

3. Estudio comparativo y randomizado



► “Estudio comparativo y randomizado: Outcome Evaluation of two hidrogels”.

Estudio comparativo entre Purilon® Gel e Intrasite Gel en 32 pacientes con úlceras vasculares con necrosis/esfacelos. Se compara los grupos de tratamiento en cuanto estado del lecho ulceral (desbridamiento), tamaño de la lesión y condiciones de la piel perilesional. En el grupo tratado con Purilon Gel se observó un desbridamiento más rápido las primeras 2 semanas y un menor número de problemas en la piel periulceral.

Outcome evaluation of two hydrogels

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Introduction

- The cost of wound management is a heavy burden on the society:
 - Approximately 0.4% of the Danish population is being treated for leg users at an estimated cost of DKK 24.000 (euro 3.200/\$ 2.800) per patient per year (2000) prices)
- Evidence based treatment protocols are needed in order to make cost-effective decisions regarding treatment choices
- Major issues in terms of cost and efficiency of wound management are:
 - Clinical efficacy (e.g. debridement effect and time to healing)
 - Cost-effectiveness of the treatment
 - Time spent by health care professionals
- The patients' Health Related Quality of Life (HRQoL)
- Fast and effective debridement of necrotic tissue is essential as it accelerates the healing process*

Objective

This evaluation compares the performance characteristics of **Purilon** Gel (Coloplast A/S) versus **IntraSite**® Gel (Smith & Nephew) in the treatment of leg users in terms of debridement effect, cost-effectiveness, and HRQoL.

Subjects and Treatment

- 32 patients with venous or mixed venous/arterial leg ulcers covered by necrotic, sloughy and/or fibrinous tissue
- Treatment period: Minimum 2 weeks and maximum 4 weeks
- Patients were randomized to treatment with either **Purilon** Gel or **IntraSite**® Gel
- A film or hydrocolloid was used as secondary dressing
- All patients wore short stretch bandages
- Weekly assessments including debridement and healing effect, per-ulear skin reactions, wound pain and gel characteristics were performed by experienced wound care professionals
- Between assessments dressing changes were recorded in a patient log

Purilon Gel: Mode of action



References

1. Gahrve, F., Olsen, L., SG - background and diagnosis, Munksgaard, Copenhagen 1989
2. Gahrve, F., Olsen, L., SG - treatment of leg ulcers, Munksgaard, Copenhagen 1989
3. Thomas, S., Quinn, NCE - time for a new? Woundmanagement 2001 June/ThomasNCE - debridement agents-review/16m August 2001 2001
4. Zipp, J., C. - The effects of cadexomer iodine paste in the treatment of venous leg ulcers compared with hydrocolloid dressing and paraffin gauze dressing. In: J. Dermatol. 1995; 37: 390-6

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Results

- The patients in the 2 groups were comparable at the time of inclusion
- Two patients in the IntraSite® Gel group dropped out of the study because of verified allergic dermatitis

Clinical efficacy (table 1)

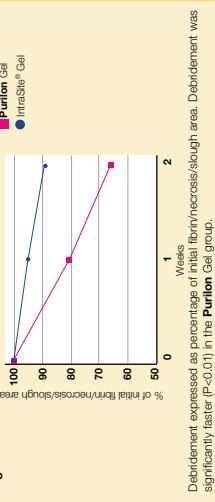
- In the **Purilon** Gel group the area covered with necrosis/fibrin/slough decreased significantly faster (P<0.01) than in the IntraSite® Gel group (figure 1)
- The area covered with granulation tissue appeared to increase faster in the **Purilon** Gel group
- The wound area decreased significantly in both groups

Table 1 - Clinical efficacy

	Purilon Gel (n=16)	IntraSite ® Gel (n=14)	P
Debridement			
• Necrosis/fibrin/slough (% of initial)	86.2%	88.1%	P<0.01
• After 2 weeks	55.6%	60.6%	NS
• After 4 weeks			
• Wound area covered with granulation tissue	53.4%	52.2%	NS
• Study start	71.1%	63.3%	NS
• After 2 weeks	72.6%	72.3%	NS
• After 4 weeks			
Healing			
• Final wound area (% of initial)	75.5%	63.4%	NS
• Patients experiencing reactions	0%	29%	NS
• Development of erythema**	19%	0%	NS (P=0.07)

* No erythema present at study start. ** Erythema present at study start

Figure 1



Performance characteristics (table 2)

- Regarding ease of application **Purilon** Gel showed significantly better performance than IntraSite® Gel
- There was no difference in wear time, however the subjective score of wear-time appeared to be better for **Purilon** Gel

Table 2 - Performance characteristics

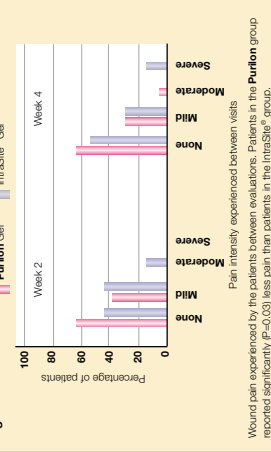
	Purilon Gel (n=16)	IntraSite ® Gel (n=14)	P
Characteristics upon application (5=excellent, 1=poor)	5	4	P<0.01
Score of wear-time (5=excellent, 1=poor)	4	3	NS
Wear-time (days)*	1.5±0.4	1.4±0.4	NS

* The scheduled weekly dressing change is included

Health Related Quality of Life (HRQoL) (figure 2)

- Patients in the **Purilon** Gel group experienced significantly (P=0.03) less pain between evaluations compared to patients in the IntraSite® Gel group
- In the **Purilon** Gel group 94-100% of the patients' ratings were in the category "none" or "mild"
- In the IntraSite® Gel group only 85-86% of the patients' ratings were in the category "none" or "mild"
- Patients in the **Purilon** Gel group never experienced severe pain whereas 15% of patients in the IntraSite® group reported severe pain

Figure 2



Cost effectiveness (table 3)

- The wound area covered with necrosis/fibrin/slough is reduced to 66.2% after only 2 weeks of treatment in the **Purilon** Gel group whereas it takes 4 weeks to reach a similar reduction in the IntraSite® Gel group
- No additional clinically relevant benefit seems to be achieved by using **Purilon** Gel beyond 2 weeks (table 1)
- Therefore it is appropriate to calculate the cost-effectiveness after 2 weeks in this study
- A useful measure of cost-effectiveness is the cost per percentage debridement*
- When considering only expenses related to the amount of gel used, the cost per percentage debridement with **Purilon** Gel is considerably lower than for IntraSite® Gel (table 3)

Table 3 - Cost effectiveness of debridement after 2 weeks of treatment

	Purilon Gel (n=16)	IntraSite ® Gel (n=14)	P
Reduction in wound area covered with necrosis/fibrin/slough	33.8%	11.9%	P<0.01
Mean number of dressing changes	9.3	10.0	NS
Gel cost per dressing change (8 g) - (\$)	2.4	2.6	NA
Cost per percentage reduction in wound area covered with necrosis/fibrin/slough (\$)	0.7	2.2*	NA

* Wholesale list prices (Kendall, August 2001) ** 1 \$ = 8.59 DKK, March 2002

Conclusion

This controlled comparative study resulted in the following outcome parameters in favor of **Purilon** Gel compared to IntraSite® Gel:

- Significantly faster and more effective debridement
- Cost-effectiveness of debridement
- Significantly easier application
- A significant difference in the patients' quality of life due to significantly lower degrees of wound pain
- No sign of allergic reactions

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