

TECHNOLOGICAL PRACTICE CASE STUDY

APRIL 2009

DIGITAL/PRODUCTION TECHNOLOGY

YEARS 1-6 / 7-10 / 11-13



**HANDS-OFF HEALING**

Measuring the healing progress of wounds can be slow and difficult. As it heals, a wound's colour and texture changes. These changes can be assessed visually by trained staff, but a more accurate method of assessment of healing that records changes in the wound was needed. Now a new hand held medical device developed in Christchurch is set to revolutionise wound care assessment world-wide.

**FOCUS POINTS INCLUDE:**

**Characteristics of Technology**

- transformation of information; collaborative, interdisciplinary practice; regulatory requirements

**Characteristics of Technological Outcomes**

- described by physical and functional properties; proper function and possible alternative functions

**Technological Products**

- appropriate use of materials to enhance fitness for purpose

**Technological Systems**

- inputs, outputs and controlled transformations within integrated subsystems; 'black box'

**Planning for Practice**

- meeting essential regulatory requirements

**SUPPORT MATERIAL:**

**Links**

- Video: [TVNZ News: 'Technology applied to wounds'](#)
- Website: [www.aranzmedical.com](http://www.aranzmedical.com)

**Curriculum-related activities**

- Discussion questions addressing aspects of the Nature of Technology and Technological Knowledge strands are on page 3.

# HANDS-OFF HEALING

*A new medical device developed in Christchurch is set to revolutionise wound care assessment world wide.*

Measuring the healing progress of wounds can be slow and difficult. Deep wounds, such as those caused by diabetic ulcers, are particularly hard to assess. Aging skin is thin and slow to heal, which means a seemingly minor wound can require substantial nursing care.

As it heals, a wound's colour and texture changes. These changes can be assessed visually by trained staff, but a more accurate method that also records changes was needed. A common method is to place an acetate sheet over the affected area then draw an outline of the wound. The area of the wound can then be calculated by placing the drawing over a grid (usually graph paper).

This procedure is reasonably accurate and inexpensive to administer but it doesn't take the depth of the wound into account. The acetate sheet also makes contact with the wound surface, which can introduce infection and delay healing.

An alternative method involves filling the wound with sterile saline, or even a dental moulding material, and measuring the volume. But this method is not suitable for shallow wounds or those occurring in angular areas like the heel.

In recent years researchers have experimented with photography, lasers and computers to capture images of wounds, interpret their area and depth, and record the state of tissue around the wound's edges. These methods need large and complicated machinery which is often difficult to move or expensive to use.

The team at ARANZ Medical Ltd has succeeded in overcoming these problems with its SilhouetteMobile device, a handheld scanner that is simple to use in clinical settings and records patient data accurately. The unit does not make contact with the patient's skin but relies on digital photography to capture and analyse an image.

*Above left: ARANZ Medical hardware engineer Phil Barclay assembling one of the SilhouetteMobile devices.*

## To market, to market

An array of SilhouetteMobile devices awaiting assembly.

ARANZ Medical is a wholly owned subsidiary of research and development, and technology innovation company Applied Research Associates NZ Ltd (ARANZ), and is charged with taking the Silhouette suite of products to market.

The product range includes a software-only data management system

called SilhouetteCentral. This processing unit typically receives information from one or more SilhouetteMobile units within an institution and acts as an interface between the units and the institution's patient record system. The third product in the suite is SilhouetteDesktop, an application for reviewing and processing the images collected by SilhouetteMobile devices.

The handheld device comprises a standard PocketPC and the SilhouetteCamera unit, which plugs into the PocketPC's compact flash slot. Inside the sealed case is a three-megapixel camera, two lasers and two circuit boards. An LED flash lights the subject, while the two fan-beam lasers guide the camera so it can capture an image of the wound.

As is essential for a medical device used in a clinical setting, the unit can be cleaned and kept sterile. The sealed case is machined out of solid aluminium and scratch-resistant acrylic covers protect the two internal lasers and the camera. The PocketPC can also be wiped clean with an antiseptic cloth.



## Assessing in minutes

To use the device, a nurse logs into the PocketPC and enters the patient's identity details before logging information about the specific wound to be measured, such as its location on the patient's body. When ready to proceed, the nurse activates the camera unit and the two lasers illuminate the skin around the wound to help to align it with the camera. The illumination also helps to normalise the colour balance to correct for ambient lighting. Two images are usually taken – one for the wound's area and one for its depth.

The nurse determines the extent of the wound by drawing around the outline of the wound image on the computer screen using a stylus. The program measures the superficial extent of the wound and its depth, graphs the average maximum depth of the wound on the screen, and compares the current image with earlier ones to graphically show the wound's healing progress. The nurse can add other relevant details about the physical appearance of the wound, such as the condition of the tissue around the margins, any exudate (discharge) that is present, pain reported by the patient and any signs of infection.

A nurse can complete an assessment in just a few minutes – all without touching the wound or causing discomfort to the patient. The SilhouetteMobile generates a report that is sent to the centralised database held in a SilhouetteCentral unit either within the institution or elsewhere. Because the units are portable they can be used by district nurses visiting patients in their own homes and information can be stored on the PocketPC for later download to the centralised database. Information held in a SilhouetteCentral unit can also be accessed via the Internet.

## New medicine

ARANZ has been at the forefront of 3-D scanning and modelling technology development since 1995. The company was established to produce a handheld scanner used by Weta Workshop to digitise and animate Gollum in *The Lord of the Rings* trilogy.

Although SilhouetteMobile is similar to its predecessor, as a medical device it faced far greater regulatory hurdles before it could be successfully sold overseas. Potential sales in the US are significant, according to Chief Executive Bruce Davey. "There are chains of wound clinics in America where our device could be used, but we couldn't sell them there without FDA approval."

ARANZ decided to improve on its existing ISO 9001 certification and set about reorganising the way the company operated. "It took us a year and a half to

get the process in place. We had to completely overhaul the company's quality system and at least one third of our staff was involved," says Mr Davey.

Changes included introducing good practice into environmental controls, risk management, record retention, and regulatory and design controls. He believes the process was very beneficial for the company, which achieved ISO 13485 certification (relating to the design and manufacture of medical devices) in June 2007. SilhouetteMobile is the first medical device to gain the FDA's 510(k) approval specifically for wound imaging, measurement and documentation.

## Taking away the guesswork

Since certification, the company has received information requests from potential clients in a number of countries. In Australia, Melbourne's Royal District Nursing Service is trialling the device. The Service employs more than 1,000 district nurses and cares for many patients who could benefit from the use of ARANZ's invention.

In Christchurch the equivalent nursing service is the Nurse Maude Association. Nurses there are currently participating in a long-term trial of the device in their specialised wound care clinics. There are four wound care clinics that simultaneously care for approximately 100 patients per week. Generally these patients have leg ulcers related to circulatory problems, but some have other wounds that are slow to heal and require specialised care.

Patients are often referred to the clinics by doctors and district nurses working in the community. An administrator sends the data collected by the units to a SilhouetteCentral computer on the premises. It is retrieved later and used to update patients' files with colour images and graphs.

Jeannie Randles, a Wound Care Resource Nurse working at the Nurse Maude Association, is very impressed by the unit she has used for about six months. "Looking at a wound and saying it has improved is very subjective," she says. "When you see a patient, say once a week, you can easily confuse one wound with someone else's. We need objective measurement to really let us know if the wound is really healing or not and that is why using the SilhouetteMobile is so helpful. It takes away a lot of the guesswork."

The device has proven its ability to aid nurses' care for patients. For example, the device picked up the increasing extent of one patient's wound. The deterioration was very small but it showed up dramatically when graphed by the Silhouette system. Alerted to the problem, nurses changed the patient's treatment and were able to see rapid improvement in the wound.

Ms Randles says the device is a huge improvement over nurses' old methods. Placing a thin plastic film over the wound and tracing over it with a pen often caused pain to patients because wound edges are frequently sensitive. The nurses then placed the drawing over square-centimetre graph paper to estimate its area. But there is a real problem with this method says Ms Randles. "Estimating how much of the square is filled in varies – some people say a square is a quarter-filled while others say it is half-filled – so the total area measured could be very different from person to person," she says. "Nurses varied in where they drew the margins – some drew just outside and some just inside. Now with the area's margins captured on the SilhouetteMobile image we can alter these later to get a more accurate picture." Before using the SilhouetteMobile, nurses did not have a method for measuring wound depth at all.

Nurses previously took coloured photographs of all wounds but because the new device takes accurate images, they now only do this for large wounds that do not fit within the device's field of view. "The best thing about using the device is that we don't need to touch the patient's wound in order to measure it. It is very easy to use and we love it."

## Digital-era wound care

To date ARANZ has concentrated on targeting the wound care market – patients with skin ulcers and injuries – but the device has other possible uses.

"There could be applications outside of medicine, such as industrial inspections, but we are not actively investigating them right now," says Mr Davey. "The US market is potentially huge for wound care and that is where we are focusing our plans." He sees opportunities with organisations conducting clinical trials into wound care and wound care products, and also long-term care facilities where residents are treated for wounds.

Jeannie Randles: "When you see a patient, say once a week, you can easily confuse one wound with someone else's. We need objective measurement to really let us know if the wound is really healing or not and that is why using the SilhouetteMobile is so helpful. It takes away a lot of the guesswork."

SilhouetteMobile is rapidly gaining popularity and acceptance by medical personnel. Last October, the device was recognised as "advancing wound assessment into the digital era" when it won the award for innovation at the New Zealand Health Innovation Awards held in Wellington.

*Claire Le Couteur is a Christchurch-based freelance writer.*

## Curriculum focus

### NATURE OF TECHNOLOGY:

#### Characteristics of Technological Outcomes Levels 1 and 6

##### FOCUS QUESTIONS:

- What range of expertise and knowledge would be involved in the design and production of the SilhouetteMobile™?
- How can this product be viewed in terms of a system?
- Identify physical and functional attributes of the product/system.

##### LEVEL 1

##### Indicators of progression:

- Explain that technological outcomes are things that are designed and made by people and therefore are different to other material things that exist in the world.
- Describe technological outcomes in terms of their physical attributes. For example – shape, size, colour, material composition, component interconnections etc.
- Describe technological outcomes in terms of their functional attributes. For example – what the outcome can do and/or provides or cannot do and/or provide.

##### Related information from the case study includes:

- The product is designed to be an improvement on existing medical systems. The design/development team includes medical, electronics, software and production specialists
- The device integrates a camera with a hand held computer. It is small enough to be able to be battery powered, light and robust and can be easily carried and cleaned. Data can be downloaded onto a desktop computer.
- It takes pictures of the wound and accurately measures how well it is healing. The wound isn't touched during the measurement process so this limits the chances of infection.
- Information can be stored and later transferred to the hospital database

##### LEVEL 6

##### Indicators of progression:

- Understand the interconnectedness of some technological products and systems and the often 'fluid' boundaries between them.
- Understand that no technological outcome operates in isolation from other technologies and/or aspects of society and developing an understanding of how things interconnect allows the development of a holistic rather than reductionist view of the world.

##### Related information from the case study includes:

- The SilhouetteMobile™ is linked to software based data management and post-processing systems.
- The device incorporates a high-resolution digital camera which photographs the wound. Embedded laser lighting is utilised for automatic image calibration which enables the depth and area of the wound to be captured and displayed.
- A stylus is used to draw around the image and the digital information is processed by software to provide a quantitative measurement of the extent of the wound.
- The device incorporates a wireless modem. Data can be E-mailed or transferred directly through a docking device to the hospital database.
- Processed information is displayed visually and can be compared with previously stored visual and digital data for ongoing recording and reporting of the healing process.

### TECHNOLOGICAL KNOWLEDGE:

#### Technological Products Level 2; Technological Systems Level 2

##### FOCUS QUESTIONS

- What considerations would have to be addressed in the choice of construction materials?
- If the operation of the device is considered in terms of a system, identify inputs, outputs and controlled transformations.

##### TECHNOLOGICAL PRODUCTS LEVEL 2

##### Indicators of progression:

- Describe the properties of the materials from which simple products are made.
- Explain that the materials in simple product are used because of specific performance properties

##### Related information from the case study includes:

- Aluminium is used for the casing because it is light, simple to machine and easy to clean.
- Acrylic is used to protect the laser lights because it is transparent, light, does not scratch easily and is easy to clean

##### TECHNOLOGICAL SYSTEMS LEVEL 2

##### Indicators of progression:

- Understand the nature of the inputs within simple technological systems.
- Understand how the inputs and the nature of the transformation process enables the creation of the desired outputs.

##### Related information from the case study includes:

- Two pictures of the wound are input into the device – one showing area and one showing depth of the wound.
- A stylus is used to draw around the screen image of the wound.
- Processing software calculates the area defined and the new measurement can be compared with stored data giving a clear indication of how well the wound is healing.
- Data can be stored to be downloaded later into the hospital database.