# Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT


• **Objective:** To compare the efficacy and tolerability of a new ionic silver alginate matrix (Askina Calgitrol Ag) with that of a standard silver-free alginate dressing (Algosteril).

• **Method:** Patients with locally infected chronic wounds (pressure ulcers, venous or mixed aetiology leg ulcers, diabetic foot ulcers) or acute wounds were eligible for this prospective, open-label, controlled and randomised trial. Patients were randomised to receive one of the two dressings for a two-week period. Criteria of efficacy were based on the evolution, from day 1 to day 15, of local signs of infection using a clinical score ranging from 0 to 18, and the evolution of the bacteriological status for each wound. The latter was determined by (blind) bacteriological examinations of results obtained from two biopsies performed at days 1 and 15. A three-point scale (deterioration, unchanged, improvement) was also used. Acceptability, usefulness and tolerance were also assessed.

• **Results:** Forty-two patients (20 women and 22 men, 68.9 ± 18.8 and 66.5 ± 15.7 years old respectively) were randomly assigned to receive either Askina Calgitrol Ag (n=20) or Algosteril (n=22). Most had chronic wounds such as pressure ulcers (57%) or venous or mixed aetiology leg ulcers and diabetic foot ulcers (29%); few had acute wounds (14%). Clinical scores of infection were comparable in both groups at inclusion, 8.9 ± 2.4 and 8.6 ± 3.2 in the Askina Calgitrol Ag group and the Algosteril group respectively (not significant), but decreased significantly in both groups at day 15, 3.8 ± 2.9 in the Askina Calgitrol Ag group (p=0.001) and 3.8 ± 3.4 in the Algosteril group (p=0.007). There was no significant difference between the two groups at day 15. Although there was also no significant difference in bacteriological status between the treatment groups, a trend in favour of Askina Calgitrol Ag was found for the relative risk of improvement, especially in patients who were not treated with antibiotics either at the beginning of the study or during it. No differences between groups were observed regarding local tolerance, acceptability and usefulness of the dressings.

• **Conclusion:** The regression of local signs of infection, local tolerance, acceptability and usefulness were similar for the two dressings. However, Askina Calgitrol Ag improved the bacteriological status of the wounds. Further trials are required to show that it has a positive impact on the healing process.

• **Declaration of interest:** The study was sponsored by B. Braun Medical SAS.


wounds; infection; antimicrobial; silver; alginate; dressings; randomised trial


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All open wounds are colonised by microorganisms, but this does not generally affect the healing process. However, if the colonisation develops into local infection, which then becomes systemic, the result can be life-threatening. Accordingly, wound care not only comprises cleansing, debridement and management of the underlying aetiology, but also measures to prevent the potential for colonised wounds becoming locally, or even systemically, infected.[1]

It has been demonstrated that local treatments play a role in promoting healing, even though treatment of the underlying aetiology remains a crucial element.[2-4] Local factors that can delay healing include the number of bacteria present on the wound surface.[5,6] However, it is often difficult to distinguish between colonisation and infection. Colonised wounds contain commensal microorganisms that pose no threat to healing, whereas infected wounds contain pathogens that are in a state of virulent bacterial replication.

For many years, the diagnosis of wound infection was based on microbiological analysis. More recently, the clinical signs and symptoms of infection have been validated. Several authors are now challenging the use of microbiological analysis to diagnose wound infection and are asking whether clinical signs are not more accurate indicators.[7-9] However, new culture-free tests based on bacterial gene virulence are being investigated to evaluate if they can help clinicians choose the right treatment strategy.[10,11]

Silver has demonstrated marked antibacterial activity against all bacterial strains found in colo-

nised wounds, including antibiotic-resistant species such as meticillin-resistant *Staphylococcus aureus* (MRSA). There is minimal risk of bacterial resistance and it is barely toxic to fibroblasts. It also has strong anti-inflammatory properties.[12-14]

Several trials have studied the effect of silver-releasing dressings. In a randomised controlled trial (RCT) involving 129 patients, Jorgensen et al.[15] compared a sustained silver-releasing foam dressing with a hydrocellular foam dressing in the treatment of critically colonised chronic venous leg ulcers (VLUs) and concluded that, after four weeks, the silver dressing significantly reduced the ulcer area and the extent of malodour, when compared with the comparator.

Meaume et al.[16] compared the effect of a silver-releasing hydroalginate dressing with that of a pure calcium alginate dressing in 99 patients with locally infected chronic wounds, none of which required antibiotics at baseline. Fewer patients given the silver dressing required antibiotics at the final study assessment (at week 4) compared with the controls (10.5% versus 0%, p=0.053). Furthermore, the closure rate was significantly greater in the silver-dressing group (p=0.024) and the wound severity score was significantly improved (p=0.034).

Verdu Soriano et al.[17] reported a significant reduction in the number of bacteria after patients were treated with an activated charcoal silver dressing. Münter et al.,[18] in a study involving 619 patients that compared local best practice with use of a sustained silver-releasing foam dressing, found that the latter was associated with a 50% reduction in wound area versus 34% for the comparator after four weeks. A study by Lazareth et al.[19] of a new silver-releasing dressing showed that a four-week treatment with this dressing hastened the closure rate of VLUs presenting with inflammatory signs that may have suggested a high bacterial load.

In a study of 37 patients with infected or critically colonised wounds (but without deep infection requiring general antibiotic treatment), Ricci et al.[20] evaluated pain, bacterial evolution (swab), change in wound surface area and clinical evolution of the infection, as defined by criteria from Harding[21] and Sibbald,[22] following use of an ionic silver alginate matrix dressing. Wound improvement with resolution of infection was observed within 14 days of treatment in 34/37 patients; performance in terms of patient/operator comfort was very high.

No study has yet evaluated the correlation between bacteriological status assessed from a biopsy and a clinical score of infection. This two-week, prospective, single-centred, controlled, randomised, parallel group, open-label trial aimed to compare the efficacy and impact on locally infected wounds of a new ionic silver alginate matrix (Askina Calgitrol Ag) with that of a standard, silver-free alginate dressing (Algosteril).

**Table 1. Clinical infection scoring system**

| Sign or symptom | Scoring options |
|---|---|
| Fever | Yes = 1<br>No = 0 |
| Local heat | Yes = 1<br>No = 0 |
| Peri-lesional erythema | Yes = 1<br>No = 0 |
| Persistent pain (between two dressings changes) | Recorded on a 0–10 VAS but quoted as 0, 1, 2 or 3 |
| Oedema, malodour, pus and exudate production | Nil = 0<br>Low = 1<br>Moderate = 2<br>Important = 3 |
| Total score | 0–18 |

VAS = visual analogue scale

## Patients and methods

### Patient population

Patients attending the wound clinic or hospitalised at Montpellier University Hospital with pressure ulcers (PUs), venous or mixed aetiology leg ulcers, diabetic foot ulcers or acute wounds (except burns) were enrolled into the study between March 2006 and December 2007. Key inclusion criteria were one or more signs or symptoms of local infection: fever, local heat, peri-wound skin erythema, persistent pain, oedema, malodour, pus and heavy exudation.[21] Exclusion criteria were:

- Known allergy to any component of the dressings under study
- Patients with burns
- Ulcers whose aetiology is associated with an infectious disease, such as tuberculosis
- Use of anticoagulants
- Patients aged under 18 or over 80.

The local ethics committee approved the study and all patients gave written informed consent.

At baseline, dressings were randomly allocated to patients using sealed envelopes.

During the trial, prophylactic antibiotic therapy was administered to patients with hyperthermia (for example, raised temperature before or during the trial or when the wound resulted from diabetes).

At baseline, data on patient demographics and wound characteristics were collected and the wound severity was assessed using a clinical score.

### Materials

The new ionic silver alginate matrix dressing, Askina Calgitrol Ag, was provided by the sponsor (B. Braun Medical SAS, Boulogne-Billancourt, France).

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**Table 2. Anthropometric data per wound type at inclusion**

| | Ulcers (n=12) | | Pressure ulcers (n=24) | | Acute wounds (n=6) | |
|---|---|---|---|---|---|---|
| | Women (n=6) | Men (n=6) | Women (n=11) | Men (n=13) | Women (n=3) | Men (n=3) |
| **Age (years)** | | | | | | |
| Mean ± SD (median) | 49.2 ± 16.0 (43) | 66.7 ± 16.0 (72) | 80.9 ± 9.0 (80) | 65.5 ± 17.7 (72) | 64.3 ± 17.9 (60) | 70.3 ± 5.5 (70) |
| **Weight (kg)** | | | | | | |
| Mean ± SD (median) | 67.3 ± 19.2 (62) | 87.0 ± 8.4 (83) | 56.4 ± 11.9 (55) | 76.1 ± 17.6 (77) | 55.3 ± 25.3 (46) | 81.0 ± 5.3 (83) |
| **Height (cm)** | | | | | | |
| Mean ± SD (median) | 162.0 ± 5.6 (163) | 179.4 ± 7.9 (178) | 159.7 ± 8.2 (161) | 170.5 ± 8.1 (170) | 155.7 ± 19.1 (153) | 168.3 ± 2.9 (170) |

**Table 3. Treatments randomly assigned to each wound type at inclusion**

| | Test-dressing group | | | Positive-control group | | |
|---|---|---|---|---|---|---|
| | Ulcers | Pressure ulcers | Acute wounds | Ulcers | Pressure ulcers | Acute wounds |
| Women | 3 | 6 | 2 | 3 | 5 | 1 |
| Men | 1 | 5 | 3 | 5 | 8 | 0 |
| Total | 20 | | | 22 | | |

**Table 4. Baseline clinical infection scores**

| | Both groups | Test-dressing group | Positive-control group | Difference between groups |
|---|---|---|---|---|
| Mean ± SD (median) | 8.8 ± 2.8 (9.0) | 8.9 ± 2.4 (9.0) | 8.6 ± 3.2 (8.0) | NS* |

* Student's t-test; NS = not significant

The positive control, a standard, silver-free alginate dressing (Algosteril, Laboratoires Brothier, France), which is already marketed, was purchased from the manufacturer.

Askina Calgitrol Ag (the test dressing) consists of a proprietary ionic silver alginate matrix and an absorbent polyurethane foam layer. The manufacturer states that, when in contact with wound exudate, the silver alginate matrix forms a moist gel that releases approximately 60 parts per million (ppm) of silver ions, while the foam allows for exudate management. Delivery of silver ions is controlled and sustained over 72 hours due to the bonding characteristics of the silver alginate molecule, which contains weak covalent silver/alginate bonds mixed with strong calcium/alginate bonds. Following absorption of exudate into the calcium alginate, the matrix swells, allowing weak bonds to dissociate and the silver ions to be liberated. The silver ions then have to escape from the swelled matrix in order to reach the wound.

### Microbiological measurements

The patients were followed up for 15 days and assessed on days 1, 8 and 15. A 15-day follow-up period was chosen because the aim was to assess the efficacy of the two dressings on inflammation/local infection as opposed to their ability to facilitate healing. An antimicrobial dressing would be expected to eradicate such symptoms of local infection within this time.

For the purposes of the study, the progression or regression of the local infection was assessed by the study investigator using an 18-point scale, based on the presence and intensity of the clinical signs (Table 1). The scale was specifically developed for the study. In addition, a tissue biopsy was performed on days 1 and 15. Quantitative culture results were obtained from biopsy samples placed in both aerobic and anaerobic media. Quantities were noted in colony-forming units per gram (cfu/g) of tissue.

The study steering committee requested that two independent experts in microbiology undertake a blind assessment of the two laboratory reports for each patient.[23] This comprised a blind review of the bacteriological raw data contained in each report for each patient on days 1 and 15. Based on this, the difference (or otherwise) in the bacteriological status of each patient's wound was graded as follows:

- Deterioration (-1)
- Unchanged (0)
- Improvement (+1).

Finally, the virulence of the strains of *Staphylococcus aureus* that were isolated in our study was estimated *in vitro* through a multiplex polymerase chain reaction (PCR)-based genetic analysis. PCR sequencing allows the investigator to identify the genetic profile of the bacteria in a sample, thereby revealing a much broader spectrum of bacteria and strains than can traditional culture. It enables mapping of the main virulence genes, which allows the investigator to decide on the colonising character of a given strain of an *S. aureus* isolate — that is, whether it is infectious or colonising. This technique has been used to explore an eventual correlation between clinical scores, bacteriological status and virulence tests.[11]

### Clinical measurements

Tolerance of the dressing was assessed by the study investigator grading the severity of erythema on peri-wound skin on days 1, 8 and 15 on a five-point scale ranging from one (minor) to five (severe).

Acceptability and usefulness of the dressing were assessed by the investigator on day 15 on a five-point scale ranging from one (excellent) to five (very bad) for each of the following:

- Ease of application and removal
- Reduction of malodour
- Reduction of persistent pain
- Improvement in the condition of the peri-wound skin
- Dressing comfort
- Cleansing effect
- Absorption properties
- Adherence to the wound.

Finally, withdrawals, adverse events, changes in a patient's health status and general treatments for other comorbidities were recorded during the course of the trial.

The primary outcome measure was the change in the local infection score. Secondary outcome measures were the bacteriological status of the wound and tolerability, acceptability and usefulness.

### Study hypothesis, data management and statistical analysis

The hypothesis was that the expected mean clinical score of infection on day 15 would be significantly lower in the test-dressing group than in the positive-control group. Based on an observed standard deviation of five for the score of infection in the same population during a pilot observational study, 40 patients (2 x 20) were necessary to reach a difference of 4.7 at day 15 with an alpha risk of 5% and a beta risk of 20%.

The trial was monitored according to good clinical practice and data were handled according to

**Table 5. Evolution of clinical infection scores through the study period**

| | Day 1 (n=41) | Day 8 (n=40) | Day 15 (n=41) | Day 15 versus day 1 |
|---|---|---|---|---|
| **All wounds** | | | | |
| Test-dressing group | 8.9 ± 2.4 | 4.8 ± 2.5 | 3.8 ± 2.9 | p=0.001* |
| Control group | 8.6 ± 3.2 | 5.0 ± 3.3 | 3.8 ± 3.4 | p=0.007* |
| Difference between groups | NS† | NS† | NS† | |
| **Ulcers** | | | | |
| Test-dressing group | 9.0 ± 1.8 | 5.0 ± 0.8 | 4.3 ± 2.6 | p=0.07* |
| Control group | 9.8 ± 2.5 | 5.8 ± 3.8 | 4.9 ± 3.6 | p=0.04* |
| Difference between groups | NS† | NS† | NS† | |
| **Pressure ulcers** | | | | |
| Test dressing group | 8.7 ± 2.8 | 3.8 ± 3.0 | 3.3 ± 3.1 | p=0.005* |
| Control group (n=1) | 7.9 ± 3.6 | 4.0 ± 2.6 | 3.2 ± 3.2 | p=0.008* |
| Difference between groups | NS† | NS† | NS† | |
| **Acute wounds** | | | | |
| Test-dressing group | 9.2 ± 1.9 | 6.6 ± 1.1 | 4.4 ± 3.1 | p=0.04* |
| Control group (n=1) | 8.0 | 10.0 | 2.0 | NA |
| Difference between groups | NA | NA | NA | |

Results are reported as mean ± SD
*Wilcoxon signed-rank test; † Mann-Whitney U test; NS = not significant; NA = not applicable

**Table 6. Bacteriological status for all wounds on day 15**

| All wounds | -1 | 0 | +1 | ND | Difference between groups |
|---|---|---|---|---|---|
| **Results reported by Dr Lavigne** | | | | | |
| Test-dressing group | 2 | 6 | 9 | 3 | NS* |
| Control group | 5 | 8 | 6 | 3 | NS* |
| *$\chi^2$; relative risk=1.68; odds ratio = 2.44 (0.95CI [0.63–9.47] | | | | | |
| **Results reported by Dr Darbas** | | | | | |
| Test-dressing group | 3 | 5 | 9 | 3 | NS* |
| Positive-control group | 7 | 7 | 6 | 2 | NS* |

* $\chi^2$; relative risk = 1.76; odds ratio = 2.63 (0.95 confidence interval [0.68–10.12])

NS= not significant; ND= not documented

**Table 7. Bacteriological status on day 15 for patients who were not taking antibiotics on day 1**

| | -1 | 0 | +1 | ND |
|---|---|---|---|---|
| **Results reported by Dr Lavigne** | | | | |
| Test-dressing group | 1 | 1 | 8 | 2 |
| Positive-control group | 4 | 5 | 4 | 1 |
| Relative risk = 2.60; odds ratio = 9.0 (95% confidence interval [1.29–63.03]) | | | | |
| **Results reported by Dr Darbas** | | | | |
| Test-dressing group | 1 | 2 | 7 | 2 |
| Control group | 4 | 4 | 5 | 1 |
| Relative risk = 1.82; odds ratio = 3.73 (95% confidence interval [0.65–21.58]) | | | | |

ND= no documented

**Table 8. Bacteriological status on day 15 for patients who received antibiotics on day 1**

| | -1 | 0 | +1 | ND |
|---|---|---|---|---|
| **Results reported by Dr Lavigne** | | | | |
| Test-dressing group | 1 | 5 | 1 | 1 |
| Positive-control group | 1 | 3 | 2 | 2 |
| Relative risk = 0.43; odds ratio = 0.33 (95% confidence interval [0.02–5.03]) | | | | |
| **Results reported by Dr Darbas** | | | | |
| Test-dressing group | 2 | 3 | 2 | 1 |
| Control group | 3 | 3 | 1 | 1 |
| Relative risk = 2.00; odds ratio = 2.40 (95% confidence interval [0.16–34.93]) | | | | |

ND= not documented

**Table 9. Bacteriological status on day 15 for patients who did not receive antibiotics during the study**

| | -1 | 0 | +1 | ND |
|---|---|---|---|---|
| **Results reported by Dr Lavigne** | | | | |
| Test-dressing group | 1 | 1 | 7 | 1 |
| Positive-control group | 4 | 4 | 4 | 1 |
| Relative risk = 2.33; odds ratio = 7.00 (95% confidence interval [0.97–50.57]) | | | | |
| **Results reported by Dr Darbas** | | | | |
| Test-dressing group | 1 | 2 | 6 | 1 |
| Positive-control group | 4 | 4 | 4 | 1 |
| Relative risk = 2.00; odds ratio = 4.00 (95% confidence interval [0.64–25.02]) | | | | |

ND= not documented

standard good practice. Descriptive analysis (mean ± SD; median) and comparisons based on the Student's t-test were performed with Excel software (current version). Statistical tests — chi-square test, Wilcoxon signed-rank test, Mann-Whitney U test — were performed with Statview (version 5).

## Results

### Demographic and baseline characteristics

Forty-two patients were recruited: 20 women and 22 men. The mean (± SD) age of the females was 68.9 ± 18.8 years and the mean age of the males was 66.5 ± 15.7 years. Of the wounds, 24/42 (57%) were PUs, 12/42 (29%) were the other types of ulcers included (venous, mixed aetiology and diabetic foot ulcers) and 6/42 (14%) were acute wounds.

There was no difference in frequency of wound aetiology between men and women. However, the mean age was significantly higher for males than for females with venous, mixed aetiology and diabetic foot ulcers, although the reverse was the case for PUs (Table 2).

Most of the leg and foot ulcers (8/12, 67%) were less than three months in duration. Nine (75%) were in the necrotic phase (defined as necrotic black [n=1] or necrotic yellow [n=8]) and three (25%) were in the inflammatory phase. Ulcers were located mainly on the leg (5/12, 42%) or the foot (5/12, 42%). The two others were located on the calf (1/12) and the ankle (1/12).

Most of the PUs (15/24, 63%) were located on the sacrum. Eleven (46%) had superficial tissue damage plus exuding blisters, and eight (33%) had tissue damage that did not extend down to the bone; 79% (19/24) of the PUs were graded 10 or more on the Norton score and 38% (9/24) equal to or over 15.

Six patients had acute wounds (one traumatic and five surgical), of which only one was in the test-dressing group, making it inappropriate to compare groups for this comparator.

Twenty patients were randomly assigned to the test-dressing group and 22 to the positive-control group (Table 3). At baseline, there was no significant difference between the groups in terms of demographic details and wound characteristics, or in infection scores (Table 4).

### Efficacy

There was a statistically and clinically significant reduction in clinical scores between days 1 and 15 for both the test and control dressings, demonstrating that both are suitable for use on wounds with signs of inflammation and/or signs and symptoms of local infection. There was no statistically significant difference between scores for the two groups at any assessed period (Table 5).

However, the culture results did not correlate with the clinical infection scores. As stated above, two

experts performed a blind assessment of the laboratory reports. Consistency between the two experts was analysed using the chi-square test. The results showed no difference between their ratings. In addition, there were no statistically significant differences between the treatment groups for this parameter, either globally for all wounds or for each wound type (Table 6).

The trend of the rate of improvement in bacteriological status was higher in the test-dressing group than in the positive-control group (45% versus 27%). This corresponds to a risk ratio of 1.68 (all wounds), meaning that a wound treated with the test dressing had 1.68 times more chances of improving its bacteriological status than wounds treated with the positive control.

This risk ratio increased to 2.6 when the patient had not received antibiotics at inclusion, and to 2.33 if the patient had not received antibiotics during the study period. Relative risks (RR) and odds ratio (OR) of improvement were thus always higher in the test-dressing group than in the positive-control group.

While these differences were not statistically significant, the trend was always consistently in favour of the test dressing in patients who had not received antibiotic therapy, either at day 1 or during the study period (Tables 6–10).

The results of the gene virulence tests showed that the highest clinical scores were associated with a high number of virulence genes, and that the test dressing was more effective than the positive control on *S. aureus* with more than four virulence genes, but further evidence is needed to confirm these results.

### Tolerance, safety and acceptability

A statistically significant improvement in the condition of the peri-wound skin was observed between days 1 and 15 for each treatment. However, there was no difference between treatment groups at any assessed period.

No adverse event was recorded during the study period. One patient included in the positive-control felt better and so decided to drop out on day 8. Another patient in the test-dressing group was excluded at the investigator's request on day 8 for malignant haemopathy requiring chemotherapy. No change in health status or general treatment for comorbidities was considered to be dressing related.

Criteria for acceptability and usefulness of each dressing (see above) were quoted in a great majority of assessments as 'excellent' to 'good', and there was no difference between treatment groups except for the criterion 'adherence to the wound', which was statistically (p=0.04) in favour of the test dressing for ulcers (less adherence) (Table 11).

All the above results confirmed that the tolerance, acceptability and usefulness of the test dressing did not differ from an existing and previously evaluated standard CE-marked positive control.

**Table 10. Bacteriological status on day 15 for patients who were taking antibiotics during the study**

| | -1 | 0 | +1 | ND |
|---|---|---|---|---|
| **Results reported by Dr Lavigne** | | | | |
| Test-dressing group | 1 | 5 | 2 | 2 |
| Positive-control group | 1 | 4 | 2 | 2 |
| Relative risk = 0.88; odds ratio = 0.83 (95% confidence interval [0.08–8.24) | | | | |
| **Results reported by Dr Darbas** | | | | |
| Test-dressing group | 2 | 3 | 3 | 2 |
| Positive-control group | 3 | 3 | 2 | 1 |
| Relative risk = 1.50; odds ratio = 1.80 (95% confidence interval [0.21–15.41]) | | | | |

ND= not documented

**Table 11. Comparison of acceptability of the two dressings when quoted as 'good to excellent'**

| | Test-dressing group (%) | Positive-control group (%) | Difference* |
|---|---|---|---|
| Ease of application | 84 | 89 | NS |
| Reduction of malodour | 89 | 74 | NS |
| Reduction of persistent pain | 44 | 35 | NS |
| Ease of use | 63 | 84 | NS |
| Ease of removal | 84 | 68 | NS |
| Improvement of the condition of the peri-lesional skin | 53 | 30 | NS |
| Dressing comfort | 84 | 89 | NS |
| Cleansing effect | 79 | 79 | NS |
| Absorption properties | 74 | 89 | NS |
| Adherence to the wound (all wounds) | 79 | 58 | NS |
| Adherence to the wound (ulcers only) | 100 | 38 | p=0.04 |

$\chi^2$; NS= not significant

## Discussion

Our study evaluated a new dressing, Askina Calgitrol Ag. In a comparative study of 10 antimicrobial wound dressings, Thomas and McCubbin[12] found

that the test dressing performed very well in all tests, probably because the silver, already in ionic form, was concentrated on the dressing surface in a hydrophilic coating, which facilitated its rapid release. In our study, it was shown that, based on bacteriological analysis, the test dressing enhanced improvement of the bacteriological status of an infected wound more than the positive control.

Bacteriological status can be assessed either by the presence or absence of microorganims on a swab taken from the wound, by bacterial counts from wound biopsies, or by the virulence bacteria analysis, as proposed by Sotto et al.[11]

In our study, changes in the number of bacteria counted on tissue samples did not demonstrate a significant relationship with clinical scores. Moreover, bacteriological counts alone could not be interpreted easily to assess the real bacteriological status of the wound. No bacteriological analysis, except PCR, was capable of determining the presence of an infection. Based on the clinical evolution, the clinical score of infection decreased in both groups, even when microorganisms reappeared afterwards.

In summary, the clinical score alone gives more meaningful information than an assessment based on a correlation between bacteriological analysis and a clinical infection score.

## Conclusion

The results of this RCT show that the test dressing can be used successfully on wounds with clinical signs of inflammation and/or infection; regression of those signs within two weeks was obtained for a large majority of wounds. However there were no significant differences between the two dressings regarding the regression of infection, as assessed by the clinical infection scores, and no correlation between bacteriological analysis and clinical infection. The results also showed similar local tolerance, acceptability and usefulness for both alginate dressings evaluated.

However, the results do indicate that the test dressing appeared to improve the blindly rated bacteriological status of clinically infected wounds when compared with the positive control.

This suggest it promote healing better as a deterioration in the bacteriological status has a negative impact on the healing process. Further trials are needed to confirm this through a more powerful study design. ■

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