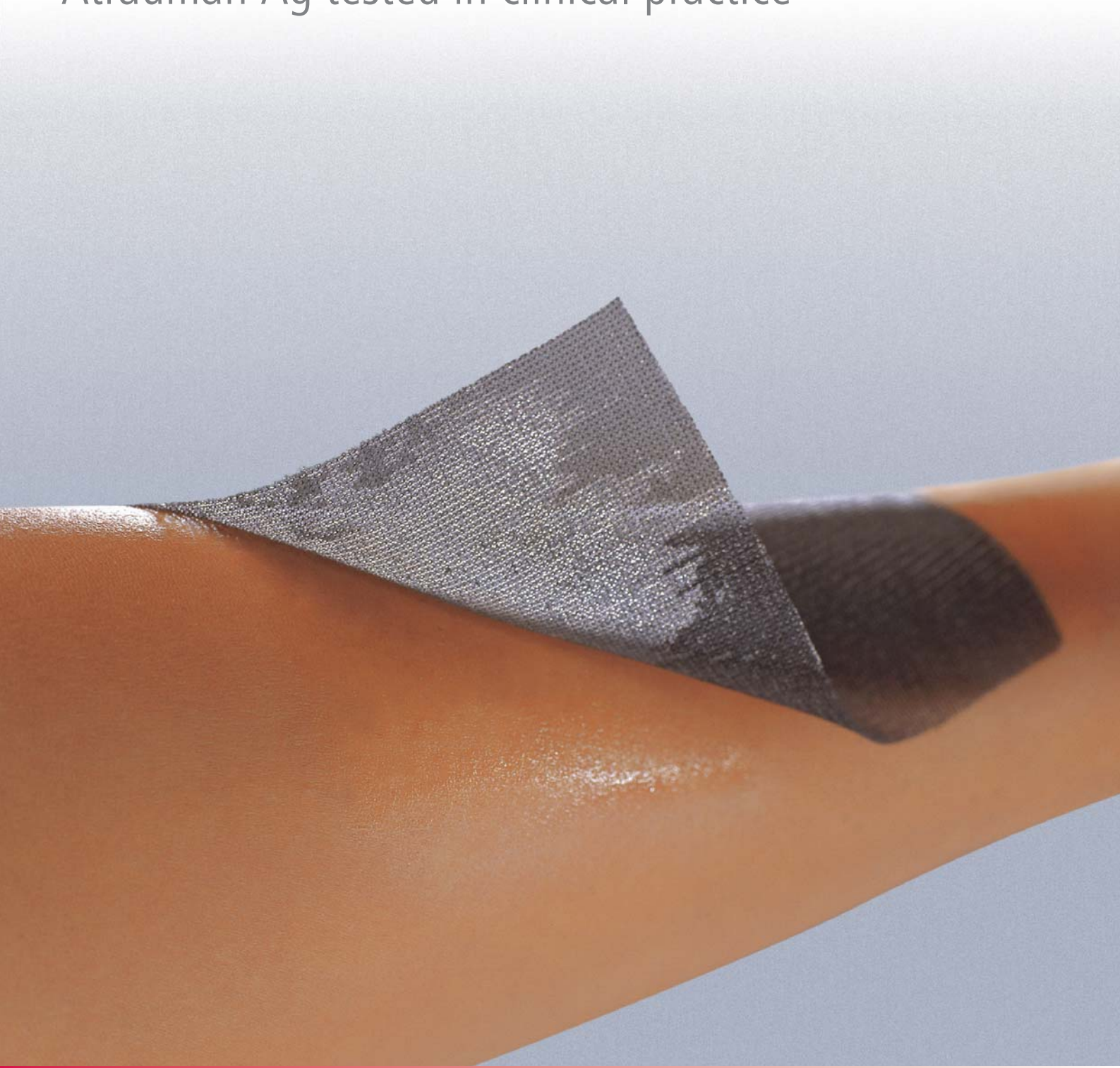
Impregnated tulle dressing containing silver promotes healing of wounds and treats the wound margins

Atrauman Ag tested in clinical practice



Conclusion

In an observational study of 86 patients (average age 73 years), the promotion of wound healing as well as the compatibility of Atrauman Ag was investigated in clinical practice. Two thirds of the patients suffered from chronic wounds, and almost every fifth was included in the test because of acute traumatic wounds. Approximately every second patient received a compression therapy accompanying the Atrauman Ag use and 60 % were taking medication.

In the course of the observational study the condition of the wounds improved clearly. Prior to treatment with Atrauman Ag an average of 59.2 % of the wound beds were covered with coatings, 27 % with granulation tissue and 12.1 % with epithelial tissue. Up to the conclusion, the proportion of coated wounds reduced to almost a third, while granulation had increased to 40 % and epithelial tissue had built up to 24.1 % of the area. At the same time, the degree of exudation and the pain felt by the patients had reduced. As well as the wound status, the condition of the wound margins had improved under the Atrauman Ag. There were clear reductions in oedema, erythema, macerations and eczema. The observational study was also able to show that Atrauman Ag could be combined with many secondary dressings both hydroactive and traditional.

All in all, the treatment was tolerated very well. Almost 90 % of both doctors and patients evaluated the tolerance of Atrauman Ag use as good or very good. The effective promotion of wound healing and tolerance were reflected in the overall judgement: over 85 % of the doctors and patients had gained a good or very good overall impression from the treatment.

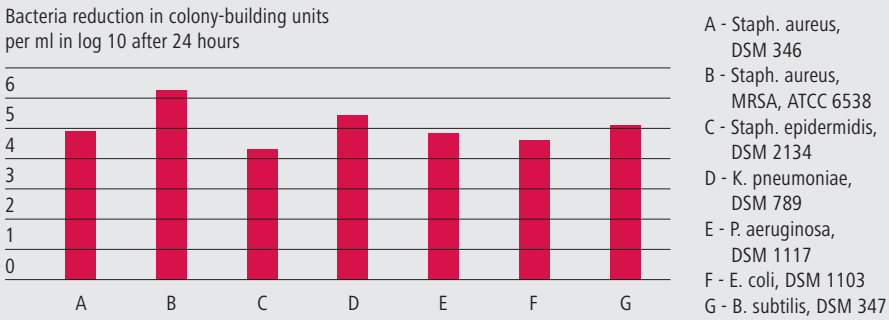
Bacterial infection is a common reason for slow wound healing. As well as chronic wounds which have a particularly high risk of infection, acute traumatic injuries are also regularly infected (J Wound Care 2002; 11:125). If a wound infection develops from a colonisation with pathogenic bacteria, the exudative healing phase is increased significantly so that the proliferative and regenerative wound healing phases are either delayed or don't happen at all. In order for healing to proceed, either the infection must be avoided or if the wound is already infected, this must be effectively managed (Laryngo-Rhino-Otol 2003; 82:36).

For critically colonised and manifestly infected wounds, impregnated tulle dressings containing silver are a local therapy option which can improve the efficacy of the accompanying antibiotic treatment. If silver dressings are applied to the wound, in an aqueous environment they give off silver ions which act against a wide spectrum of pathogenic bacteria. The silver ions develop their bactericide effect even in low concentrations, so far in clinical use without the problem of resistance occurring, as is the case for antibiotics. (Br J Nurs 2004; 13:S6).

Atrauman Ag, a silver-containing impregnated tulle dressing, is indicated for wounds which are critically colonised or are already infected. Atrauman Ag also supports the healing process both in the prophylaxis against wound infection and as a supplementary measure to an antibiotic therapy.

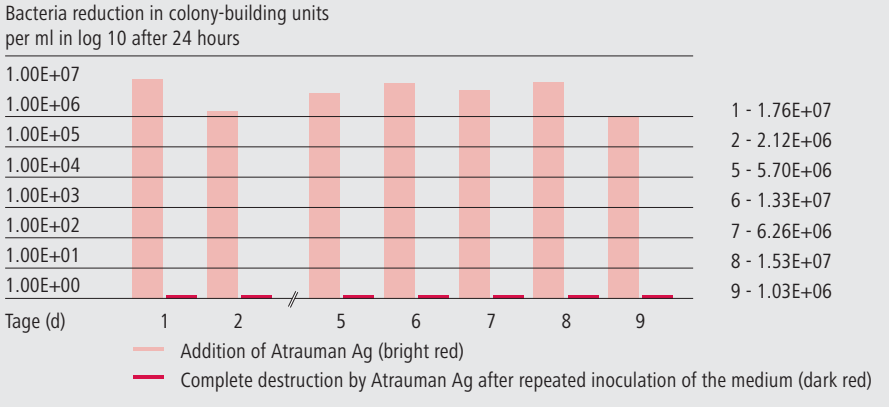
The effective action of Atrauman Ag has been demonstrated in laboratory tests against a broad spectrum of different strains of bacteria which could cause wound infection (Diag. 1). Even methicillin-resistant Staphylococcus aureus strains are reduced by more than 10^6 within 24 hours, therefore destroying 99.99 % of the bacteria. Moreover, the efficient bactericide action doesn't just act in the short term, but over a period of at least 9 days, as was demonstrated in another laboratory test.

Atrauman Ag bacteria reduction – various bacteria



Diag. 1 Bacteria reduction effect of Atrauman Ag

Long therm efficacy of Atrauman Ag in Staph. aureus



Diag. 2 Long therm efficacy of Atrauman Ag

This test showed that Atrauman Ag effectively destroyed both Staphylococcus aureus as well as Klebsiella pneumoniae despite continuous re-inoculation of the medium over a period of 9 days (Diag. 2).

Efficacy also in clinical practice is confirmed by application study

The observational study was able to demonstrate that Atrauman Ag with its very good anti-microbial action supports the healing of chronic and acute wounds. At the same time it not only prevented infections of the wound and guaranteed an undisturbed wound healing, Atrauman Ag also supported the successful treatment of infected wounds during systemic antibiotic treatment. All in all the patients included in the observational study tolerated the treatment with Atrauman Ag very well, undesired side effects were rare.

The participants in the observational study were 16 doctors in practice, (GP's, dermatologists and surgeons) as well as a care agency: they treated a total of 86 patients with Atrauman Ag. Using a standard questionnaire, at the beginning of the examination and in the course of three visits (a total of 3 dressing changes), the following information was obtained: age, sex, general state of health, type, condition and location of the wound, size of wound, previous treatment, discolouration, supplementary medication as well as the duration of the wound. At the beginning and end of the observational study the doctors measured the percentage of coatings, granulation and epithelialisation on the whole wound bed. Furthermore, they noted the course of the wound healing at each change of dressing based on the following parameters:

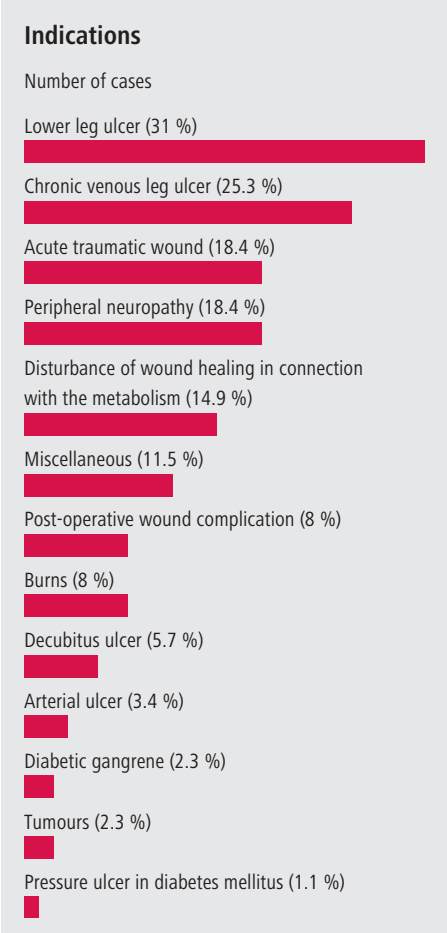
- Quantity of exudate
- Condition of the wound margin
- Wound pains
- Wound infections.

At the conclusion of the treatment with Atrauman Ag, the doctors evaluated the properties of the dressing based on their experience. Furthermore they were to estimate if their expectations of the dressing had been fulfilled. The patients were also asked to give their findings on tolerance, wear comfort and overall impressions including if the treatment met their expectations.

Two thirds of the patients had chronic wounds

The patients had an average age of 73 years and the majority were women (64 %). According to the opinion of the doctors, the majority of patients (59 %) had a general state of health corresponding to their age, 16 % were in good general health. Nonetheless every fourth patient had a poor general health due to a range of illnesses.

A total of 87 wounds were treated with Atrauman Ag on 86 patients in the course of the observational study (one patient had two wounds) (Diag. 3). Most frequently the dressing was used for leg ulcers from which approximately one third suffered. Every fourth participant in the study suffered from a mixed leg ulcer. Other wounds which were treated with Atrauman Ag were acute traumatic wounds (18.4 %), wounds due to a peripheral neuropathy as well as a disturbance of wound healing connected with the metabolism (14.9 %).



Diag. 3 Indications and information about the wounds (multiple entries possible): More than two thirds of the patients were suffering from chronic wounds.

All together two thirds of the patients suffered from chronic wounds (e.g. leg ulcer, mixed chronic venous leg ulcer, arterial ulcer, Decubitus ulcer).

The wounds treated were on average of one year's duration and ranged from acute to chronic, some of which had existed for several years. The average size was 4 cm long and 3.3 cm wide.

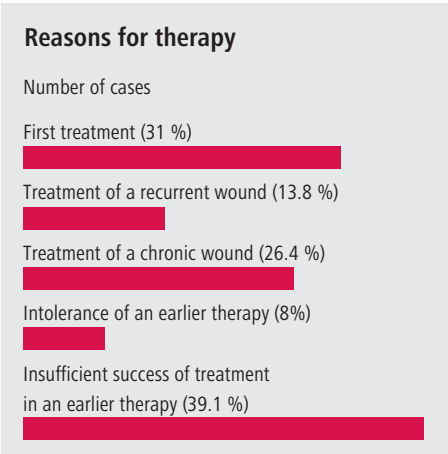
Until their inclusion in the observational study, the patients had been treated with various dressings, both modern and traditional (e.g. dressings containing silver, Betaisodona-gauze dressings, Alginate, foam dressings, a total of 31 different products). In 29 cases, no dressings had been used previously.

Reasons for inclusion in the study

As reported by the doctors, 39.1 % of the wounds were treated with Atrauman Ag because other therapies had been unsuccessful (Diag. 4). For 31 %, the use of Atrauman Ag was the first treatment. Other reasons given by the doctors for using Atrauman Ag were the wish to heal chronic wounds (26.4 %) and recurrent wounds (13.8 %), as well as the intolerance of an earlier therapy (8 %).

Supplementary measures to the use of Atrauman Ag

Almost every second patient (47 %) was having an supplementary treatment with a compression therapy and for 17 % pressure relieving devices were used. Approximately 60 % of the participants in the study were taking accompanying medication (Tabl. 1).



Diag. 4 Reasons given by doctors why patients were included in the observational study (multiple entries possible).

Table 1 Proportion of the patients who were taking medication simultaneously with the Atrauman Ag treatment.

	Number [n]	Number [%]
None	35	40.7
Anticoagulants	11	12.8
Systemic cortical steroids	1	1.2
Immuno suppressants	1	1.2
NSAR	10	11.6
Miscellaneous (above all antihypertensives, diuretics, analgesics, anti-diabetics)	42	48.8

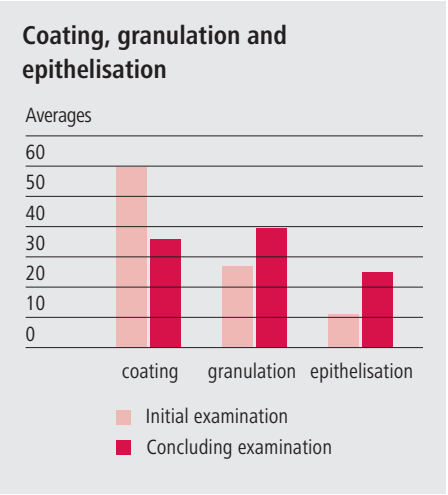
13 patients were being treated with topical ointments. Secondary dressings used included gauze and foam.

Atrauman Ag was changed every three days

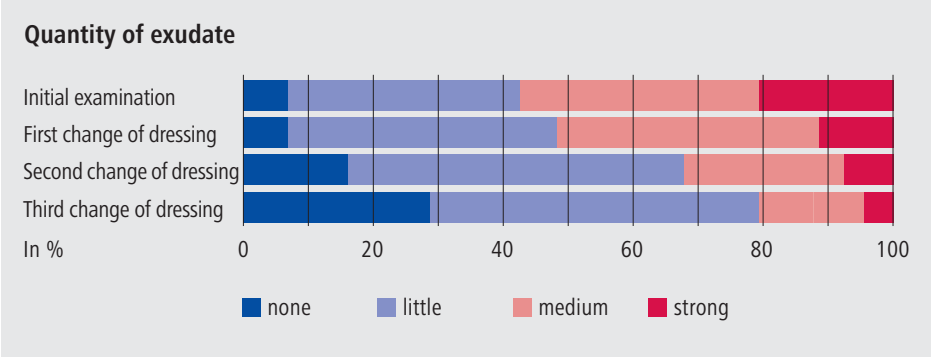
The patients were treated with Atrauman Ag for an average of eight days (between 3 and 21 days); during this time three changes of dressing were carried out. The time between changes of dressing were an average of three days with a maximum application time on the wound of 15 days.

Less coating, more granulation and epithelial tissue

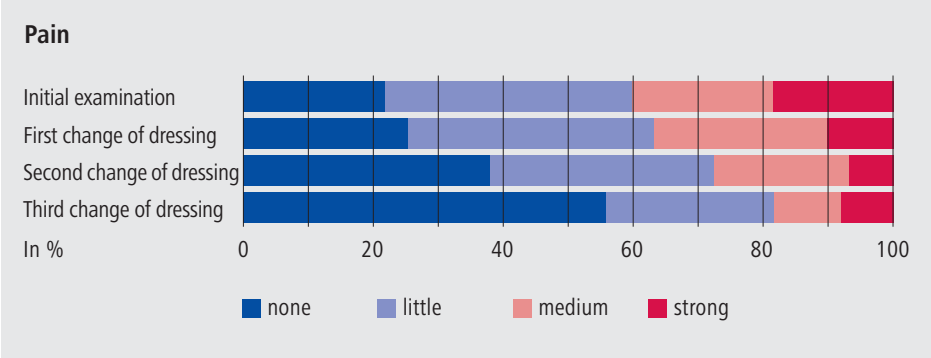
At the beginning of the treatment of the wound with Atrauman Ag, an average of 59.2 % of the wound base was covered with coating, 27 % with granulation and 12.1 % with epithelial tissue. By the time of the final examination i.e. after 3 changes of dressing, the proportion of the coated area had reduced to 35.8 %



Diag. 5 Proportions of coatings as well as granulation and epithelisation at the beginning and end of the study



Diag. 6 Development of quantity of exudate in the course of the observational study



Diag. 7 Development of pains using Atrauman Ag

At the same time there was a clear increase in granulation and epithelial tissue. At the end of the observational study 40 % of the wound base was granulated and a further quarter had epithelial tissue (Diag. 5).

Following on from the increased re-epithelisation, the average size of the wound was reduced. The length was reduced in the course of the 3 dressing changes by 0.7 cm and the width by 0.6 cm.

Less exudation

In assessing the healing process it was shown that when using Atrauman Ag the volume of exudate was reduced. At the beginning of the study only 7 % of the wounds had nil exudate; at the end of the treatment it was 28.7 %. In parallel, the proportion of wounds strongly exudating reduced from 19.5 % to 2.3 % (Diag. 6)

The condition of the wound edges changed minimally. At the beginning 69 % of the wound edges were flat and 30 % were curled up and at the end it was 71.3 % and 25.3 % respectively.

Fewer pains during change of dressings

In the course of the three dressing changes the patients suffered less and less pain. At the beginning 28.1 % said they had no pain, there was an increase to 47.1 % after three changes of dressing. At the same time the proportion of patients with pain decreased continuously: at the beginning 21.8 % had moderate and 16.1 % strong pain, but at the end it was only 10.3 % and 5.7 % respectively.

Less oedema and erythema in the wound environment

As well as the wound status the condition of the wound margins also improved (Table 2). Whereas at the beginning the doctors diagnosed 23 % of the patients with oedema and 39.1 % with erythema, at the end of the treatment with Atrauman Ag it was only 12.6 % and 25.3 % respectively. Furthermore, there were also reductions in the proportion of patients with both macerations (13.8 % to 4.6 %) and eczema (10.3 % to 3.4 %). Finally the number of patients with inconspicuous wound margins increased from 34.5 % at the beginning to 52 % after the end of the treatment.

Number of infected wounds reduced

From the 87 wounds which were treated with Atrauman Ag, according to the opinions of the doctors treating them, 21 were infected. 14 of them were treated with antiseptic or antibiotic preparations (e.g. with Unacid PD tablets, Ciprofloxacin, irrigation with Betaisodona solution, Cefaclor etc).

Table 2 Condition of the wound margin during the observational study

	Initial examination		First change of dressing		Second change of dressing		Third change of dressing	
Wound margin	Abs.	%	Abs.	%	Abs.	%	Abs.	%
Inconspicuous	33	34.5	40	46.0	42	48.3	46	52.6
Edema	20	23.0	17	16.5	15	17.2	11	12.6
Erythema	34	39.1	23	26.4	25	28.7	22	25.3
Hyperthermia	15	17.2	15	17.2	13	14.9	11	12.6
Maceration	12	13.8	7	8.0	5	5.7	4	4.6
Eczema	9	10.3	7	8.0	4	4.6	3	3.4
Hyperkeratosis	3	3.4	4	4.6	4	4.6	4	4.6
Blisters	2	2.3	0	0.0	0	0.0	1	1.1
Infection	2	2.3	1	1.1	0	0.0	0	0.0
Miscellaneous	7	8.0	2	2.3	2	2.3	2	2.3

Table 3 Development of the wound infections using Atrauman Ag

	Initial examination	First change of dressing	Second change of dressing	Third change of dressing
Wound infection				
Yes	21	12	10	7
Treatment of the infection				
Yes	14	9	9	7

According to the doctors, after three changes of dressing the number of infected wounds was reduced to seven. Particularly between the initial examination and the first change of dressing, the number reduced from 21 to 12 (Table 3).

Atrauman Ag was tolerated very well

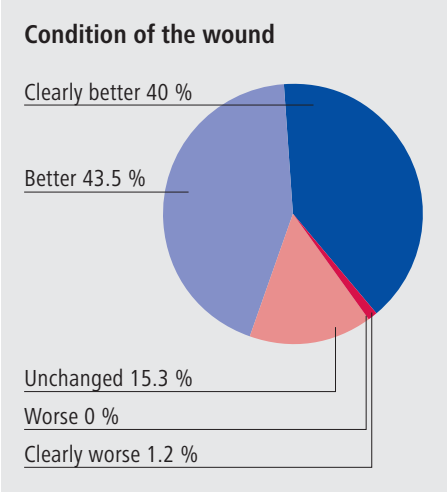
Side effects were only occasionally seen when using Atrauman Ag. In fact 88 % of the doctors rated the tolerance of the dressing as very good or good.

The treatment of two patients with Atrauman Ag was stopped prematurely. According to the doctors treating them, the patients complained of pain, which they blamed on the dressing. Furthermore, in 4 patients wound exudate was unable to pass through the dressing.

In the course of the observational study, there was a discolouration of the wound and the wound edge for some patients. There was a discolouration of the wound in twelve patients and the wound edge in18. It is improbable that the discolouration observed was caused by the use of Atrauman Ag because firstly, many additional and different secondary dressings were used and prior to the study the wounds had been treated with diverse products. Secondly because of its firmly fixed metallic silver Atrauman Ag only releases a low concentration of silver into the wound, therefore it cannot be deduced that the wound or the wound area has discoloured due to the silver released.

Doctors and patients very satisfied with the efficacy

The good clinical efficacy of Atrauman Ag is reflected in the product assessment by the examining doctors. 83 % of them stated that in comparison to the initial examination, the condition of the wounds had improved. Only 15 % of the doctors were of the opinion that the use of Atrauman Ag had not influenced the status of the wound (Diag. 8).



Diag. 8 Condition of the wound in comparison to the initial examination, assessment of the efficacy of Atrauman Ag by the examining doctors

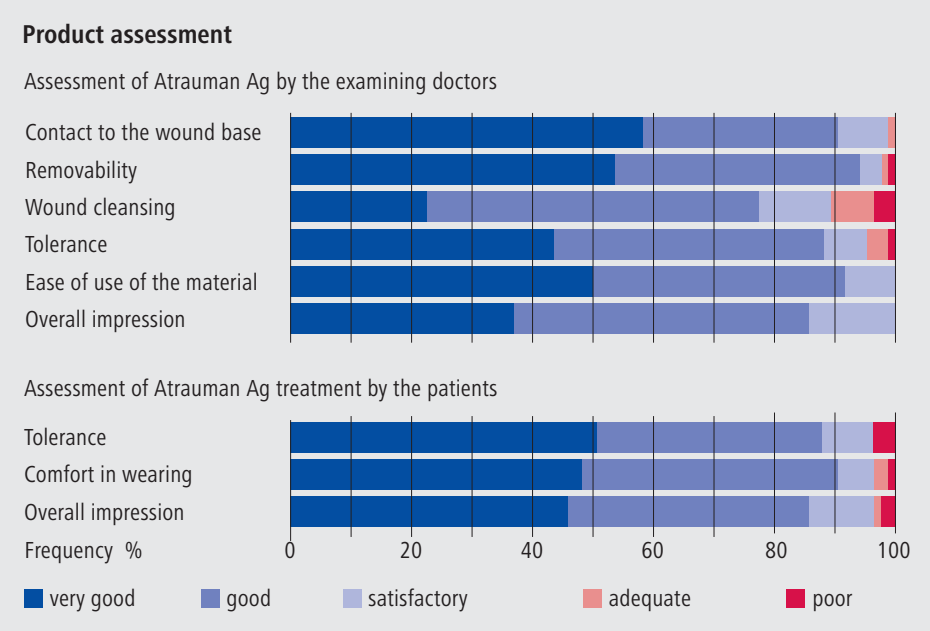
The expectations that the doctors had placed on the wound dressing prior to the start of the treatment were either exceeded or at least fulfilled in almost three quarters of the cases. Only 7 % stated that they had expected more from the treatment. Among those doctors who had no previous experience of using dressings containing silver their expectations were frequently exceeded (36.8 %).

Apart from the tolerance, the average assessment of the use of the dressing was good (91.7 % very good or good), including the conformability to the wound base as well as its drapability (90.4 % very good or good). The wound cleansing effect was judged by 22.6 % as very good and 54.8 % as good. Another important criteria was met in the ease of removal of the dressing with more than 94 % of doctors stating that it was good to very good to remove from the wound and did not adhere. (Diag. 9). They thought the dressing left residues only rarely: more than three quarters of the doctors (76.2 %), thought that it left no residue and 21.4 % thought that only a little product-residue remained in the wound.

Asked about their overall impression, 36.9 % of the doctors evaluated the wound treatment with Atrauman Ag as very good, 48.8 % as good and 14.3 % as satisfactory (Diag. 9).

The response from the patients regarding Atrauman Ag was similarly positive. Both tolerance and comfort in wearing was judged by approx. 90 % as very good or good. 'Very good' was the overall impression of 45.8 % of the patients with 39.8 % judging it as 'good' (Diag. 9).

The dressing had fulfilled or exceeded the expectations of the wound treatment of more than 70 % of the patients. Less than one in ten stated that their expectations were not quite fulfilled, while only 3.7 % said they were not fulfilled at all (Diag. 10).



Dig. 9 Assessment of Atrauman Ag by the examining doctors and patients

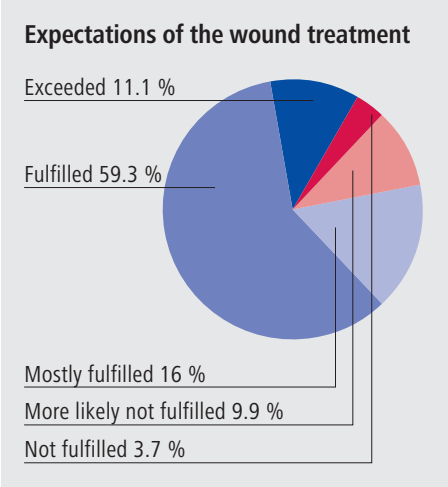
Conclusion

The majority of the patients treated with Atrauman Ag in the observational study suffered from chronic wounds which were difficult to heal. Doctors reported that for 40 % of the participants previous treatments had been unsuccessful. The condition of the wounds at the time of their inclusion in the study was correspondingly poor. Almost 60 % of the wound bases were covered in coatings; only a quarter showed signs of granulation. At the same time, every fifth wound was heavily exudating. In the course of the observational study all the parameters of the wound improved clearly. Coatings reduced and granulation and epithelial tissue built up increasingly. The size of the wounds and the volume of exudate reduced. The healing process documented by the doctors therefore points to the fact that the use of Atrauman Ag promoted the healing of both chronic and acute wounds.

In the treatment of problem wounds, the use of Atrauman Ag also affects the wound margins positively. These are often very sensitive and prone to maceration, oedema, erythema and other abnormal changes. Under certain circumstances, all of these factors can impede the healing process, therefore the wound margins should be carefully observed. As the observational study was able to show, the many complications otherwise expected can be considerably reduced by the use of Atrauman Ag. Due to the impregnation in the dressing the condition of the wound area improved considerably in the course of the three dressing changes. The proportion of the wounds with inconspicuous wound margins increased from 34.5 % to 52.6 %. The treatment also reduced complications like maceration, oedema, eczema and erythema.

Atrauman Ag - safe to use

On the whole, the wound treatment was tolerated by patients very well. In the observational study the results that were already known from the in-vitro tests could be confirmed: that Atrauman Ag releases just sufficient silver ions into the area to ensure an effective action. Because of the relatively low concentration of silver ions in the wound, the cytotoxicity of Atrauman Ag is also very low and the tolerance during treatment correspondingly high. During the period of the study, only two patients ended their treatment prematurely. Good tolerance was confirmed by both doctors and patients. Almost 90 % of both groups stated that the tolerance was 'very good' or 'good'. A key reason is: that Atrauman Ag rarely adheres to the wound and is therefore very easy to remove from the wound. This was confirmed by the doctors of whom 83 % evaluated the removability as very good or good. Because Atrauman Ag did not adhere to the wound in most cases, there was little or no wound pain at dressing change. 90 % of the doctors assessed the application as good or very good, the reason for this would certainly be that the application technique of Atrauman Ag does not differ greatly from its predecessor tulle dressings that have been used successfully in wound treatment for decades. Therefore, the risk of application errors occurring is reduced considerably.



Diag. 10 The patients' expectations of the wound treatment with Atrauman Ag

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