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Major Article

Does the new low-frequency ultrasonic debridement technology pose an infection control risk for clinicians, patients, and the clinic environment?

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Background: Low-frequency ultrasonic debridement (LFUD) is a technology that uses sound waves conducted through saline mist to debride wound tissue. Whilst this technology purportedly reduces wound-healing times, the airborne mist generated is potentially problematic. Theoretically, the saline mist could carry an increased number of microbes into the surrounding environment, posing an infection control risk to the patient, clinician, and clinical environment. This research aimed to establish the degree and extent to which there is microbial spread during the use of, and following the use of, LFUD. The total number of colony forming units was identified for use of LFUD without the suction attachment (control) and with the suction attachment (intervention).

Methods: This was a prospective, observational study with repeated measures across each treatment (before, during, and after). Quota sampling in a $2 \times 2 \times 2$ factorial design was undertaken so that half of the 24 treatments were conducted at each health service (Monash Health vs Peninsula Health), in different treatment environments (inpatient vs outpatient), and half were conducted with and without suction. The use of suction was not randomized but was determined at the treating clinician's discretion. Patients treated in the inpatient environment lay on their beds, whereas patients in the outpatient environment sat in a treatment chair.

Results: There was higher microbial count during treatment ($P < .001$) with a higher microbial count associated with lower ultrasound amplitude ($P = .028$), lower saline flow rate ($P = .010$), no suction attachment ($P = > .001$), and a larger wound area ($P = .002$). All were independently associated with greater microorganism aerosolization. There was no correlation between the type of handpiece selected, the presence of wound infection, and the treatment time or treatment environment.

Conclusions: This research has assisted in developing guidelines for cleaning of equipment and environments following treatment, as well as around the use of personal protective equipment required to protect the staff member and the patient during the use of LFUD. Additionally, recommendations have been made regarding the specific LFUD settings to reduce the risk of cross-infection to the clinic environment. These include selecting a higher ultrasound amplitude and saline flow rate as well as the use of suction where clinically possible.

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Treatment of chronic wounds frequently requires a combination of therapies to facilitate healing. Debridement is considered an important part of treatment because it removes devitalized tissue from the wound bed that can delay healing and harbor infective organisms. There are different methods of wound debridement, including sharps debridement that can be performed in an operating room or in a clinical setting, mechanical debriding agents, autolytic debriding through dressings, biological debridement through use of sterile larvae, and the use of chemical enzymes.[1-3] Low-frequency ultrasonic debridement (LFUD) is a newer method of debridement introduced as an alternative method of wound debridement. The size and portability of the LFUD unit make it attractive for use within and across different health care settings.

The LFUD technique works by delivering sound waves through a constant flow of sterile saline to the wound surface. Ultrasound results when electric energy is converted to sound waves at a frequency above the range of human hearing (20 kHz). These sound waves are then transmitted to tissue via a liquid medium through the treatment applicator. Nonthermal effects of the ultrasound waves have been shown to cause 2 phenomena at the wound surface: acoustic streaming[4-6] (a steady mechanical force) and cavitation[4-6] (the formation of gas bubbles causing microshockwaves). The combined effects of acoustic streaming and cavitation are thought to alter cell membrane activity and increase the activity of each cell, leading to debridement of necrotic and infected tissue, a bactericidal effect, and cellular proliferation.[5,7,8]

Whilst the use of LFUD has been demonstrated to have a positive effect on wound healing rates and outcomes,[9-11] there has been little research into the effects on the environment related to the use of LFUD in clinical settings. The aim of this study was to establish the degree and extent of microbial spread during the use of LFUD and to determine what infection control risk LFUD poses to clinical environments, to patients, and to clinicians administering the treatment.

METHODOLOGY

This was a prospective, observational study with repeated measures across each treatment (before, during, and after). Quota sampling in a $2 \times 2 \times 2$ factorial design was undertaken so that half of the 24 treatments were conducted at different sites (Monash Health vs Peninsula Health), in different treatment environments (inpatient vs outpatient), and half were conducted with and without suction. The Human Research Ethics Committees of Monash Health (14077Q) and Peninsula Health (QA/14/PH/4) approved this study.

Patients

Eighteen patients with a foot or leg wound being treated with LFUD were advised that environmental testing was being performed between June 2014 and April 2015. Patient consent was not required for this study because data collection was not related to treatment. Treatments were measured from a convenience sample at 2 public hospitals—Monash Health (Monash Medical Centre) and Peninsula Health (Frankston Hospital)—and performed by 2 podiatrists according to the predetermined study protocol. No randomization of treatment environments or suction use was undertaken. The only inclusion requirement was that a minimum treatment time of 10 minutes of LFUD was required. The leading treating clinicians judged whether the appearance and size of the wound were suited to this treatment.

Measurements

Measurement of dependent variables

Colony forming units were the main dependent variable used in this study to determine the degree of microbial burden on the environment. To determine baseline airborne microbes before treatment, passive air testing using horse blood agar (HBA) plates were used. These plates were placed at 30 cm, 1 m, and 2 m on either side of the wound, on the floor, in both treatment settings. Additional HBA plates were placed 3 m from either side of the wound atop a high surface in only the outpatient setting (space available on inpatient wards was insufficient for this test). Active air testing (Merck MAS 100; Merck, Darmstadt, Germany) was performed with a single HBA plate at 1.5 m from the wound using air sampling.

Postdebridement sampling for both on-ward and outpatient environments included a single swab taken for culture from the LFUD handpiece end plated on HBA. Additional testing was performed in the outpatient environment 30 minutes after treatment to confirm the return of airborne microbes to baseline. Only the Monash Health site had access to the use of the active Merck air sampler. Peninsula Health used an opened HBA passive settle plate. Air sampling was conducted at 1.5 m at the baseline, debridement, and 30-minutes posttreatment time points. Baseline testing of colony forming units was undertaken for 10 minutes while the clinician set up the room for treatment. Testing during LFUD included both passive and active air sampling in the same setup as the settle plates. Each HBA plate was incubated aerobically at 35°C for 48 hours and microbes were counted and reported as colony forming units. Microbes were further speciated per standard laboratory protocols. This testing was undertaken in the Microbiology Laboratory at Monash Health.

Measurement of independent variables

The Sonoca 185 (Söring, Germany) LFUD was used for each treatment. The equipment settings for the handpiece (hoof, spatula, or double ball), maximum saline flow rate (milliliters), maximum ultrasound amplitude (%), the treatment time, and the use of suction were variable. Following a thorough wound assessment these settings were determined by the treating clinician based on the clinical appearance of each wound.

Procedure

A total of 24 LFUD treatments on 18 patients were performed per the study protocol. The settings used for each treatment (handpiece, amplitude, and flow rate) were determined by the treating podiatrist based on the clinical presentation of each wound.

The on-ward treatments were performed with the patient lying on his or her bed and the privacy curtains or door closed. The layout of the settle plates was designed to minimize interference by the treating podiatrist or other passers-by. The outpatient clinic room treatment was performed with the patient seated on the treatment chair and the door closed. The treatment was performed per standard procedure for both sites, as determined by existing clinical practice guidelines within both health organizations.

The treating podiatrist donned personal protective equipment during treatment, including a plastic disposable long-sleeve gown, surgical mask, face shield with plastic visor, and nonsterile gloves. Patients were given the option of wearing a mask; however, no other personal protective equipment for patients was offered. Plastic sheeting was placed in the immediate work area to capture aerosolized droplets up to 1 m away and was also used to cover exposed shelves. Per standard procedure, gauze was used to shield the end of the handpiece whilst maintaining visibility for the treating podiatrist. After each procedure, a 1-m wipe of the area and instruments was