diagnostic aids; health payer coverage is not widely offered, whereas biopsy costs are fully funded; and dermatologists may not see the added value versus their own experience with the adjunctive use of dermoscopy and photography.[47] Until costs fall, there may be limited uptake of the technology other than in institutional settings.

Implementation Issues

The devices varied with respect to manufacturers' suggestions regarding use beyond trained dermatologists. Based on marketing materials, both Aura and MoleMate could be suitable for primary care providers,[6,12] whereas MelaFind is recommended for use by dermatologists only.[11] Place in therapy also varies. For example, the manufacturer of MelaFind states that the device is to be used to aid dermatologists in their decision to perform a biopsy and is not to be used to make or confirm a melanoma diagnosis,[11] whereas the other two manufacturers do not emphasize this point.

An issue for all of the reviewed devices is that the technology (with present specificity and sensitivity values) has high negative predictive value but low positive predictive value. This means that many biopsies of benign lesions will still occur, although possibly fewer than with clinical examination alone. Crucially, the evidence base for all three devices is limited, with one key trial for each. Thus far it is not clear how the devices will perform in a non-research setting, or what their optimal place is in diagnosis. Multi-centre confirmatory studies will be helpful in this respect. A combination of the various technologies available for optical screening of melanoma in the same device could produce the greatest diagnostic utility.

References

1. Canadian Cancer Society's Advisory Committee on Cancer Statistics. Canadian cancer statistics 2013 [Internet]. Toronto: Canadian Cancer Society; 2013. [cited 2014 Feb 20]. Available from: http://www.cancer.ca/~/media/cancer.ca/CW/publications/Canadian%20Cancer%20Statistics/canadian-cancer-statistics-2013-EN.pdf
2. Kupetsky EA, Ferris LK. The diagnostic evaluation of MelaFind multi-spectral objective computer vision system. Expert Opin Med Diagn. 2013 Jul;7(4):405-11.
3. Divito SJ, Ferris LK. Advances and short comings in the early diagnosis of melanoma. Melanoma Res. 2010;20(6):450-8.
4. Herman C. Emerging technologies for the detection of melanoma: Achieving better outcomes. Clinical, Cosmetic and Investigational Dermatology [Internet]. 2012 [cited 2013 Nov 22];5:195-212. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3508547/pdf/ccid-5-195.pdf

5. Lui H, Zhao J, McLean D, Zeng H. Real-time Raman spectroscopy for in vivo skin cancer diagnosis. Cancer Res. 2012 May 15;72(10):2491-500.
6. Verisante Aura™ [Internet]. Vancouver: Verisante Technology. 2014 [cited 2014 Feb 21]. Available from: http://www.verisante.com/products/aura/
7. Fayerman P. Vancouver skin cancer detection device ready for market: Nobel prize-winning research behind it [Internet]. Vancouver: Vancouver Sun; 2013 Dec 14. [cited 2014 Feb 20]. Available from: http://blogs.vancouversun.com/2013/12/14/vancouver-skin-cancer-detection-device-ready-for-market-nobel-prize-winning-research-behind-it/
8. Monheit G, Cognetta AB, Ferris L, Rabinovitz H, Gross K, Martini M, et al. The performance of MelaFind: a prospective multicenter study. Arch Dermatol. 2011 Feb;147(2):188-94.
9. MelaFind® - P090012. Summary of safety and effectiveness data (SSED) [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2011 Nov 1. [cited 2014 Feb 21]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090012b.pdf
10. Cleveland Clinic [Internet]. Cleveland: Cleveland Clinic. Cleveland Clinic names top 10 medical innovations for 2013; 2012 Oct 31 [cited 2014 Feb 21]. Available from: http://my.clevelandclinic.org/media_relations/library/2012/2012-10-31-cleveland-clinic-names-top-10-medical-innovations-for-2013.aspx
11. MelaFind [Internet]. Irvington (NY): MELA Sciences; 2014. What is MelaFind®; 2014 [cited 2014 Feb 20]. Available from: http://www.melafind.com/patients/about-melafind
12. SIMSYS™ MoleMate™ [Internet]. Mississauga (ON): MedX Health Corporation. 2014 [cited 2014 Feb 20]. Available from: http://simsys-molemate.com/
13. Tehrani H, Walls J, Price G, Cotton S, Sassoon E, Hall P. A novel imaging technique as an adjunct to the in vivo diagnosis of nonmelanoma skin cancer. Br J Dermatol. 2006 Dec;155(6):1177-83.
14. Medical Devices Active Licence Listing (MDALL) [Internet]. Ottawa: Health Canada. SiaScope; Licence no. 88176; 2012 Jan 31 [cited 2014 Feb 21]. Available from: http://webprod5.hc-sc.gc.ca/mdll-limh/start-debuter.do?lang=eng
15. Canadian Broadcasting Corporation. Skin cancer detector approved [Internet]. Toronto: CBC; 2011 Oct 19. [cited 2013 Feb 20]. Available from: http://www.cbc.ca/news/health/skin-cancer-detector-approved-1.1121389
16. Zehr L. Verisante readies Aura launch for skin cancer [Internet]. New York: BioTuesday Publishing Corporation; 2012 Jun 26. [cited 2014 Feb 20]. Available from: http://biotuesdays.com/2012/06/26/verisante-readies-aura-launch-for-skin-cancer/
17. Zehr L. Verisante to seek FDA approval of Aura skin cancer device [Internet]. New York: BioTuesday Publishing Corporation; 2013 Jun 11. [cited 2014 Feb 21]. Available from: http://biotuesdays.com/2013/06/11/verisante-to-seek-fda-approval-of-aura-skin-cancer-device/
18. Rosenberg-Yunger ZR, Daar AS, Thorsteinsdottir H, Martin DK. Priority setting for orphan drugs: an international comparison. Health Policy. 2011 Apr;100(1):25-34.
19. Food and Drug Administration. Letter to: MELA Sciences, Inc. [Internet].2011 Nov 1. [cited 2014 Jan 13]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf9/p090012a.pdf
20. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2014. Post-approval studies; 2014 Jan 13 [cited 2014 Jan 13]. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=429485&c_id=580
21. MelaFind® [Internet]. Irvington (NY): MELA Sciences. 2014 [cited 2014 Feb 20]. Available from: http://www.melafind.com/
22. Brickates Kennedy V. Mela rockets 60% on EU product approval [Internet]. In: MarketWatch. New York: Dow Jones & Co; 2011 Sep 7 [cited 2014 Jan 13]. Available from: http://www.marketwatch.com/story/mela-rockets-60-on-eu-product-approval-2011-09-07.
23. Corley G. MelaFind lesion imaging device receives CE marking. MedGadget [Internet]. 2011 Sep 8 [cited 2014 Jan 13]. Available from: http://www.medgadget.com/2011/09/melafind-lesion-imaging-device-receives-ce-marking.html
24. Melanoma [Internet]. Vancouver: B.C. Cancer Agency; 2013. Surveillance and early detection in high risk patients. [cited 2014 Feb 20]. Available from: http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Skin/Melanoma/Surveillance.htm

25. Morrow T. MelaFind improves chances for accurate melanoma diagnosis. Manag Care. 2010 Mar;19(3):54-5.

26. Could it be melanoma? [Internet]. Irvington (NY): MELA Sciences; 2013. [cited 2014 Feb 20]. Available from: http://www.melafind.com/wp-content/uploads/patient_brochure.pdf

27. Melanoma skin cancer [Internet]. Atlanta: American Cancer Society; 2014 Jan 9. [cited 2014 Feb 21]. Available from: http://www.cancer.org/acs/groups/cid/documents/webcontent/003120-pdf.pdf

28. National Guideline Clearinghouse [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); [1997] -. Guideline summary: Screening for skin cancer: U.S. Preventive Services Task Force recommendation statement; 2009 Feb [cited 2014 Jan 21]. Available from: http://www.guideline.gov/content.aspx?id=13695

29. Wang SQ, Hashemi P. Noninvasive imaging technologies in the diagnosis of melanoma. Semin Cutan Med Surg. 2010 Sep;29(3):174-84.

30. Melanoma [Internet]. Vancouver: BC Cancer Agency; 2013. Melanoma incidence, demographics, predisposing factors and prevention. [cited 2014 Feb 20]. Available from: http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Skin/Melanoma/start.htm

31. National Guideline Clearinghouse [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); [1997] -. Guideline summary: Early detection of cancers. In: Guidelines for preventive activities in general practice, 8th edition; 2012 [cited 2014 Feb 20]. Available from: http://www.guideline.gov/content.aspx?id=43855&search=melanoma

32. Health Policy Advisory Committee on Technology. MelaFind® for the detection of melanoma among atypical melanocytic skin lesions [Internet]. Brisbane (Queensland): HealthPACT Secretariat; 2012 May. [cited 2014 Feb 21]. Available from: http://www.health.qld.gov.au/healthpact/docs/briefs/WP099.pdf

33. Braun RP, Gutkowicz-Krusin D, Rabinovitz H, Cognetta A, Hofmann-Wellenhof R, hlgrimm-Siess V, et al. Agreement of dermatopathologists in the evaluation of clinically difficult melanocytic lesions: how golden is the 'gold standard'? Dermatology. 2012;224(1):51-8.

34. Ferris LK, Harris RJ. New diagnostic aids for melanoma. Dermatol Clin [Internet]. 2012 Jul [cited 2013 Nov 21];30(3):535-45. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3623959/pdf/nihms387679.pdf

35. New Zealand Guidelines Group. Melanoma: an aid to diagnosis [Internet]. [Wellington]: Ministry of Health (New Zealand); 2008 Nov. [cited 2014 Feb 20]. Available from: http://www.health.govt.nz/system/files/documents/publications/melanoma_card.pdf

36. Canadian Agency for Drugs and Technologies in Health. Dermoscopy for patients with skin lesions: a review of the clinical effectiveness, cost-effectiveness, and evidence-based guidelines [Internet]. Ottawa: The Agency; 2012 Nov 26. (Rapid response report: summary with critical appraisal). [cited 2014 Feb 21]. Available from: http://www.cadth.ca/media/pdf/htis/nov-2012/RC0415%20dermoscopy%20Final.pdf

37. Bergstrom KG. MelaFind is approved by the FDA: where does it fit in dermatology? J Drugs Dermatol. 2012 Mar;11(3):420-2.

38. Menzies SW. Evidence-based dermoscopy. Dermatol Clin. 2013 Oct;31(4):521-4, vii.

39. Monheit G, Cognetta A, Gutkowicz-Krusin D, Ferris LK. Prospective multicenter study of an objective computer-vision system for early melanoma detection [abstract]. J Am Acad Dermatol. 2010;62(3 Suppl 1):AB7.

40. Wells R. Comparison of diagnostic and biopsy/referral sensitivity to melanoma between dermatologists and MelaFind: A pilot survey study. J Drugs Dermatol. 2011;10(9):1078.

41. Wells R, Veledar E, Chen S, Ferris L. "Pilot survey study - Comparison of diagnostic and biopsy/referral sensitivity to Melanoma between dermatologists and MelaFind" [abstract]. J Invest Dermatol. 2010;130 Suppl 1:S143.

42. Wells R, Gutkowicz-Krusin D, Veledar E, Toledano A, Chen SC. Comparison of diagnostic and management sensitivity to melanoma between dermatologists and MelaFind: a pilot study. Arch Dermatol. 2012 Sep 1;148(9):1083-4.

43. Ahnlide I, Bjellerup M. Accuracy of clinical skin tumour diagnosis in a dermatological setting. Acta Derm Venereol. 2013 May;93(3):305-8.

44. Walter FM, Morris HC, Humphrys E, Hall PN, Prevost AT, Burrows N, et al. Effect of adding a diagnostic aid to best practice to manage suspicious pigmented lesions in primary care: randomised controlled trial. BMJ [Internet]. 2012 [cited 2014 Feb 20];345. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3389518

45. Aura™ [Internet]. Berlin: Verisante Technology. 2013 [cited 2014 Jan 22]. Available from: http://www.verisante.com/aura/medical_professional/

46. MelaFind [Internet]. Irvington (NY): MELA Sciences; 2014. About MelaFind®; 2014 [cited 2014 Feb 20]. Available from: http://www.melafind.com/dermatologists/about-melafind#features-and-benefits

47. Computer-aided multispectral digital analysis (MelaFind) for assessing atypical skin lesions. Manag Care. 2012 Aug;21(8):12-3.

48. Singer N. Dissent over a device to help find melanoma [Internet]. New York: The New York Times; 2013 Jul 20. [cited 2014 Feb 20]. Available from: http://www.nytimes.com/2013/07/21/business/dissent-over-a-device-to-help-find-melanoma.html?pagewanted=1&_r=2

49. Perrone M. MelaFind, device that screens for melanoma with light, approved by FDA [Internet]. Washington: The Huffington Post; 2011 Nov 2. [cited 2014 Feb 20]. Available from: http://www.huffingtonpost.com/2011/11/02/melafind-device-that-scre_n_1071451.html

50. Wilson EC, Emery JD, Kinmonth AL, Prevost AT, Morris HC, Humphrys E, et al. The cost-effectiveness of a novel SIAscopic diagnostic aid for the management of pigmented skin lesions in primary care: a decision-analytic model. Value Health. 2013 Mar;16(2):356-66.

51. Sattler E, Kastle R, Welzel J. Optical coherence tomography in dermatology. J Biomed Opt. 2013 Jun;18(6):061224.

52. Guitera P, Menzies SW. State of the art of diagnostic technology for early-stage melanoma. Expert Rev Anticancer Ther. 2011 May;11(5):715-23.

53. SciBase [Internet]. Stockholm: SciBase AB. Nevisense now commercially available in Germany, Australia and Nordic markets; 2014 [cited 2014 Feb 21]. Available from: http://www.scibase.se/en/about-scibase/available-markets/

54. VivoSight [Internet]. VivoSight. 2014 [cited 2014 Feb 20]. Available from: http://www.vivosight.com/our-history/

55. VivoSight OCT Education Centre [Internet]. Kent (UK): Michelson Diagnostics. 2014 [cited 2014 Feb 20]. Available from: http://www.vivosightatlas.com/

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A clinical expert in dermatology was consulted by CADTH in preparing this report.

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