Non-invasive & Non-radioactive Optical Image Capturing and Management System for Skin Disorder Diagnosis

26 Mar 2018

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Smart Healthcare, MedTech & Optics, Automotive and Electronics
Background

- What is Melanoma
  - Melanoma is a malignant tumor of melanocytes, which are cells that produce the dark pigment, melanin, which is responsible for the color of skin.
  - Melanoma is the most dangerous type of skin cancer. It is the leading cause of death from skin disease.
    - Less common than other skin cancers.
    - However much more dangerous if it is not found early.
    - Causes the majority (75%) of deaths related to skin cancer.*

Background (Cont.)

• The risk of melanoma increases with age, but frequently effects young, otherwise healthy people.

• Melanoma is an aggressive type of cancer that can spread very rapidly.

• It is more common in women than in men. In women, the most common site is the legs and melanomas in men are most common on the back*.

* Cancer Research UK statistics team 2010.
Quick facts for skin cancer

Globally:
- One in every three cancers diagnosed is a skin cancer
- Up to 3 million non-melanoma skin cancers & 132,000 melanoma new cases each year
- One in every five Americans will develop skin cancer in their lifetime

In HK:
- Top 10 cancers in HK since 02'

MOTIVATION
Start from a problem
How Common is Skin Cancer

- Other Cancers
- Skin Cancer

How Serious is Melanoma

- Deaths
  - ~71%
  - ~5%

Gender

- Melanoma affects both men and women

Age

- Average age of diagnosis: 52
- However, melanoma is the 2nd most common cancer in people aged 25-29.

Ethnic Group

- Melanoma is 20 times more common in whites than in African Americans.

References:
Current Medical Procedures

- (1) (2) **Naked eye examination / with amplifiers** is with lower sensitivity and specify / not convenient for long-term monitoring

- (3)–(6) **Skin biopsy and histopathology** can confirm clinical diagnosis but is invasive and with more complex procedures

- (7) Dermoscopy helps reduce the needs for biopsy and is especially helpful for melanoma diagnosis. However, **large scan systems / camera mounted dermoscopy** require lengthy set up and are not convenient in busy clinics.
Daily medical Services
• Diagnosis
• Therapy
• Intervention
• Outcome evaluation
• Operation procedures
• Resources management

Knowledge-based Interpretation

Biomedical Engineering
• R&D
• Functional prototype
• Clinical evaluation
• Manufacturing
• Marketing
• Regulatory requirements
Our Solution: A Non-invasive & Non-radioactive Optical Image Capturing System for Skin Applications
Hardware Development

Schematic diagram of hardware device

Patented Design

HKPC
Hardware Development

**Polarizer Unit Development – Linear Polarizer**

- Every other LED on ring fixture operates as first and second light sources. As shown in the left upper figure, the even LEDs are filtered by a first polarization ring. As shown in the left lower figure, the odd LEDs and camera lens are filtered by a second polarization ring, which is crossed-polarized relative to the first polarization ring.
- Above mentioned two polarizer rings were overlapped together for polarization function of the hardware (right figure).
Hardware Development

Image Capturing Unit - Lenses

- Through computer aided simulation and optimization, as shown in the left figure, camera lens was designed by ZEMAX to realize general and 10x magnify mode for 2D pigmented skin lesion images capturing.
- Aspherical achromatic lens was used as the magnifying lens to achieve less dispersion, better chromatic correction and smaller RMS spot size. The image distortion can be controlled below 1%.
Hardware Development

Image Capturing Unit - Lenses

Factors that affected the image quality in design v1.0 - Optical aberrations & Chromatic aberrations

Improvements in v2.0:
• Aspheric Achromatic Lenses (amplifying lens)

 ✓ Correction of spherical aberration
 ✓ Better chromatic correction than traditional achromatic lenses
 ✓ Less dispersion in optical glass (than optical plastics with the same refractive index)
 ✓ Smaller RMS spot size

• Effective focal length (amplifying lens)
 ✓ Allow better positioning of illumination unit

Camera lens design by ZEMAX

Aspherized Achromatic Lenses

Spot Size

Aspheric Achromatic

Traditional Achromatic
• **Chromatic aberration (色差)**
  
  – Because lenses have a different refractive index for different wavelengths of light.

  – Chromatic aberration manifests itself as "fringes" of color along boundaries that separate dark and bright parts of the image, because each color in the optical spectrum cannot be focused at a single common point.
• Spherical aberration (球差)
  – Due to the increased refraction of light rays when they strike a lens or a reflection of light rays when they strike a mirror near its edge, in comparison with those that strike nearer the centre.
Hardware Development

**Illumination Unit**

<table>
<thead>
<tr>
<th>General information of selected White LED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of LED</td>
<td>6</td>
</tr>
<tr>
<td>LED</td>
<td>Cree XPEWHT-L1-WD0-Q4</td>
</tr>
<tr>
<td>Color</td>
<td>Cool White</td>
</tr>
<tr>
<td>CCT Range (k)</td>
<td>5,000 - 10,000</td>
</tr>
<tr>
<td>Luminous Flux (lm)</td>
<td>100</td>
</tr>
<tr>
<td>Viewing Angle (deg)</td>
<td>115</td>
</tr>
<tr>
<td>DC Forward Current (mA)</td>
<td>700</td>
</tr>
<tr>
<td>Forward Voltage (@700 mA) (V)</td>
<td>3.4</td>
</tr>
<tr>
<td>LED Junction Temperature (°C)</td>
<td>150</td>
</tr>
</tbody>
</table>

**Light source:** white LED

**PCB ring with LED array**

**Illumination Simulation by LightTools**

**Illuminance distribution at amplifying mode**
Hardware Development

Other Feature

“Can you make it more easy to use and to check the images?”

Bi-mode image capture:

- General Mode: enabling the acquisition of skin lesion location and patient identification information
- Amplified Mode: providing amplified dermoscopic images of the skin lesion
Software Development

Enabled Long Term Monitoring after both Hardware and Software Upgrade
Software Development

ABCD Rules

- The ABCD rule has been proven to be a reliable method providing a more objective and reproducible diagnosis of melanoma.
Software Development

ABCD Rules

× The ABCD rule, which has been proven to be a reliable method providing a more objective and reproducible diagnosis of melanoma.

**A – Asymmetry**

![Asymmetry Image]

**B – Border**

![Border Image]

**C – Color**

Presence of 6 colors: white, red, light brown, dark brown, blue-gray and black, will be calculated

**D – Dermoscopic Structures**

Presence of network, structureless or homogeneous areas, branched streaks, dots, and globules

http://www.dermoscopy.org/consensus/2b.asp
Software Development

Snapshot of determining the Dermoscopic Structure
Interface Overview

Please click the button to separate the photos into individual folders.

choose folder
Software Development
Deliverables

Version 2.0 (v2.0)

**HKPC Demographic Analyzer**

<table>
<thead>
<tr>
<th>File</th>
<th>View</th>
<th>ADCD Analysis</th>
<th>About</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) folder management</td>
<td>1) Select Patient</td>
<td>2) Body Location</td>
<td>3) ADCD Analysis</td>
</tr>
</tbody>
</table>

**HKPC**

**AN ADVANCED DESIGN OF NON- RADIOACTIVE IMAGE CAPTURING AND MANAGEMENT SYSTEM FOR APPLICATIONS IN NON-INVASIVE SKIN CANCER DIAGNOSIS**

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Hong Kong Productivity Council
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**Introduction**

Skin cancer is the most common type of all cancers, which accounts for nearly half of all cancers in the United States. Skin cancer, excluding melanoma, was the 7th most common cancer in Hong Kong in 2016 and the trend has increased to the 7th in 2020 [2]. Melanoma is reported to account for more than 90% of all skin cancer cases but the vast majority of skin cancer deaths is in the 2nd stage when treatment is to the early stage was significantly affect the survival rate.

Currently the most common ways for preliminary diagnosing skin cancer is by visual judgement, in which the accuracy is highly subject on the experiences of doctors. Besides the visualization in inspectors and can easily produce the variation of information of the lesion, which is greatly demanded by the doctors during diagnosis and treatment. The unique design of an optical imaging system has been developed to use precise earlier [9]. In this manner, an advanced design of imaging capturing and data management system will be further presented.

**Method**

In this study, the computer-based simulations for optical design and illumination distribution were conducted using ZEMAX and Autodesk commercially separately as in [3]. A prototype was further developed, with the imaging platform and ADCD lighting module is successfully in a self-designed form (Fig. 1). It has been reported in various studies that the distance between subject and lighting module (L) would greatly affect the uniformity of illumination distribution [4]. A significant improvement of design in this study was made by computationally considering of the design of lighting module and magnifying module, to optimize the uniformity of the illumination distribution. Advanced magnifying lens and high resolution CCD were utilized to feedback the scanned image separately.

**Results and Discussion**

With appropriately selected lens and arranged LEDs, the device prototype was able to reduce the influence resulted from chromatic dispersion, spherical aberration and vignetting, and provide satisfactory quality of image with resolution of captured image increased by 17% compared with the prototype developed in [3]. The scanning flow as well as a map of image analyzed with the software system could be shown in Fig. 7. With the satisfactory results from this preliminary study, trial study on human beings will be further conducted with the developed prototype as well as management software system in the next step.

**Reference**


**Acknowledgement**

The authors would like to thank [2] for the financial support given and the [7] for the permission to use their images. This research was supported by [3].
Pre-trial Study

Example Cases:

Cancerous cases:
Pre-trial Study (cont.)

– Examples of lesion photos captured from subjects:

Diagnosis remark: non-suspicious (epidermoid cyst)
Pre-trial Study (Cont.)

– Examples of lesion photos captured from subjects:

Diagnosis remark: suspicious (seborrheic keratosis in a cancer patient)
Pre-trial Study (Cont.)

– Examples of lesion photos captured from subjects:

Diagnosis remark: suspicious (non-melanoma skin cancer)
Pre-trial Study (Cont.)

– Examples of lesion photos captured from subjects:

Diagnosis remark: suspicious (non-melanoma skin cancer)
Trial Study

– Objective:
  • To evaluate the dermoscopic features of common skin problems in Chinese children using the developed dermoscope functional prototype

– Participants:
  • 185 Chinese children aged 0 to 18 yrs (mean: 5.2 yrs), 86 boys vs. 99 girls

– Operators:
  • Paediatricians trained in dermoscopy

– Location:
  • UCH
Clinical Significance

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Clinical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melanocytic naevi</td>
<td>Detection of melanoma&lt;sup&gt;1&lt;/sup&gt; Serial follow-up</td>
</tr>
<tr>
<td>Café-au-lait macule</td>
<td>Early differentiation from congenital melanocytic naevi</td>
</tr>
<tr>
<td>Port-wine stain</td>
<td>Early differentiation from haemangioma&lt;sup&gt;2&lt;/sup&gt; Prognosis on response to laser</td>
</tr>
<tr>
<td>Haemangioma</td>
<td>Timely initiation of appropriate monitoring and treatment&lt;sup&gt;3&lt;/sup&gt; Early planning of treatment</td>
</tr>
<tr>
<td>Viral wart</td>
<td>Easy and accurate diagnosis&lt;sup&gt;4&lt;/sup&gt; Differentiation from callus and corn</td>
</tr>
<tr>
<td>Molluscum contagiosum</td>
<td>Confirm clinical diagnosis</td>
</tr>
<tr>
<td>Sebaceous naevus</td>
<td>Early diagnosis&lt;sup&gt;5&lt;/sup&gt; Monitoring for tumourous change</td>
</tr>
<tr>
<td>Alopecia areata</td>
<td>Support clinical diagnosis&lt;sup&gt;6&lt;/sup&gt; Assess disease activity&lt;sup&gt;7&lt;/sup&gt; Identify signs of early clinical response and adverse effects to treatment</td>
</tr>
<tr>
<td>Cutis aplasia</td>
<td>Differentiate from sebaceous naevus&lt;sup&gt;8&lt;/sup&gt; Avoid unnecessary treatment and follow-up</td>
</tr>
<tr>
<td>Atopic dermatitis</td>
<td>Support clinical diagnosis&lt;sup&gt;9&lt;/sup&gt; Monitor disease severity</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>Aid clinical diagnosis&lt;sup&gt;10&lt;/sup&gt; Evaluation of treatment outcome</td>
</tr>
</tbody>
</table>


<sup>1</sup> Top twelve diagnosis reported
<sup>2</sup> Grouped under four main categories:
- Pigmentary and vascular birthmarks
- Infections
- Hair problems
- Inflammatory dermatoses
<sup>3</sup> Forty two dermoscopic features identified
### Examples of Dermoscopic Features Identified

<table>
<thead>
<tr>
<th>Diagnosis (No. of patients)</th>
<th>Dermoscopic features (No. of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigmented nevus (41)</td>
<td>Mixed (26)</td>
</tr>
<tr>
<td></td>
<td>Globular (13)</td>
</tr>
<tr>
<td></td>
<td>Homogeneous (6)</td>
</tr>
<tr>
<td></td>
<td>Reticular (6)</td>
</tr>
<tr>
<td>Café-au-lait naevus (15)</td>
<td>Perifollicular hypopigmentation (10)</td>
</tr>
<tr>
<td></td>
<td>Reticular (5)</td>
</tr>
</tbody>
</table>

Non-invasive and Non-radioactive Opto-mechatronic System for Skin Applications

- Total Solution for assisting medical doctors for melanoma and skin disorder early diagnosis
- Small size & User friendly
- Reduce the usage of biopsy
- The bi-mode image capturing method helps facilitate the ease of management on image data
- Patented design integrating opto-mechatronics technologies, 3D printing technology, precision engineering, image processing, software engineering, etc.
- Enabling technology for knowledge-base system towards dermoscopic database & AI

Medical Advisors:
Dr. David Luk & Dr. Maria Gonzalez (Cardiff University)
R&D work* presented at:
SPIE Photonics West 2015 - BiOS:
"Advanced Biomedical and Clinical Diagnostic and Surgical Guidance Systems XIII” track
Workshop on “Dermoscopy”
Organizer: The Hong Kong Paediatric and Adolescent Dermatology Society

Practice for biopsy tissue acquisition

Functional prototype developed by HKPC
## Core Competence

<table>
<thead>
<tr>
<th>R&amp;D</th>
<th>Prototypes</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opto-Mechatronics</td>
<td>Medical 3D Printing</td>
<td>Clinical Trial Protocol</td>
</tr>
<tr>
<td>Sensors &amp; Acquisition Technologies</td>
<td>Precision Engineering</td>
<td>Testing &amp; Compliance</td>
</tr>
<tr>
<td>Image Recognitions &amp; Application Software Programming</td>
<td>Design for Manufacturing &amp; Small Batch Production</td>
<td>Regulatory</td>
</tr>
</tbody>
</table>
Funding opportunities

Innovation and Technology Commission (ITC)

1. ITSP*
   - Tier 2**: 90% Gov. + 10% Sponsor = Platform
   - Tier 3: 100% Gov. ≤ 1.4 mil

2. R&D Cash Rebate Scheme (CRS)*
   - 40% Gov. + 60% Industrial partner = CRS
   - IP owned by industrial partner

3. ITF/ R&D Centres (e.g. APAS)*
   - 90% Gov. + 10% Sponsor = Platform
   - IP owned by research institutes (except R&D centres)

4. General Support Programme (GSP)
   - 90% Gov. + 10% Sponsor = GSP

5. Technology Voucher Programme (TVP)*
   - 66% Gov. + 34% Sponsor = TVP
   - ≤ 200k

* Please refer to the Funding websites for details

** Tier 2: 40% Gov. + 60% Sponsor = CRS

1. ITSP* ...

3. ITF/ R&D Centres (e.g. APAS)* ...

4. General Support Programme (GSP) ...

5. Technology Voucher Programme (TVP)* ...

* Please refer to the Funding websites for details

** Tier 2: 40% Gov. + 60% Sponsor = CRS

1. ITSP* ...

3. ITF/ R&D Centres (e.g. APAS)* ...

4. General Support Programme (GSP) ...

5. Technology Voucher Programme (TVP)* ...

* Please refer to the Funding websites for details
Funding opportunities

Trade and Industry Department (TID)

6. Fund on Branding, Upgrading and Domestic Sales (BUD) *

Enterprise

≤ 500k

Gov. 50% + Industrial partner 50% = BUD

Organization

≤ 5 mil

Gov. 90% + Industrial partner 10% = BUD

7. SME Development Fund (SDF) *

Gov. 90% + Industrial partner 10% = SDF

Innovation and Technology Bureau (ITB)

8. Innovation and Technology Fund for Better Living, (FBL) *

Gov. 90% + Industrial partner 10% = FBL

Eligible organization for FBL
- Non-governmental organisations (receiving subvention from the Social Welfare Dept)
- Public bodies (e.g. HKPC)
- Professional bodies
- Trade associations

* Please refer to the Funding website for details
Integrated Professional Services

Funding Facilitation

Trustworthy Partnership

HKPC Smart Healthcare & MedTech
Our Advantage
Carol LIU 劉音博
Consultant
Smart Healthcare, MedTech & Optics Unit
Automotive & Electronics Division
Hong Kong Productivity Council
香港生產力促進局汽車及電子部
智能保健，醫療科技及光學組 顧問
carolliu@hkpc.org / (852) 2788 5550

Responsible for:
 Biomedical Engineering R&D and Medical Technology Development
 Consultancy on Medical Device Regulatory Affairs (Pre-market, GCP, CSV)
 Medical Professional and Technology Upgrade Services

Other Capacities 其他公職:

○ Secretary, Asian Harmonization Working Party (AHWP)
  亞洲醫療器械法規協調組織 秘書處
○ Co-opted Member, Biomedical Division, The Hong Kong Institution of Engineers (HKIE)
  香港工程師學會-生物醫學分部 委員
○ Executive Committee, Engineering in Medical & Biology Society HK-Macau Joint Chapter, Institute of Electrical & Electronics Engineers (IEEE-EMBS)
  電機及電子工程師學會-生物醫學工程學會-香港澳門分會 委員
Thank You
Licensing Arrangement

- Licensing arrangement:
- 2014 – 2020: European Union, PRC, Australia, New Zealand
## Hardware Development

### Specification of the prototype for the current image capturing system

<table>
<thead>
<tr>
<th><strong>Imaging Unit</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera Lens</td>
<td>Doublet magnifying lens with effective focal length = 25mm</td>
</tr>
<tr>
<td>Focus</td>
<td>TTL Auto Focus</td>
</tr>
<tr>
<td>Image Distortion</td>
<td>&lt;0.4% (Pincushion), &lt; 1% (Barrel)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Illumination Unit</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Light Source</td>
<td>White LED</td>
</tr>
<tr>
<td></td>
<td>Cree High Power LEDs (XPEWHT-L1-WD0-Q4) x 12pcs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Polarizer Unit</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Polarizer</td>
<td>Cross polarized high contrast Viewing polarizer &amp; LED polarizer with alternative LED polarizer</td>
</tr>
</tbody>
</table>

### Others:

<table>
<thead>
<tr>
<th><strong>Image Sensor</strong></th>
<th>16M  1/2.3”- CCD Sensor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LCD Display</strong></td>
<td>3” Color LCD 460K dots</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>Internal flash memory: 16MB External memory: supporting SD Card Digital output connector: USB2.0/WIFI</td>
</tr>
<tr>
<td><strong>Power Source</strong></td>
<td>Li-ion battery</td>
</tr>
</tbody>
</table>

### Operation Modes:

- **Mode I:** General capture mode
- **Mode IIa:** Amplifying Mode (White LEDs)
- **Mode IIb:** Amplifying Mode (White LEDs + Polarizer)
Blue Naevus - wlh

TDS: 3.6
Nevus compound – yly 103530q

TDS:3.1
Nevus face - naevus face akhi vember pharmacist

TDS:3.6
Nevus face - yhd

TDS:3.1
Nevus foot – shn 17 yo

TDS: 3.6
Nevus foot – ty, SAM_0246

TDS:3.6
Nevus foot – ty, SAM_4150

TDS: 3.6
Nevus reticular - Adolescent

TDS:3.6