CLINICAL EVALUATION

Clinical Evaluation of a Novel Silver Nano-Particulate Containing Wound Dressing for the Assessment of Biofilm and Infection

Dr. Manpreet K Gill, Dr. Claas Roes, Nyerngoor Korda Hewitt, Dr. Graeme Kettlewell

INTRODUCTION

An observational clinical study was performed to collect data for a novel silver nano-particulate containing wound dressing during clinical use on patients. The study observed many variables including antimicrobial properties, achievement of treatment goals, maintenance of a moist wound environment, safety, and handling.

This is an ongoing study and early results for the antimicrobial properties of the dressing are presented here. The questions were: Is biofilm visible at the end of treatment? Did the dressing control infection? And did the dressing protect the wound from infection?

METHOD

Patient population

The study is an international, multicentre, single arm observational study with 36 patients and 7 users. The patients' age ranged from 20-86 (average age 63.25), and the gender of patients was 20 male (61%) and 16 female (48%). Patients presented with various indications, as described in Table 1.

Table 1. Treated Indications.

Number of patients presenting with wound	Location/type of wound
1	Second degree burn
12	Leg ulcer
5	Pressure ulcer
3	Diabetic ulcer
10	Post-operative wound
3	Traumatic wound
2	Wound with high bleeding tendency

DRESSING

A novel silver nano-particulate containing wound dressing produced by SFM was used to treat the patients within this study. The dressing is a soft, conformable non-woven fabric made from sodium carboxymethyl cellulose and strengthening cellulose fibre(s) with antimicrobial silver. The silver in the wound dressing has an antimicrobial effect upon many of the various wound bacteria held within the dressing. Through the gel formation, debris and any bacteria found in the wound exudate can be retained inside the fibre dressing and removed when the dressing is changed. When dry, the novel dressing can easily be cut to the size of the wound. When gelled, the dressing retains its structure. High vertical absorption of exudate into the dressing forms a gel which assists in maintaining a moist wound environment, supporting autolytic debridement, protects the wound edge and surrounding skin from maceration, thus supporting the healing process. The dressing can also be used under compression.

Treatment

Patients were treated with the novel dressing made from sodium carboxymethyl cellulose and strengthening cellulose fibre with antimicrobial silver. Treatment time was 17.78 days on average. No additional stress was exerted onto the patients.

Outcomes

Biofilm determination was visually assessed before and after treatment by the user. Signs of infection were determined by the Visual Analog Scale (VAS) to include:

- redness
- overheating
- restricted movement
- swelling
- pain
- odour

RESULTS

Is biofilm visible at the end of treatment?

At the start of the study, a biofilm was visible in 22 out of 36 patients. Figure 1 shows that after treatment no biofilm was visible in 12 of the 22 patients (55%), biofilm was partially visible in 8 patients (36%), and biofilm was visible in 2 patients (9%).

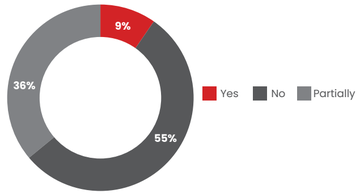

Figure 1: Is Biofim Visible After Treatment

Did the dressing control infection?

The users wanted to control infection in 17 of the 36 patients. Figure 2 shows that in 16 of the 17 patients (94%) the infection was controlled during treatment, and 1 patient in 17 (6%) was partially able to achieve this goal.

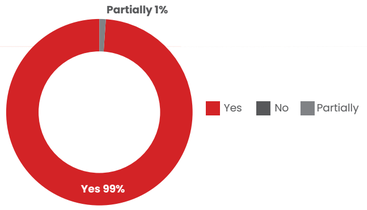

Figure 2: Was Iinfection Controlled?

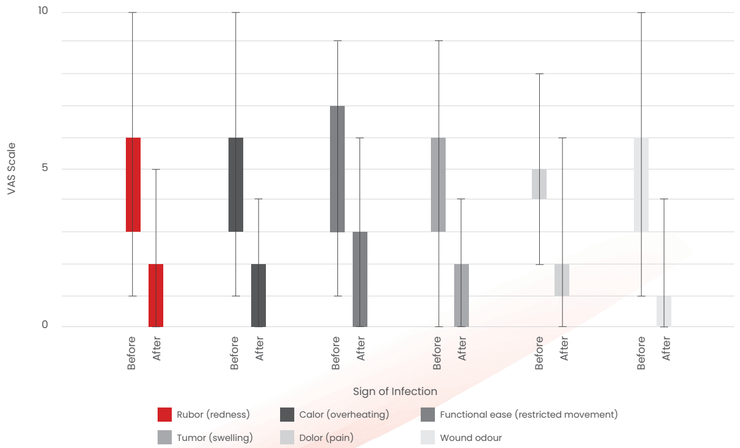

Figure 3. Reduction of Infection Signs

Additionally, the following signs of infection were assessed using the VAS scale before and after treatment: redness (rubor), overheating (calor), restricted movement (functional ease), swelling (tubor), pain (dolor), and odour. Figure 3 shows the successful reduction in each parameter following the treatment period.

Did the dressing protect the wound from infection?

The users also wished to protect the wound from infection in 19 patients, and this goal was achieved in all 19 patients after treatment with the novel dressing. (100%).

Users recorded the treatment goal for each patient; each patient could have more than one treatment goal. Figure 4 shows that over 90% of treatment goals were successfully reached for each patient.

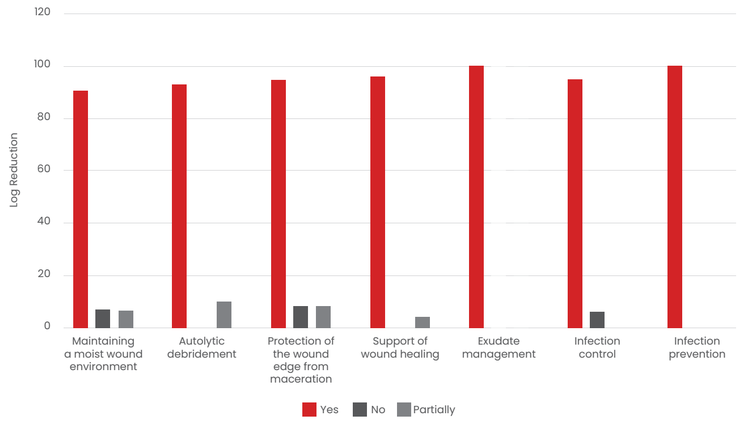

Figure 4: Achieving Treatment Goals

Discussion

The application of a novel silver nano-particulate containing wound dressing successfully demonstrated the ability to reduce biofilm in this ongoing observational clinical study. The dressing was also able to successfully reduce signs of infection or remove infection altogether from the wound in all patients.

The novel silver nano-particulate containing wound dressing successfully supported the treatment goals of the users in over 90% of the patients.