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# A retrospective- multicenter study: Evaluation of the same brand (Confort) negative pressure wound therapy (NPWT) with silver coated and standard foam in diabetic foot ulcers

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**Abstract**

Diabetic foot ulcers are hard to treat ulcers that are common in population. This situation causes amputations and extremity loss. Among therapeutic options negative pressure wound therapy (NPWT) seems a good option to treat specially non osteomyelitic and non ischemic wounds. This method can be widely used in deep, large and infected wounds. The antibacterial effect of silver on wounds has been used for centuries. Silver wound closure sets, which are also used in NPWT systems, have gained importance in recent years. In this study, the effect of Confort brand NPWT with and without silver on wound healing evaluated retrospectively. This is a multi center study involving five different institution. As a success criterion, a reduction of >50% in the initial dimensions of the wound (width/length/depth) after 7 applications is accepted. When the silver coated and standard foam Confort NPWT groups were compared, the reduction of 50% or more in the wound volume was relatively shorter in the silver group; while it was 3.2 +/- 1.2 weeks in the silver group, it was 5.14 +/- 2.3 weeks in the silver-free group (p=0.08).

**Keywords:** Diabetic foot infection, negative pressure, silver foam

## Introduction

As a result of rapid global population growth and prolongation of life expectancies, there has been a significant increase in number of chronic and hard-to-heal wounds. In some cases this seems unsolvable problems for patients, healthcare systems and governments. Diabetic foot ulcers are the most common form of chronic wounds seen in the field. The annual incidence of diabetic foot ulcer worldwide is between 9.1 to 26.1 million. Around 15 to 25% of patients with diabetes mellitus develop a diabetic foot ulcer during their lifetime and 50 to 70% of these ulcers recur within 5 years of complete healing [1]. Furthermore, 50% of lower limb amputations of non traumatic origin are due to diabetic foot [2]. NPWT of chronic wounds has become widely available across the world. It can be used for the treatment of hard-to-heal wouds and ulcers except osteomyelitis and inadequate arterial circulation in the area. NPWT is a dynamic system that promotes healing in deep, large and infected chronic wounds. NPWT application is carried out with the homogenized distribution of the negative pressure required for the wound in continuous or intermittent modes by closing the foam in the closure set on the wound. Closure sets are changed according to the specification of the wound (24-72 hours). The total application time is variable. In this process, the factors that positively affect wound healing are still a matter of debate. The anti-bacterial effect of silver on wounds has been used for centuries. Silver wound closure sets, which are also used in NPWT systems, have gained importance in recent years. In this study, the effect of Confort brand NPWT with and without silver on wound healing

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is evaluated retrospectively. As a success criterion, a reduction of >50% in the initial dimensions of the wound (width/length/depth) after 7 applications is accepted.

## Material and Methods

Ethical approval was obtained for the study from Ethics Committee of İzmir Katip Çelebi University (Date:20.01.2022, number:0020). The study was carried out in accordance with the Declaration of Helsinki. This is a retrospective, multicenter (5 centers) observational non-intervention follow-up and comparison study between January.01.2021 and December.31.2021. Data records in accordance with the clinical patient follow-up form were collected retrospectively from patients who underwent Confort brand NPWT and silver and silver-free foam treatment then groups were compared. The exlusion criteria were as follows: patients under 18 years old, and patients having treatments except NPWT. NPWT applicated patients were selected from hospital records. Routine blood tests (hemogram, acute phase reactants, hemoglobin A1c (HbA1c)), microbiological culture test results were reviewed retrospectively. Patient measurements were recorded and pictured (from the front, in the light position where the width and height borders can be clearly distinguished) at attendance and post-treatment visits. If the pre-application width-length-depth measurements were not taken during the treatment visits, only the first and last application criteria were taken into consideration. A limitation criterion for the total number of NPWT applications was not applied, but as for the standardization, those with less than 7 applications were excluded from the general evaluation and additional statistical evaluation was made. Wound Closure Groups; it was recorded in the patient notification form as those who were treated with and without silver. In these two groups, patients whose wound width-length-depth measurements, laboratory and imaging (photograph) data could be accessed were evaluated.

## Results

A total of 69 patient records meeting the defined criteria were reached from 5 centers. NPWT was applied to 43 (62.3%) with silver and 26 (37.7%) without silver. The mean age of the study group was 64.7±6.4; the female/male ratio is 1/2. A total of 52 microbiological sample results were obtained in the study group (69 patients). Microbiologic culture was negative in 10 (19.2%) patients. Gram positive bacteria in 9 patients (9/42, 21.4%) (4 meticilline-sensitive *Staphylococcus aureus* (MSSA), 4 (meticilline-resistant *Staphylococcus aureus* (MRSA), 1 *Enterococcus faecalis* (*E. faecalis*)) and Gram negative bacteria (*Escherichia coli* (*E. coli*)-12, *Acinetobacter baumanii* (*A. baumanii*)-8, *Pseudomonas aeruginosa* (*P. aeruginosa*) -6, *Proteus spp*.-4, *Morganella morganii* (*M. morganii*)-1, mixed-2) were observed in 33 (78.6%) patients. In laboratory parameters, baseline erythrocyte sedimentation rate (ESH) mean was 68±11.7; mean C reactive protein (CRP) level was 128 +/- 24.86; mean white blood cell (WBC) was 16.800±1.458; Mean HbA1c was 9.6±3.6. Mean baseline wound volume of patients was 53.2±23.4 mm3; after a total of 7 NPWT application, the mean wound volume was 4.33±2.33 $mm^3$. Average total wound volume was 75% decreased. It was observed that all of the patients were given oral/parenteral single or antibiotic combinations. Peroral antibiotherapy in 27 patients (39.2%) was preferred; fluoroquinolone alone in 9 (9/27; 33.3%) patients (4 ciprofloxacin, 3 levofloxacin, 2 moxifloxacin); 9 (9/27; 33.3%) patients received clindamycin/ornidazole/metronidazole/sodium fusidate/ trimethoprime-sulfamethoxazole (TMP-SXT)/ beta-lactam-lactamase inhibitor combination combined with ciprofloxacin and 6 patients (6/27; 22.2%) sodium fusidate alone. It was observed that in 3 patients moxifloxacin/ levofloxacin combined with TMP-SXT/ sodium fusidate/amoxycillin-clavulanate. It was observed that all parenteral antibiotic administrations (42/69; 60.8%) were in combination as; Carbapenem+glycopeptide in 27 (27/42; 64.3%) patients; cefoperazone-sulbactam (SCF)/Piperacillin-tazobactam+ciprofloxacin/moxifloxacin+metronidazole/ornidazole in 9 patients (9/42; 21.4%); carbapenem+glycopeptide+colistin in 4 patients (4/42; 9.5%); carbapenem+glycopeptide+TMP-SXT in one patient; carbapenem+glycopeptide+ciprofloxacin were given in one patient. When all antibiotics were examined, it was observed that ciprofloxacin was preferred the most (15/69; 21.7%). The mean total duration of antibiotic treatment was found to be 28.73±13.52. Among the NPWT groups; no significant difference was found in terms of total mean duration of antibiotic treatment, mean acute phase reactants (ESH and CRP), mean HbA1c and mean WBC. When the silver coated and standard foam Confort NPWT groups were compared, the reduction of 50% or more in the wound volume was relatively shorter in the silver group; while it was 3.2±1.2 weeks in the silver group, it was 5.14±2.3 weeks in the silver-free group (p=0.08). Examples of wound healing process of our patients were given in figures 1,2,3,4.

**Figure 1.** NPWT with silver coated foam treated wound examples

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**Figure 2.** NPWT with silver coated foam treated wound examples

**Figure 3.** NPWT with silver coated foam treated wound examples

**Figure 4.** NPWT with silver coated foam treated wound examples

## Discussion

The NPWT method is especially applied in deep chronic wounds to provide tissue expansion and shorten the healing time. This treatment accelerates wound healing by increasing blood supply, initiating angiogenesis, removing exudation, reducing oedema, decreasing bacterial colonization, decreasing wound size by applying mechanical irritation and finally enhancing formation of granulation tissue. In our study after mechanical cleaning, wound is irrigated with antiseptic solution, foam used in this system especially saturated with silver ions providing a serious advantage in exudation control. Silver coated foam also might show anti biofilm effect. Since 1970s, silver compounds are being used for wound healing. When the silver ion enters the bacterial cell, it basically deactivates the respiratory enzymes and generate reactive oxygen species and causing problem in replication and reproduction, resulting in death of the microbes mainly due to reactive oxygen species which acts as a key component in the mechanism of action for silver [3]. The most studies in literature are comparing the effects of silver coated foam dressings and NPWT especially in dogs and cats [4,5] but there are few about NPWT application with silver. Hahn et al. found lower bacterial colonization rates in the silver NPWT group in acute traumatic wounds of lower extremity [6].

In this study, the objective indicator; although it was not statistically significant, the reduction time of 50% or more of the wound volume was shorter in the silver foam group (3.2 weeks vs. 5.14 weeks). However, the major disadvantage of this study is; silver coated form (43/69) and standard foam (26/69) groups were not equally distributed in terms of number.

## Conclusion

The therapy of NPWT with silver coated foam can shorten the the healing time in managing diabetic foot infections.

**Conflict of Interests**
*The authors declare that there is no conflict of interest in the study.*

**Financial Disclosure**
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**Ethical Approval**

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