Chapter 12

Medical Device Concept for Burn Wound Exudate Detection

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Background

Wound infection is dreaded in plastic surgery as this ultimately increases patient morbidity and sometimes mortality, particularly for burn wounds. The state of the wound dressing is a day-to-day concern in burn wards. A clean and dry wound dressing is desirable while dirty soaked wound dressings portend infections. Efforts at preventing dressings from reaching the soaked stage have the potential to reduce wound infections.

This chapter illustrates the design of a device to detect imminent strikethrough of wound exudate to alert nursing staff that wound dressings need changing, in response to a need identified at University College Hospital, University of Ibadan. A conceptual design is presented.

The impact of burn wound infection

Burns are a major public health concern. They are recognized by the World Health Organization as the fourth most common type of trauma globally with devastating and sometimes life-long consequences (WHO, 2017).

Infection is one of the leading causes of death of burn patients worldwide (Williams et al., 2009; Ramakrishnan, Bai & Babu, 2016). Burn patients are susceptible to infection due to the loss of the protective skin barrier and immune system impairment (Barlow, 1994; Weber & McManus, 2004). This is directly related to the severity of the burn. Burn wound infection, to which every burn patient is prone if wounds are not adequately and aggressively managed, has a significant impact on morbidity, cost of care and mortality (ISBI. Practice Guidelines Committee, Steering Subcommittee & Advisory Subcommittee [ISBI], 2016). Treatment of infection can be challenging due not only to the cost of antimicrobials but also due to the frequent occurrence of multidrug resistant biofilms on burn wounds (Ramakrishnan et al., 2016). Ogundipe, Adigun and Solagberu (2009) have reported that the highest expense incurred by patients is on the procurement of antimicrobials. The prevention of burn wound infection is integral to favourable outcomes in burn patients (Barlow, 1994; ISBI, 2016; Ramakrishnan et al., 2016).

Approximately 90% of burns occur in low- and middle-income countries. More than a million people per year are affected in low-income countries with 238,000 deaths per year (Peden, McGee & Krug, 2002). This is of great concern as the management of burns is cost and capital intensive. In resource-rich and established healthcare systems the high cost of burn care is borne by the system while in low-income

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countries with poor healthcare systems it is borne largely by the patient and the patient's family (ISBI, 2016). Achieving the required standard of care therefore is challenging in low-resource countries.

The significance of wound exudate strikethrough

One major characteristic of the burn wound is its propensity to be heavily exudative. The visible presence of the exudate on the surface of the saturated dressing is called strikethrough (World Union of Wound Healing Societies [WUWHS], 2007), as shown in Figure 1.

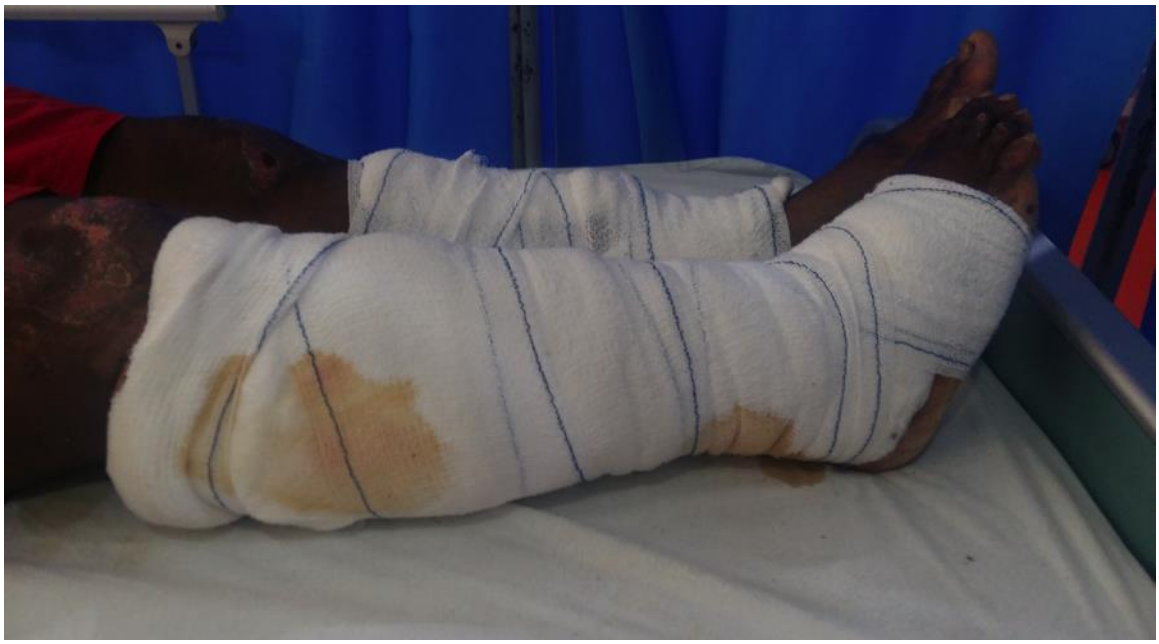

Figure 1: Wound exudate strikethrough on burn wound dressing.

This exudate is a protein-rich fluid that leaks from the wound. It contains electrolytes, inflammatory mediators, enzymes and inflammatory cells (WUWHS, 2007). When exudate leaks out, it not only creates an unsanitary environment but also, due to its protein content, is a nutrient rich medium for colonization and proliferation of microorganisms that can lead to burn wound infection (Weber & McManus, 2004; WUWHS, 2007; ISBI, 2016). Therefore, the burn dressing must incorporate a highly absorptive component that prevents leakage of the exudate onto the dressing surface and the bedding. Wound dressing agents that have the ability to absorb large amounts of exudate while still maintaining a moist environment necessary for healing are ideal; examples include hydrocolloids, alginates, and carboxymethyl cellulose dressings (WUWHS, 2007). However, these dressings are expensive and not practical for use in resource-poor countries. Gamgee is a low-cost surgical dressing invented by Sampson Gamgee in 1880 (Barlow, 1994). It comprises a thick layer of cotton wool wrapped in a thin layer of gauze. This is readily available in low-income countries as it can be bought, or custom made as is done in Nigeria (Olawoye, Osinupebi & Ayoade, 2013).

Current practice of burn wound care at the University College Hospital

The burn unit at University College Hospital, University of Ibadan, is a 12-bed ward that sees approximately 87 acutely burned patients per year (Adejumo & Akese, 2012). Gamgee is used as the absorbent dressing for all burn patients. Burn wounds are cleaned with normal saline and the 4-layer dressing applied (Adejumo & Akese, 2012; Olawoye et al., 2013). The first layer, directly on the wound, is antiseptic impregnated paraffin gauze that serves as a non-adherent layer. The next layer is made up of a thin layer of gauze that acts as a wick, transmitting the wound exudate to the third absorbent layer, which is Gamgee. The fourth layer is crepe bandage, which serves to keep the dressing in place. The signal for a change of dressing is usually the occurrence of strikethrough and this can be seen from 12 to 48 hours after dressing application depending on the rate of wound exudation.

The ideal environment for burn care is to have one burn patient per cubicle. The single open ward system that prevails in low-income countries, increases the risk for cross-infection (Weber & McManus, 2004; ISBI. Practice Guidelines Committee, 2016). Additionally, strikethrough may go undetected and unchanged for hours due to a low nurse to patient ratio and the unavailability of dressing materials. This increases the potential for a wound infection, an example of which is shown in Figure 2.

Figure 2: Wound infection

Concept for a medical device

Weak collaborations between the Department of Plastic Reconstructive and Aesthetic Surgery of the University College Hospital and the Faculty of Technology of the University of Ibadan led to an invitation to attend a workshop on Biomedical Engineering under a National Institutes of Health, Fogarty International Center, grant at Lagos, Nigeria, in September 2015. At this workshop, the idea of developing a wound care device to detect imminent strikethrough was developed. Discussions with the

Chair of the Department of Biomedical Engineering, Northwestern University (NU), on this need, and subsequent involvement of students from a senior-level biomedical engineering capstone design course sequence at NU, resulted in the development of the design concept for the device.

User needs

The design requirements for the device, based on the five needs of medical staff from the burn ward at University College Hospital, Ibadan, are outlined below.

Reliability: The device reliably alerts staff that strikethrough is imminent. False alerts would lead to unnecessary dressing changes and increased cost to patients and workload for staff.

Minimal interruption of workflow: The device will deliver alerts noticeably but without interruption to the usual workflow in the burn ward. An audible alert would disturb other patients and the staff, while unconscious or sleeping patients may not pick up somatosensory alerts (e.g., vibrations). Application of the device, and subsequent interactions with the device, should not lead to significant increases in time spent with the patient.

Longevity: The erratic power supply experienced at University College Hospital dictates that the device should be able to operate independently of the main power supply.

Affordabilty: The device should be cost effective. The marginal increase in cost for the hospital should be considerably lower than that of having to manage an infected wound.

Sanitisability: The device should be sanitisable so it can be reused. Methylated spirit and povidone iodine are common agents used for sanitisation and should be able to be safely applied to the device. Alternatively, if the device is not sanitisable, its cost will be low enough to justify single use.

Based on the above needs, requirements and specifications for the device were identified as illustrated in Table 1.

Table 1. User needs, requirements and specifications for the medical device.

User need	Design requirement	Metric	Value
Reliability	Ability to detect imminent strikethrough	Number of remaining layers of Gamgee prior to strikethrough	1–2 layers
	Acceptable detection rate	Detection rate	50% of all true positives
Minimal disruption to workflow	Fast alert	Time it takes the nurse to detect need for dressing change	30 seconds
	Fast application	Additional time required to apply the dressing	5–10 minutes
Longevity	Able to withstand erratic power supply	Time the system is able to run without an external power source	10 days
Affordability	Cheaper than managing an infected wound	Average cost of device	$50 per unit
Sanitisability	Available materials should be used for sanitisation	Components can be sanitised by alcohol or iodine solution	yes/no

Design concept

The design concept comprises three levels of electronic components:

- Detection modules
- A supermodule
- A nurse's station module (NSM)

The modules are placed on the dressing but under the crepe bandage to detect exudate in the Gamgee. The modules emit infrared (IR) light which is reflected off the exudate. When they detect a certain level of exudate in the bandage they send an alert to the supermodule by emitting IR light to the supermodule. There are 11 modules per supermodule. The supermodule in turn sends an alert to the NSM via a Bluetooth signal, informing the nurses that the dressing should be changed. The detection of the exudate is illustrated in Figure 3, while Figure 4 depicts the module configuration and signal propagation.

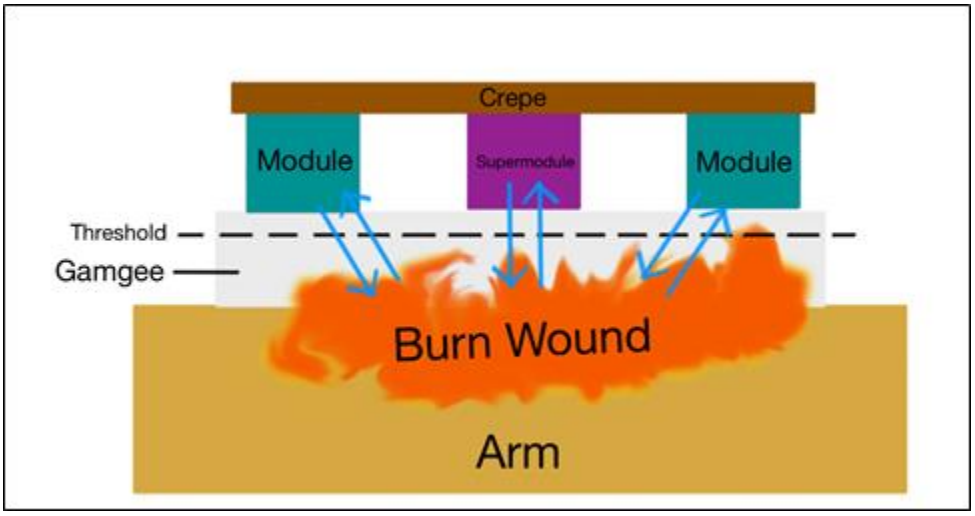

Figure 3: Concept for detection of imminent strikethrough from a burn wound on a patient's arm.

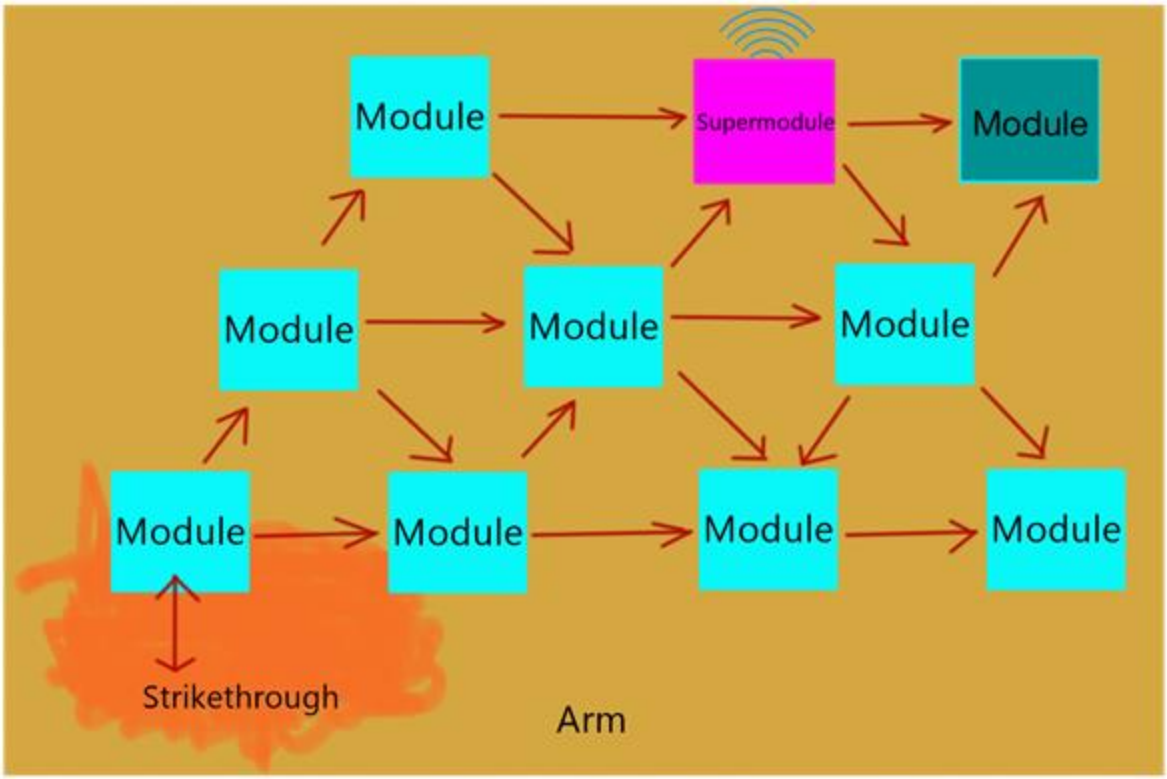

Figure 4: Module configuration and signal propagation for detection of imminent strikethrough.

The primary function of each module is to direct IR light through the dressing, measure the light reflected back, and determine the level of strikethrough that has been reached. To accomplish these tasks, each module consists of a microcontroller, an IR light emitting diode (LED), and an IR phototransistor. The IR LED is responsible for directing IR light through the dressing. The IR phototransistor detects the

amount of IR light incident on the module and translates that reading into a voltage. The module will then determine whether this voltage level indicates approximately 1–2 layers of Gamgee remaining.

Additionally, each module is responsible for transmitting its status to the supermodule, as seen in Figure 4. To enable this, each module will require a built-in personalized identification (ID) signal. The modules will transmit information to the supermodule tagged with their personalized ID. The module placement will be such that that neighbouring modules can detect each other's signals. These modules will send signals in four separate situations: (1) when they are first told to initiate function, (2) when they detect that exudate has reached threshold strikethrough level, (3) at regular intervals when they are checking in with the supermodule to confirm they are still functional, or (4) to propagate a signal that has been sent by a neighbouring module. When the modules send a type 1 or 3 signal they will simply transmit their ID number; when they send a type 2 signal they will send an alert signal that is common across all of the modules. In order to provide a mechanism for extended transmission of these signals, all modules will be monitored at prescribed intervals for signals from their neighbouring modules. When a type 1, 2, or 3 signal is detected from a different module, the module will re-transmit that signal. In this way all signals will eventually propagate through redundant pathways to the supermodule, which will address them further. Modules will have enough memory to record the signals they have sent and will send them no more than once per hour to save power.

These modules will remain in a detect-only "sleep mode" the majority of the time, waking up for only a few seconds per hour under normal operating conditions to check for strikethrough and indicate that the modules are still operational. However, this mode will be interrupted whenever a signal from a different module is received in order to propagate this signal as previously explained.

Supermodule

The supermodule is responsible for receiving the data the modules provide, detecting which modules are present, and alerting the user that strikethrough is imminent by sending a signal to the NSM. Each supermodule will contain the detection system described above for the modules, but it will also contain a bluetooth chip capable of communicating with the NSM. Its communication to the NSM will be stamped with a device ID so that the NSM will be able to differentiate between supermodules located on different patients.

When the system is initiated at the beginning of a cycle, the supermodule will be responsible for collecting and storing the individual ID signals transmitted by each of the individual modules. It will furthermore be responsible for checking to make sure all of these modules are transmitting regularly by determining if their ID numbers are still being transmitted. If either a module alert signal is detected or one of the modules' ID numbers is not transmitted, the supermodule will send an alert to the NSM that will signal to the user that the dressing needs attention.

These supermodules will remain in a detect-only "sleep mode" the majority of the time, waking up for only a few seconds every hour under normal operating conditions to check for strikethrough in the same manner the modules do. This mode will be interrupted whenever a signal from a module is received to log the module's ID number or alert the NSM to a dressing needing attention.

Nurses's station module

The NSM is responsible for receiving a signal from each of the supermodules in use and communicating to the nurses the status of the dressing associated with each supermodule. Each dressing will have one supermodule with a unique ID recognised by the NSM. The NSM will contain a bluetooth chip that can communicate with each of the supermodules. The NSM will use this bluetooth connection to check if the supermodule is functioning properly at regular intervals and will additionally continuously monitor for an alert signal from any of the supermodules. To do this the NSM will have a processor capable of differentiating between the signals sent from each of the supermodules and will have sufficient memory storage to keep track of the alert history from each supermodule. The NSM will also have an LED screen to communicate the status of each supermodule. This screen will notify the nurse's station of any problems communicated by the supermodules through a visual alert.

Design considerations for the modular system

Table 2 illustrates the decision-making process that drove the design of the wireless, modular system and the type of data transmission used. Table 3 shows the ranking of the solutions against the user needs, with ease of implementation added. The ability to be sanitised is not considered here as the housing, rather than the components, would be sanitised. Bluetooth was selected for the communication with the NSM and IR for communication between modules.

Table 2. Alternatives matrix detailing advantages and disadvantages of the types of data transmission initially considered.

	Description	Advantages	Disadvantages
Wired	Medical grade electrical wires used for a direct device connection	- Limited signal interference - No theoretical maximum range	- Add clutter to patient's space - Limits patient mobility
Infrared	IR light (700nm–1mm) used to transmit data between devices	- IR LED and photosensors are extremely cheap - Minimal sources of outside interference - Simple, cost-effective solution for our communication requirements - Capable of preventative signalling	- Effectiveness of signal dependent on line-of-sight / scattering properties of the medium - Data not easily securable - Low information density - Low signalling range
Bluetooth Smart	Low-energy version of standard Bluetooth protocol (2.4–2.485 GHz) used to transmit data between devices (1 MB/s)	- High data security - Moderate data transmission rate - Moderate information density- Capable of preventative signalling	- Moderate/Low power consumption - Possible signal interference from commercial devices - Maximum range of 20 m
RFID	RF signal transceivers that operate between 120 kHz (LF) and 433 MHz (UHF); used to transmit data between devices	*Passive RFID*: - No internal power requirements - Extremely low-cost and low-maintenance *Active RFID*: - Capable of preventative signalling - Moderate detection range	*Passive RFID*: - Not capable of preventative signalling - Data typically not rewritable - Short detection range *Active RFID*: - Extremely high costs for readers and tags - Relatively high power consumption for provided data transmission rate / information density
Wifi	Wireless communication operating at 2.4 GHz / 5 GHz (IEEE 802.11) used to transmit data between devices	- High transmission rate - High information density - High signal range - High data security	- High power consumption - High costs - Possible signal interference from commercial devices

Table 3. The criteria are ranked on a 5-point scale (1 = Poor, 5 = Good) and assigned a weight on a 3-point scale (1 = Low Priority, 3 = High Priority). The totals are calculated using the weight multiplied by the ranking of the criterion.

Weight	Criteria	Wired	Infrared	Bluetooth	RFID	Wifi
3	Reliability	5	2	4	4	4
3	Affordability	5	5	4	1.5	2
2	Ease of implementation	2	4	4	4	3
2	Longevity	2	5	4	4	2
1	Minimal disruption to workflow	5	5	5	5	5
	Total	43	44	45	37.5	33

Future considerations

The nature of the casing for the modules, the attachment method to secure the modules to dressing, and the specific electronic components to be used in the modules, must be considered against the design requirements and specifications. These considerations will be followed by construction and testing of prototype systems.

Conclusion

We have presented the design concept for a device to detect imminent strikethrough of wound exudate to prevent burn wound infection. Our largest user-base will be medical professionals, and while the design arose in response to needs of a specific hospital, the potential user base will be medical staff throughout hospitals and medical centres in developing nations.

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