The clinical contamination of amorphous hydrogels

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Summary

Amorphous hydrogel products are commonly used in wound management practice in the treatment of shallow to full thickness open wounds. Whilst some of the products currently used in clinical practice are intended for single use only, they are often re-used in the interests of reducing costs and wastage, despite the potential risk of contamination in re-used products. In this study, packs of Intrasite Gel™, Solugel™ and Duoderm Hydroactive Gel™ were re-used in the clinic over a 1 month period. Samples were qualitatively analysed for microbial contamination each week.

Flasks containing fluid casein soy lecithin polysorbate-20 (FCSLP-20) medium were inoculated with used hydrogel samples and incubated overnight. Flasks displaying 'growth' were subcultured onto selective media for preliminary identification of the contaminating organism(s). One 'no growth' flask from each product sample was subcultured onto nutrient agar to confirm the absence of contamination.
Microbial contamination was absent in samples of each product during the 1 month period. Control strains were successfully grown in flasks and isolated on selective media. Negative control flasks showed 'no growth'.

The 'single use only' packs of Solugel™, Intrasite™ Gel and Duoderm Hydroactive Gel™ amorphous hydrogels were free of microbial contamination during product re-use in this study, despite use in an active wound clinic situation. This study highlights the need to review the use of these hydrogels and address the safety in the re-use of these products.

Introduction

The use of amorphous hydrogels has become part of routine wound management practice. Whilst amorphous hydrogel products are intended for single use only, it is common practice to re-use open packs because often only a small amount of hydrogel is needed at a time, costs are reduced and the products provide enough hydrogel for several applications.

The products are therefore considered no longer sterile and potentially harbour microbial contaminants that may consequently be introduced into a wound on reapplication. Empirically, however, wound healing has been a success despite the re-use of hydrogel packs.

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In this study, three commercial amorphous hydrogel products were used in the wound clinic over a 1 month period and qualitatively tested for microbial contamination. The intention of the study was to determine whether or not the products are contaminated during times of consequent re-use and reapplication.

Materials and methods

Amorphous hydrogels have no definite structural form. They are highly water based and generally contain an appreciable amount of propylene glycol as the humectant and, in addition, as a co-polymer for stability and manageability. Amorphous hydrogels provide a moist wound healing environment when applied to shallow and full thickness open wounds inducing pressure sores, leg ulcers, surgical wounds and burns. They rehydrate and thus facilitate re-epithelialisation, promote the autolytic process of debridement of necrotic tissue and absorb excess exudate [1]. The three products used are outlined below:

Intrasite™ Gel (Smith & Nephew)

The 25 gram plastic pack consists of a long nozzle with a snap

off tip and a replaceable blue cap. The hydrogel is a colourless to pale yellow transparent aqueous gel containing 3% w/w of a modified carboxymethylcellulose (CMC) polymer, 20% w/w propylene glycol and 77% water [1, 2].

Solugel™ (Johnson & Johnson)

The colourless amorphous hydrogel containing 25% w/w propylene glycol in normal saline (0.6% w/w) and 75% water is supplied in a 30 gram plastic tube with a screw-on cap [3].

Duoderm Hydroactive Gel™ (Convatec)

The 15 gram metal tube with a plastic screw-on cap contains an amorphous hydrogel consisting of a pectin and sodium carboxymethylcellulose (gel forming agents) in water and proplylene glycol base [4].

Methodology

Twenty packs of each product were opened in the presence of patients and medical staff and used in the wound clinic on a typical working day. The procedure simulated normal practice at the clinic. Firstly, hands were washed with Microshield™ handwash mild, containing propyl and methyl hydroxybenzoates, and tapwater dispensed at a consulting room basin, then dried with a paper towel. A single pair of clean disposable latex gloves was worn. On Day 1, each pack was opened and a small amount of hydrogel squeezed onto a clean wooden tongue depressor ready for application.

Each pack was then recapped and placed back into the original product packaging. The procedure was performed away from the patient above a clean stainless steel trolley on Days 1, 7 and 14. On Day 21, the procedure was performed directly in front of a patient whose wound was being redressed and who was free to talk. The containers were stored in the clinic cupboard where the temperature was 22-23^{0}C. On Days 7, 14, 21 and 28, a sample of five of the 20 packs of each product was removed for analysis and the procedure above was repeated for the remaining packs.

Test for microbial contamination

The samples were analysed for microbial contamination on Days 7, 14, 21 and 28 in the Microbiology Laboratory, Victorian College of Pharmacy. A sterile 5mL or 2.5mL plastic syringe was used to remove 1mL of hydrogel from the opening of each pack sampled. The hydrogel was placed into 100mL flasks each containing 49mL of previously prepared and steam sterilised fluid casein digest-soy lecithin-polysorbate 20 (FCDSLP-20) growth medium. This, a 1 in 50 fold dilution, would eliminate the antimicrobial property of propylene glycol in particular.

A negative control flask was inoculated with 1mL of sterile Intrasite™ Gel (20% w/w propylene glycol) in 49mL FCDSLP-20 medium. Each positive control flask containing 1mL of sterile Solugel™ (25% w/w propylene glycol) was separately inoculated with a colony of either *Staphylococcus aureus* ATCC 9144, *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853 or *Candida albicans* ATCC 90028. An inoculating needle was used for this purpose. All flasks were mixed well to disperse and dissolve the hydrogel then incubated at 37^{0}C for 24 hours.

Flasks were observed for 'growth' and 'no growth'. Four loopsful of 'test' species in control flasks were subcultured onto designated selective media: Eosine Methyline Blue agar for *E. coli*, Mannitol Salt Agar for *S. aureus*, Pseudomonas-CFC Agar for *P. aeruginosa* and Sabauraud Agar for *C. albicans*. Where 'growth' was observed in sample flasks, four loopsful were inoculated onto each of the selective media for preliminary identification. Where sample flasks displayed 'no growth', one of the flasks of each product sample was selected and four loopsful inoculated onto nutrient agar. Flasks containing some undissolved sediment were chosen in preference to flasks containing clear broth. Inoculation of 'no growth' flasks onto nutrient agar was intended to confirm the absence of growth. All plates were incubated at 37^{0}C for 24 hours.

Results

Controls

Each 'test' organism was successfully cultured in broths containing 1mL Solugel™. Results of subcultures observed on selective agars were as follows:

- Pseudomonas-CFC Agar (pale yellow colour): *Pseudomonas aeruginosa* appeared as opaque cream coloured, flat, smooth, shiny, entire edged spherical colonies on an olive green agar.
- Mannitol Salt Agar (pale red colour): *Staphylococcus aureus* appeared as tiny, pale yellow, low convex, shiny, sperical colonies on a yellow agar.
- Eosine Methyline Blue Agar (blood red colour): *Escherichia*

coli appeared as spherical, flat, metallic green colonies on a purple agar.

- Subauraud Agar (pale yellow): *Candida albicans* appeared as cream or off white coloured, convex, circular colonies on a pale yellow agar.

Tables 1-5 detail the product used, the number of samples removed every 7 days, the number of samples displaying 'growth' in flasks of FCDSLP-20 medium (broth) for each product and positive and negative control results.

Table 2 shows one Intrasite™ flask displayed moderate turbidity and was subcultured onto selective agars. Small, shiny, pale yellow, slightly raised circular colonies on a pale yellow coloured Mannitol Salt Agar were identified as *S. aureus* with reference to the control *S. aureus* colonies. *S. epidermidis*, suggested as a possible alternative skin derived contaminant, was considered unlikely to grow on MSA. Identical growth was also seen on Sabauraud Agar. The contamination was an isolated incident, and most probably occurred inadvertently in the laboratory, however, clinical contamination is also a possibility.

Discussion

The results of this series show no contamination in all but one sample pack. A possible explanation is that microorganisms (if any) that had contaminated the hydrogels during their use and/or re-use could not survive or proliferate in the three products and were therefore not viable at the time of re-use. This is most probably due to the high content of propylene glycol in the hydrogels which ranges from 20% w/w in Intrasite™ Gel to 25% w/w in Solugel™ which is inhospitable to bacteria and fungi. The propylene glycol provides a moist environment at the wound site and evidently preserves the gels on storage as well.

It has been found that effectiveness of proylene glycol falls off below concentrations of 20% w/w in amorphous hydrogels whereas it inhibits re-epithelialisation above 30% w/w, the optimal concentration being 25% w/w [5]. Whilst the storage temperature of 22-23^{0}C in the wound clinic cupboard would seem favourable to growth, freedom of contamination may also be due to the absence of nutrients required for microbial proliferation in the hydrogels. Furthermore, handwashing, the use of clean disposable gloves and product exposure to the environment for a very short time when used, perhaps no longer than fifteen seconds, limited the chance of contamination.

Also, the hydrogels were applied to non-sterile but clean tongue depressors in an aseptic manner, rather than to the wound site directly as suggested in product directions of use. The hydrogels were exposed away from the patient in the first 3 weeks of product use. In the fourth week, products were deliberately re-used in front of an actual patient and nurse whilst the patient's wound was redressed. The patient was free to talk during the hydrogel squeezing and application procedure. Despite this added risk of contamination, no growth was observed in the products 7 days later.

Table 1. Product packs used on Day 1, then tested for microbial contamination on Day 7.

Product name	Number sampled	No. flasks showing growth	Nutrient agar
SOLUGEL™	5	0	No growth
INTRASITE™	5	0	No growth
DUODERM™	5	0	No growth

Controls	FCDSLP-20 Broth	Selective agar
E. coli ATCC25922	Growth	Growth (EMB)
S. aureus ATCC9144	Growth	Growth (MSA)
P. aeruginosa ATCC27853	Growth	Growth (P-CFC)
C. albicans ATCC90028	Growth	Growth (Subauraud)
Negative (with Intrasite)	Growth	

Table 2. Product packs used on Days 1 & 7, then tested for microbial contamination on Day 14.

Product name	Number sampled	No. flasks showing growth	Nutrient agar
SOLUGEL™	5	0	No growth
INTRASITE™	5	1	No growth
DUODERM™	5	0	No growth

Controls	FCDSLP-20 Broth	Selective agar
E. coli ATCC25922	Growth	Growth (EMB)
S. aureus ATCC9144	Growth	Growth (MSA)
P. aeruginosa ATCC27853	Growth	Growth (P-CFC)
C. albicans ATCC90028	Growth	Growth (Subauraud)
Negative (with Intrasite)	Growth	

Table 3. Product packs used on Days 1, 7 & 14, then tested for microbial contamination on Day 21.

Product name	Number sampled	No. flasks showing growth	Nutrient agar
SOLUGEL™	5	0	No growth
INTRASITE™	5	0	No growth
DUODERM™	5	0	No growth
Controls		**FCDSLP-20 Broth**	**Selective agar**
E. coli ATCC25922		Growth	Growth (EMB)
S. aureus ATCC9144		Growth	Growth (MSA)
P. aeruginosa ATCC27853		Growth	Growth (P-CFC)
C. albicans ATCC90028		Growth	Growth (Subauraud)
Negative (with Intrasite)		Growth	

Table 4. Product packs used on Days 1, 7, 14 & 21, then tested for microbial contamination on Day 28.

Product name	Number sampled	No. flasks showing growth	Nutrient agar
SOLUGEL™	5	0	No growth
INTRASITE™	5	0	No growth
DUODERM™	5	0	No growth
Controls		**FCDSLP-20 Broth**	**Selective agar**
E. coli ATCC25922		Growth	Growth (EMB)
S. aureus ATCC9144		Growth	Growth (MSA)
P. aeruginosa ATCC27853		Growth	Growth (P-CFC)
C. albicans ATCC90028		Growth	Growth (Subauraud)
Negative (with Intrasite)		Growth	

Table 5. A summary of the number of samples showing growth for each product over the 4 week period.

Product	Week 1	Week 2	Week 3	Week 4	Total
Solugel	0	0	0	0	0
Intrasite	0	1	0	0	1
Duoderm	0	0	0	0	0

Although no contamination or presence of viable microorganisms was detected in this study, for practical reasons shorter periods of storage were not considered. Thus, it is not known if microbial contaminants were viable in the products one, two or three days following product use. Challenging the hydrogels with common skin and wound contaminants and quantitatively measuring the level of contamination in hydrogel packs over time could be considered as a useful future investigation. A quantitative approach would provide useful information on the level of viable cells remaining in the products after time. It would indicate whether growth is supported, simply inhibited or whether there is a reduction in the number of viable cells.

Conclusion

The results in this study show no evidence of microbial contamination in the hydrogels after storage of 7 days following initial use. Consequent re-use of packs over a 1 month period also showed no evidence, with the exception of one sample out of the 60 tested.

No growth was observed in samples applied to tongue depressors away from the patient during the first 3 weeks, nor was there growth where the products were used directly in front of a patient in Week 4. Follow up quantitative studies would help to clarify the situation, however, these results indicate a need to review the current recommendation on non re-use of these hydrogels.

Acknowledgments

I wish to thank Dr. Khairy Majeed for his assistance in the planning of the methodology and Helen Lycette and Peter Krotsis for their advice and practical assistance in the laboratory.

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