A LARGE REAL-LIFE STUDY ON THE USE OF A NOVEL GENTLE SILVER ANTIMICROBIAL BARRIER DRESSING, TLC-AG* IN THE MANAGEMENT OF WOUNDS DURING THE COVID-19 PANDEMIC

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INTRODUCTION

This study aimed to evaluate the clinical outcomes of wounds at risk of infection or presenting with clinical signs of local infection in an unselected cohort of patients, when treated with…treated with two antimicrobial contact layers impregnated with silver, TLC Ag* (Technology LipidoColloid-Ag healing matrix), under real-life conditions during the COVID-19 pandemic.

The Technology LipidoColloid (TLC) matrix consists of a proven gentle atraumatic non silicone adhesive that incorporates within it the gel forming agent carboxymethyl cellulose. This matrix is coated on to a perforated polymer membrane to allow exudate to freely pass through. The matrix is also incorporated with a powerful yet gentle ionic silver antimicrobial barrier agent that is designed to prevent infection and the construct is then called the TLC-Ag* matrix. In contact with wound exudate, the carboxymethyl cellulose component in TLC or TLC-Ag forms a gentle, nonadherent gel layer that is ideal for placement on sensitive wounds. The matrix can also be applied to an absorbent foam, and then provided with an atraumatic/gentle border to form the bordered version of the TLC Ag bordered products.

Both the TLC technology and the silver containing TLC Ag technology have been studied via randomized controlled trials (RCTs). Due to its very gentle nature, the TLC technology has also been studied, demonstrating excellent results, on the pediatric population which is deemed a population particularly sensitive to pain for obvious reasons. Remarkably, it is one of the very few dressing technologies which have been studied on a large cohort of pediatric patients with epidermolysis bullosa, a condition that is associated with much pain and misery. RCTs on the technology that have been done, consisted of well structured inclusion and exclusion criteria that may exclude some patients who present with wounds at the clinics and are still good candidates for the novel dressings. This study reported is a somewhat different in that it is a large observational study with an “all comers” approach, an approach that is true to real life, in the sense physicians will use the product as they deem it fit for any patient they treat.

The objective of this study was to check if clinical effectiveness, a hallmark of observational studies, could be established on a large population of patients treated with all the variables, such as serious advanced age, comorbidities, the use of immunosuppressive drugs, etc. that are screened out of tightly controlled randomized controlled trials that are more designed show clinical efficacy than clinical effectiveness.

METHOD

A large (728 patients), prospective, multicentered, observational study with two TLC-Ag dressings (TLC-Ag, and TLC-Ag bordered) was conducted between May 2020 and May 2021. After recording the description of the treated patients and wounds, the main objectives were to assess the wound healing outcomes, the changes in wound infection status over a maximum period of four weeks of treatment. Also, the overall clinical assessment of performance, local tolerance and acceptability of dressings were studied. All patients received adequate standard of care, judged appropriate by the investigating physicians, considering their expertise in this field of wound care. Reduction of antibiotic usage over time was monitored.

RESULTS

A total of 728 patients with wounds of various etiologies and wound infection status were treated with the evaluated dressings in 39 centers for a mean duration of 26±19 days, with an intermediate visit conducted in 712 (97.8%) patients after a mean period of 12±9 days. At the initial visit, it was established that the majority of patients (60.4%) had a wound infection, based on direct indicators and/or clinical signs, while the remaining cohort presented first one or some (not all) clinical signs of a local wound infection (25.1%) or were at risk of wound infection based on clinical judgment (13.2%) (unclear status in 1.2%). Throughout the study period, all the parameters of wound infection continuously decreased, resulting at the final visit in a reduction by 78.9% of the prevalence of local wound infections and by 72.0% of the clinical signs of wound infection, the most rapidly diminished clinical sign being wound deterioration. Table 1 and Figure 1 shows the change in wound infection, direct indicators and clinical signs of wound infection over the treatment period.

Concurrently, in terms of the healing process, 92.1% of the wounds healed or improved, 3.2% remained unchanged and 1.7% worsened (data missing for 3.0%), and an improvement of the periwound skin was reported in 65.7% of the patients (Figure 2). Overall, the two dressings were ‘very well accepted’ by the majority of patients, with no uncomfortable feeling at wearing and no pain at dressing removal. The TLC Ag technology was assessed by the physicians as ‘very useful’ in the majority of the cases with a ‘very good’ efficacy in terms of antimicrobial activity and promotion of the wound healing process. Similar results were reported regardless of the wound type treated or of the TLC-Ag dressing evaluated. Final results of these patient and clinician inputs are shown in Figure 3. Success of the dressing seen under the challenging times of COVID 19 when many patients had to change dressings at home shows that this TLC Ag technology is patient friendly enough for them to learn how to use the product, and to use it successfully at home without visiting a clinic.

CONCLUSION

These results are consistent with previous clinical evidence on TLC-Ag dressings. They support the good efficacy, good tolerability and usefulness of these antimicrobial dressings in the management of patients with wounds at risk or with clinical signs of local infection, in association with appropriate standard of care.

Table 1. Change in wound infection, direct indicators and clinical signs of wound infection over the treatment period

	Initial visit (n=728)		Intermediate visit (n=728; 16 missing visits)		Final visit (n=728; 22 missing visits)		Reduction versus initial visit	
	n	%	n	%	n	%	Intermediate visit (%)	Final visit (%)
Wound infection	**440**	**60.4**	**247**	**33.9**	**93**	**12.8**	**43.9**	**78.9**
Direct indicators of wound infection	**304**	**41.8**	**155**	**21.3**	**72**	**9.9**	**49.0**	**76.3**
Purulent discharge	199	27.3	67	9.2	13	1.8	66.3	93.5
Surgical septic wound	97	13.3	47	6.5	30	4.1	51.5	69.1
Positive laboratory test*	101	13.9	58	8.0	35	4.8	42.6	65.3
Clinical signs of wound infection	**600**	**82.4**	**382**	**52.5**	**168**	**23.1**	**36.3**	**72.0**
Spontaneous pain/tenderness	366	50.3	197	27.1	71	9.8	46.2	80.6
Increased local temperature	356	48.9	158	21.7	33	4.5	55.6	90.7
Induration/swelling/oedema	258	35.4	137	18.8	74	10.2	46.9	71.3
Increased in level of exudate and/or change of exudate colour or smell	216	29.7	73	10.0	19	2.6	66.2	91.2
Wound enlargement/worsening	124	17.0	8	1.1	5	0.7	93.5	96.0
Wound stagnation/wound healing delay	84	11.5	35	4.8	15	2.1	58.3	82.1
Erythema	25	3.4	16	2.2	1	0.1	36.0	96.0
Suspicion of biofilm presence	22	3.0	8	1.1	3	0.4	63.6	86.4
Others	20	2.7	19	2.6	10	1.4	5.0	50.0

*Laboratory tests were performed in 178, 118 and 94 patients at the initial, intermediate and final visits, respectively.

Figure 1

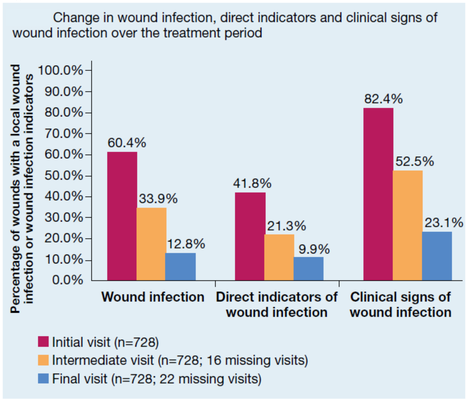


Figure 2

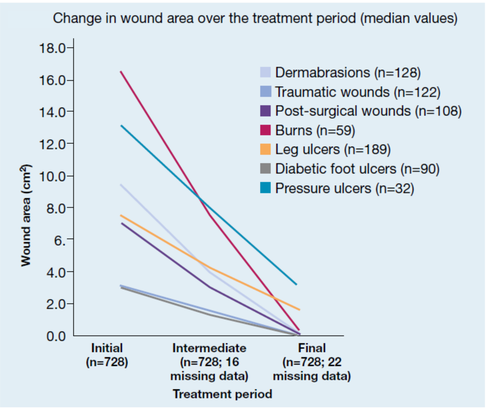
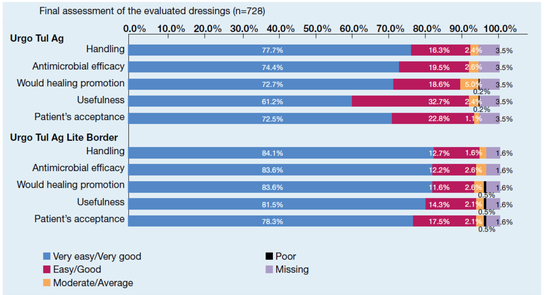


Figure 3



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*TLC Ag Dressing: Urgotul Ag and Urgotul Ag bordered dressings, Urgo Medical

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