COMPARISON OF TWO WOUND CONTACT LAYERS IN ACUTE WOUNDS

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INTRODUCTION

- Non serious acute wounds only require, in most cases, application of a well adapted wound contact layer (WCL)[1]
- There are a number of 'ideal characteristics' that should be considered when choosing a WCL (Table 1) [2]

Table 1: Ideal Characteristics of a WCL

Easy to apply
Able to maintain a moist wound environment
Able to transfer wound exudate to secondary dressings
Transparent (i.e. allowing wounds to be inspected whilst the WCL is *in situ*)
Capable of being left *in situ* for extended periods (e.g. for up to 14 days, depending on the condition of the wound)
Able to adhere to intact skin but not to the wound bed
Easy to remove and does not leave residues

- These ideal characteristics promote the concept of undisturbed wound healing by minimising trauma and pain at dressing removal[2]

AIMS

Primary Study Objective:

- To compare pain levels upon removal of two WCLs (a soft silicone wound contact layer, SSWCL* and a lipido colloid wound contact layer LCWCL**)

Secondary Study Objectives:

- To compare the two dressings in terms of complete healing at day 21, condition of the wound, condition of the surrounding skin, in-use characteristics (clinician and patient assessments), and safety

* Mepitel® One
** UrgoTul®

REFERENCES

[1] Haute Autorité de Santé (HAS). Dressings: recommended indications and use. Recommendations. 2011 Apr

[2] Barrett S. Mepitel One: a wound contact layer with Safetac technology. Br J Nurs 2012;21(21):1271-1277

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METHODS

- Open, randomised, multi-centre study in a general practice setting
- Conducted over a 21 day period
- Inclusion/exclusion criteria (Table 2)
- Subjects were randomised to receive either the SSWCL* or the LCWCL** (web-based allocation)
- Subjects were assessed at 3 visits (Table 3)

Table 2: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Acute wound: traumatic wound (dermabrasion, skin tear, other) or benign burn requiring the use of dressings	Infected wound, moderately to strongly exudative/haemorrhagic wound
Wound size between 3cm^2 and 240cm^2	Diagnosed underlying disease (e.g. neuropathy) which, as judged by the investigator, could interfere with the pain assessment
Wound duration ≤ 3 days	Known allergy/hypersensitivity to any of the components of the investigational products
Male or female, aged ≥18 years	Participation in other clinical investigation within one month prior to start of investigation
	Pregnant or breast-feeding women

Table 3: Study Design

Visit	Assessment Criteria
Visit 1 (Day 0)	Assessment of wound* and surrounding skin; pain assessment after application of investigational product (100mm visual analogue scale (VAS))**
Visit 2 (Day 3)	Assessment of wound* and surrounding skin; pain levels assessed immediately after first dressing removal**; complete healing assessment; adverse events (AEs)/adverse device effects (ADEs); clinician assessment of use
Visit 3 (Day 21)	Assessment of wound* and surrounding skin; complete healing assessment (wound considered completely healed when 100% epithelialised); AEs/ADEs; subject assessment of use

*Overall wound evolution was blindly assessed using digital photography by 2 independent and experienced reviewers

**A VAS score of ≥30 mm was considered as clinically relevant pain[3]. VAS is a 100mm straight line ranging from 0 (no pain) to 100 (extremely severe pain) :

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REFERENCE
[3] Collins SL, et al. The visual analogue pain intensity scale: what is moderate pain in millimetres? Pain 1997;72(1-2):95-97

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RESULTS

- 123 patients enrolled by 21 general practitioners
- 82% of traumatic wounds: dermabrasion, skin tears
- Groups were comparable at baseline for all evaluated parameters (Table 4)

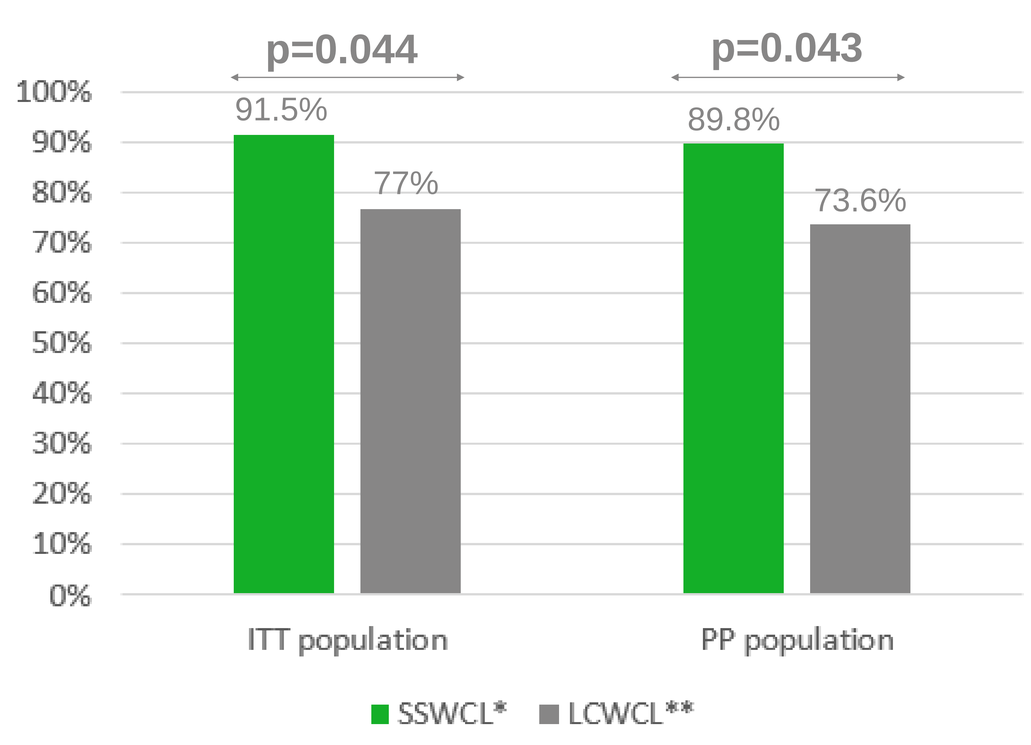
Table 4: Patient Demographics (ITT population)

	SSWCL*	LCWCL**	p-value
Age Mean ± SD	64.8 ± 21.2	59.8 ± 23	0.24
Gender	Male : 47.5% Female : 52.5%	Male : 54.8% Female : 45.2%	0.47
Analgesic use at baseline	11.9%	8.1%	0.55
Wound type : Traumatic wound Benign burn	 84.7% 15.3%	 80.6% 19.4%	0.63
Wound area at baseline (cm^2, digital software) Mean ± SD	5.66 ± 6.69	10.8 ± 22.3	0.49

Pain

At 1st dressing removal, pain VAS level was < 30 mm in 89.8% and 73.6% of patients allocated to SSWCL* and LCWCL** dressings respectively (p=0.043; PP population) (Figure 1).

Figure 1 : Percentage of patients without clinically relevant pain at dressing removal



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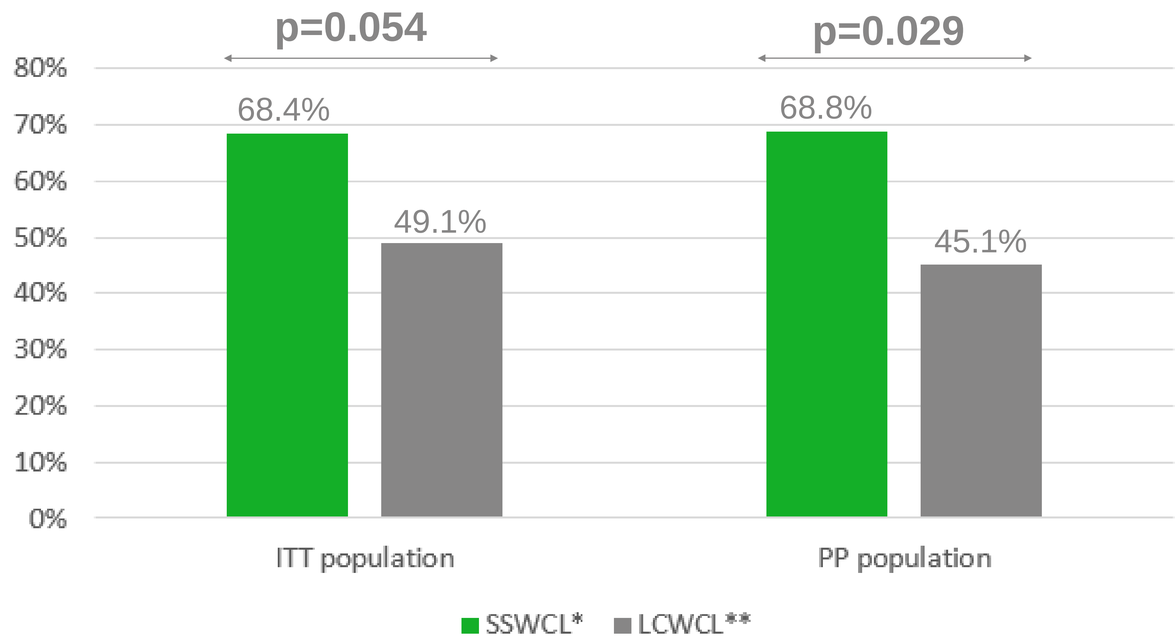
Wound Closure

Wound closure rate was significantly higher in the SSWCL* group: 68.8% vs. 45.1%; p=0.029; PP population (Figure 2).

Peri-Wound Skin Condition

There were no significant differences between the two groups for any of the variables (inflammatory signs, irritation, allergic rash/eczema, blistering, skin stripping, maceration, dry, trauma to wound edges, product degradation).

Figure 2 : Wound closure rates at Day 21



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Investigator and Patient Assessments

Figure 3 : Percentage of "Very Good" ratings by investigator (ITT population)

*** p<0.0001**

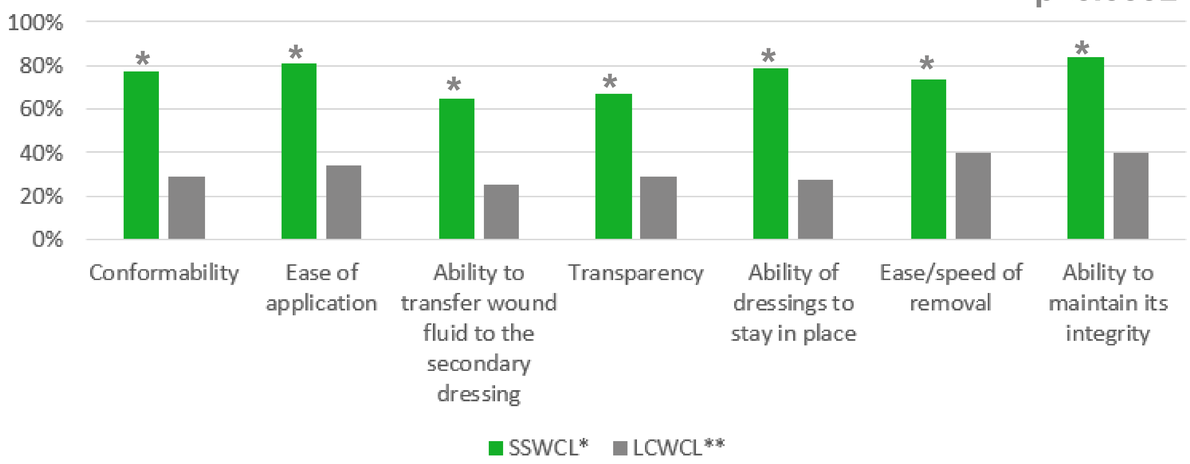
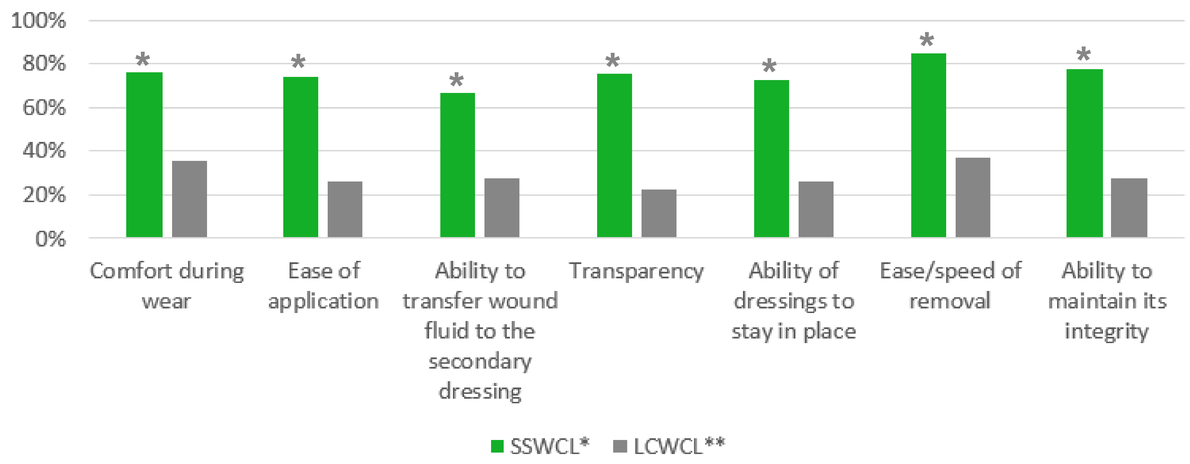


Figure 4: Percentage of "Very Good" ratings by subject (ITT population)

*** p≤0.0001**



The SSWCL* was rated by both the investigators and patients as being superior to the LCWCL** in relation to a variety of in-use parameters (Figures 3 and 4).

CONCLUSION

- These study results indicate that the management of acute wounds with the SSWCL* is associated with significantly less pain at dressing removal and leads to a smoother wound healing trajectory than with the comparator dressing
- Clinician and patient assessments of the dressings also indicate that the SSWCL* was superior to the LCWL** in terms of numerous in-use characteristics

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