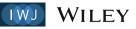
#### ORIGINAL ARTICLE



# Expanding access to maggot containment dressings through redesign and innovation

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#### Abstract

There are two major styles of maggot debridement dressings: (1) confinement dressings that form a cage around the wound, and (2) containment dressings that completely surround the maggots within a sealed porous bag. For producers and clinicians wanting to prepare containment dressings using readily available polyester bags, it is currently difficult to seal these bags without expensive high-temperature plastic welders. This study aimed to identify simple and affordable methods for sealing maggots within polyester net bags. Heat sealing was the most effective and simplest method to seal the polyester net bags, but the high melting point of polyester required industrial grade heat sealers. An inner lining of polyethylene or polypropylene film at the open side of the bag allowed for complete sealing using low-cost hand-actuated impulse heat sealers. This design even facilitated the addition of plastic zipper-locks, allowing secure closure of the bag without electricity or special equipment. Other sealing methods were identified, but most were time-consuming, required practice or not consistently successful. The maggot containment bag designs and closure methods described herein should prove useful to clinicians without access to contained maggots and to maggot producers without the resources to seal polyester containment bags. Clinical trials are expected to follow.

#### KEYWORDS

debridement, dressing, larva, maggot, wound

#### **Key Messages**

- In many parts of the world, maggot containment dressings (bagged maggots) are not available for wound debridement because they are more difficult and more costly to produce than confinement ('free-range') maggot dressings.
- This study evaluated a variety of methods for sealing medicinal maggots into readily available polyester net bags, and qualitatively assessed the simplicity, cost and structural integrity of those methods.

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- Heat sealing was the simplest and most effective method for sealing polyester net bags, but it required industrial equipment. Adding a layer or extension of polymers with lower melting points, such as polypropylene and polyethylene, allowed the bags to be sealed (welded) easily, using more affordable hand-actuated impulse heat sealers.
- Certain tapes, adhesives and surgical ties also sealed the netted maggot containment bags successfully, although these methods were a bit cumbersome, required practice and produced inconsistent results.
- Bag clips and hot glue guns were simple, effective and inexpensive methods for sealing the maggot containment bags, but their thickness and stiffness pose a risk of pressure injuries.

#### **1** | INTRODUCTION

The efficacy and safety of maggot debridement therapy (MDT) have been documented repeatedly in controlled clinical studies,<sup>1–16</sup> comprehensive reviews<sup>17–25</sup> and scores of case reports.<sup>26–112</sup> The benefits of maggot therapy include not only rapid debridement and relative safety, but also its low cost, and the fact that the application of maggot dressings does not require advanced resources such as electricity or highly skilled personnel. Thus, MDT can be performed even in the most austere settings.<sup>113,114</sup> There are very few drawbacks other than the fact that medicinal maggots, being living airbreathing fly larvae, are highly perishable and very active during this life stage. The short shelf-life of between 24 and 72 h (depending on storage and transport conditions) makes it necessary that medicinal maggot production is located close to the point-of-care or else linked through a transportation network that can deliver them promptly to the end-user.<sup>115</sup> While feeding, the maggots remain within the wound, but it is their natural instinct to leave the host as soon as they are satiated or there is no more necrotic tissue to dissolve and consume.<sup>116</sup> This necessitates special dressings that prevent maggots from escaping the wound into the hospital or the patients' home environment before the clinician is ready to remove them.

For decades, medicinal maggots were placed directly on the wound bed and then covered with a cage-like net dressing.<sup>29,116–118</sup> These types of maggot dressings are now called 'confinement' or 'free-range' maggot dressings because they confine the maggots to the wound, while still allowing the maggots to wander freely about the wound bed, dissolving the infected necrotic tissue, wherever it may be. Twenty years ago, that concept of a maggot dressing was reversed: instead of placing a net over the maggot-laden wound, the maggots themselves were placed within a sealed net bag, and that bag was placed on top of the wound bed.<sup>119</sup> Studies showed that applying 'contained maggots' (also called 'bagged maggots') still resulted in effective wound debridement, although slower than that observed with confined maggots.<sup>6,8,13,48,120</sup> Containment dressings need to be porous enough to allow oxygen to reach the air-breathing maggots within, allow the egress of the maggots' digestive enzymes into the wound bed, and permit the flow of liquefied necrotic tissue and wound secretions into the bag to feed and hydrate the maggots. If the pores are too large and larvae escape, or if the seals break, then the product fails to 'contain' the maggots.

One of the major advantages of contained maggots is that they are much simpler to handle than free-range maggot dressings. Application is easier and faster because bagged maggots do not require constructing or placing a cage dressing to confine the maggots to the wound, and bagged maggots are not as likely to escape as 'free-range' maggots are, if the dressings break loose, or when they are removed.<sup>121</sup> Another advantage of maggot containment dressings is that there is no need for a wide margin of intact skin upon which to mount a cage dressing. Bagged maggots can be placed on wounds abutting eyes, fistulae, tracheotomies or other sensitive anatomy for which the risks of escaping maggots crawling into these neighbouring areas would be unacceptable.<sup>40,121</sup>

Containment dressings also help to overcome some of the psychological drawbacks of maggot therapy. Some therapists<sup>17,122-127</sup> and patients<sup>17,128-130</sup> are repulsed by the thought of maggots in a wound; others fear that the maggots will escape from the wound. Among health care providers, the discovery of uninvited maggots in patients' wounds or body cavities can have reputational and even legal repercussions, whether justified or not, because the presence of maggots in the health care environment is often interpreted as neglect.<sup>131</sup> While such fears are usually unfounded in the context of maggot therapy, they are a reality that makes free-range maggot therapy unacceptable to many. Maggots contained and concealed in net bags help substantially with this problem, as the larvae are not easily seen and they cannot easily escape.<sup>17,128–131,132</sup> Indeed, for some therapists, the idea of free-range maggots is so abhorrent that they will only use maggots when they are contained in bags (personal communications).

There are, of course, some disadvantages associated with bagging maggots for treatment. First and foremost, net bags prevent maggots from accessing the crevices and sinuses of the wound. As a result, debridement with bagged maggots takes about twice as long to achieve.<sup>6,13,48</sup> Another disadvantage of bagged maggots is that they are more expensive to produce,<sup>120</sup> in part because their production requires additional handling (labour), and in part because the sealing of the polyester net bags requires special expensive equipment to reliably achieve the very high sealing temperatures needed to weld the polyester net fabric.<sup>133</sup> Such heat sealers typically cost over US \$10 000, and ultrasonic welders can be even more expensive.

Bagged maggots are the preferred maggot therapy dressing in most hospitals and clinics of the United Kingdom and Europe, with leading manufacturers now selling only bagged maggots.<sup>134</sup> Our personal communication with leading producers and clinicians, as well as our review of producer websites, suggests that bagged maggots are not even available in the United States or Canada, nor in most other countries across Central and South America, Africa, the Middle East, Asia and the South Pacific.

Consequently, the goal of this research was to design a maggot containment bag that can be sealed with less effort and less expense, making the technology more widely available.

A wide variety of sealing methods were tested. Most methods resulted in either incomplete closure of the bag, allowing maggots to escape, or in seals that did not withstand autoclaving (steam sterilization). Eventually, a few simple, low-cost alternatives for creating maggot-filled polyester net bags were identified. Herein we describe our simple assays for testing maggot bag sealing techniques, and those sealing methods that were found to be most useful for therapists, pharmacists or technicians to seal maggots in bags at the clinic, the hospital pharmacy or even at the bedside.

#### 2 | METHODS

#### 2.1 | Medicinal maggots

Medical-grade (disinfected) *Lucilia sericata* eggs (known by the brand name Medical Maggots<sup>TM</sup>) were obtained from Monarch Labs (Irvine, CA). Hatch rates were assessed independently (Monarch Labs) to be between 60% and 85%.

# 2.2 | Net bag materials and sealing methods

#### 2.2.1 | Net fabric

Unless otherwise noted, the net fabric used in these experiments was a polyester monofilament fixed weave fabric with a pore size of  $105 \ u$  (PES 105/33 by SaatiTech, Fountain Inn, SC), pre-cut and sealed on three sides to create a 4.45 cm  $\times$  6.35 cm pouch ('Histology Bag'; SaatiTech; Figure 1A). To prevent even the youngest 'hatchling' maggots from escaping through the mesh pores themselves, a mesh with a pore size smaller than 110 u was used. This is important to maximize the utility of the bags by allowing both older and therefore larger maggots or eggs to be loaded. Using polyester net with a fixed-weave pore size of 105 u, the maggots were only able to escape from the containment bags as a result of imperfections or breakage of the pouch seals.

#### 2.2.2 | Bag design

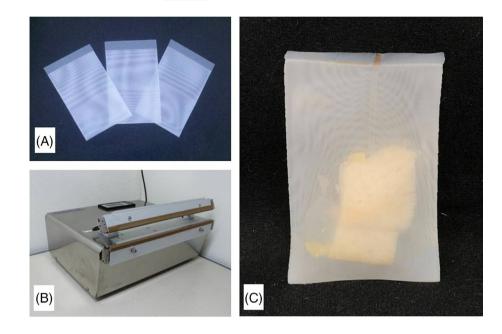
Variations of two basic designs for maggot bags were developed and tested: (A) unmodified polyester bags were sealed either with heat or other materials and techniques, or (B) polyester bags were fabricated in such a way as to permit low-temperature heat welding.

#### Design A

Commercial polyester bags (above) sealed on three sides were loaded with medicinal maggots and subsequently cold-sealed by employing a variety of adhesives and other sealing materials, listed in Table 1. The control method against which the new sealing methods were evaluated involved the same commercial polyester bags sealed with an industrial heat sealer (Model PW7016; Packworld USA, Nazareth, PA). This is the method commonly used to seal commercially marketed bagged maggot products. A secure seal was achieved with a welding temperature of 190°C applied for 1.5 s, with a release temperature of 50°C. Unlike most other industrial sealers fit for cleanroom application, this model requires only electricity (110–120 V) but not compressed air.

#### Design B

Given that high-temperature instruments for the sealing of polyester bags are prohibitively expensive for smallscale and low-and middle-income country producers,



**FIGURE 1** Medicinal maggots sealed in a polyester net bag, using an industrial-grade, variable-temperature heat sealer. "Histology Bags" (A) with extended edge for easy filling (SaatiTech, Fountain Inn, SC), manufactured from SaatiTech PES 105/33 polyester net, were sealed with a Packworld USA (Nazareth, PA) PW7016 electrical heat sealer (B) after filling the bags with maggot-impregnated gauze (C).

modifications to the polyester bags were explored that would allow them to be sealed with inexpensive lowtemperature impulse heat sealers. To that end, polyester bags were fitted with polyethylene or polypropylene 'collars', with and without a zipper closure system. The most successful modifications were created by extending the unsealed side of the polyester bag with a collar of 6 mil (0.1524 mm) polyethylene or 4 mil (0.1016 mm) polypropylene, cut from standard plastic bags (U-Line; Pleasant Prairie, WI), with or without a zipper-like snap closure (Figure 2). These plastic collars were created by heatsealing (185°C for 1.5 s) a 1-cm-wide strip of the polyethylene or polypropylene film to two opposing ends of the polyester net fabric before folding the fabric in half and heat welding it into the shape of a bag (Figure 3). The collared bags with a plastic zipper were able to be locked simply by pressing the male and female sides of the plastic zipper against each other until they engaged to form a tight seal. Collared bags without a zipper were easily heat sealed with low-temperature impulse heat sealers.

#### 2.3 | Assays

Two assays were created to test these seal characteristics: (1) a sealing integrity assay, and (2) a bond strength and durability assay. The sealing integrity assay tested whether there were gaps in the seal through which the tiny first instars (hatchlings) could escape. The bond strength and durability assay tested whether mature larvae were able to force their way out of the bag by tearing open the seal. In this set of experiments, sealing methods were considered effective only if they passed both assays

without allowing a single maggot to escape. A third assay tested the integrity of the bags and their modifications during steam and chemical sterilization.

#### 2.3.1 | Sealing integrity assay

Approximately 250 eggs were placed on a folded  $2'' \times 2''$  $(5 \text{ cm} \times 5 \text{ cm})$  8-ply woven gauze pad (McKesson; Irving, TX) and inserted into the net pouch. The open end of the net pouch was sealed by any of the various tapes, adhesives or devices being tested (Table 1). Once sealed, the bag was placed into a 120-mL specimen vial containing 10 g of beef liver, ensuring that the bag did not touch the liver, thus denying the young maggots the opportunity to feed from within the bag. Denied nutrition, the larvae were thus forced to crawl about in search for food. If there were any gaps in the bag seals large enough for the young larvae to escape, they could reach the meat in the container, feed outside the bag and grow large enough to be seen easily and counted. Larvae in this assay were monitored for at least 3 days. Only those sealing strategies that passed this seal integrity assay continued their evaluation by advancing to the bond strength and durability assay.

#### 2.3.2 | Bond strength and durability assay

To test the bond strength and durability of the various sealing methods, eggs and gauze were also loaded into the polyester bags, but this time 10 g of beef liver was added to the bags prior to sealing. In this way, larvae

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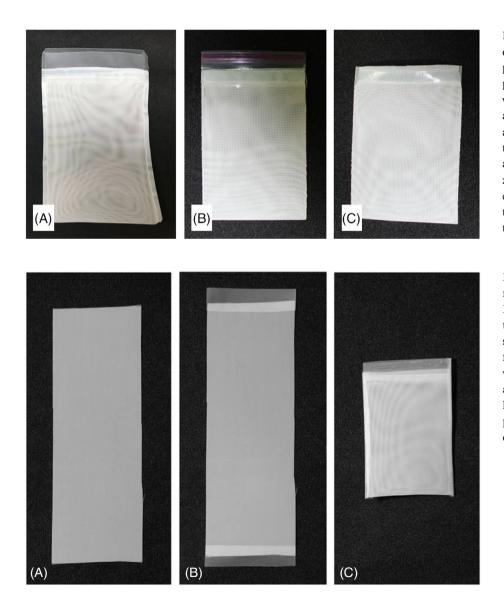
#### TABLE 1 Materials and methods tested as potential bag-sealing solutions.

Products	Manufacturer and model	Comments					
Fabrics, polymers							
Polyester net, a pore size of 105 <i>u</i>	PES 105/33; SaatiTech; Fountain Inn, SC	Hatchlings escaped through fabric pores $>110 u$ , but second instars (the smallest maggots that arrive to the end user) did not escape through pores as large as 160 $u$ .					
Polyester net, a pore size of 160 <i>u</i>	PES 160/40; SaatiTech	The polyester fabrics (including nylon stockings) required high temperatures to weld them, but welding of polyethylene and polypropylene could be achieved with					
Nylon stockings	Triumph Hosiery; Hollywood, FL	low-cost hand-actuated impulse heat sealers. The nylon stockings could be sealed securely by tying the suture around the open end.					
6 mil (0.1524 mm) polyethylene	Polybags; U-Line, Pleasant Prairie, WI						
4 mil (0.1016 mm) polypropylene	Polypropylene bags; U-Line						
Tapes							
Fabric medical tape	Duopore; 3M; Minneapolis, MN	Tapes must extend beyond, or securely fold over, the edges of the net bags (Figure 4). An effective bond formed only					
Zinc oxide tape	Hy-Tape International; Patterson, NY	where the two adhesive layers touched each other, adhesive side to adhesive side.					
Transparent membrane dressing	Tegaderm; 3M; Minneapolis, MN						
Adhesive films							
Medical-grade adhesive film	3M 1577; 3M; Minnesota, MN	This product melted in the autoclave. It was more expensive, and more difficult to acquire, than medical tapes.					
Adhesive liquids and sprays, gels							
Silicone gel	Perfecto Manufacturing; Noblesville, IN	Most liquid adhesives were too slow to dry and produced					
Contact cement	DAP; Baltimore, MD	inconsistent seals. Gem-Tac fabric glue worked best (although drying took 3 hours) because the cured bond was soft and flexible. Medical and non-medical cyanoacrylates					
Gem-Tac	Beacon Adhesives; Mount Vernon, NY	dried more quickly, but their seal was stiff, brittle, and					
Ostomy adhesive	NuHope; NuHope Industries; Mission Hills, CA	inconsistent. Contact adhesives appeared to work reasonably well, and					
Medical spray adhesive	Hollister Incorporated; Libertyville, IL	they tolerated autoclaving, but they were not readily available to the retail market except in inconvenient shapes					
Cyanoacrylate	Locktite Super Glue; Henkel Corporation; Westlake Ohio	and sizes, such as "Glue Dots." Hot melt glues and clips sealed very well, but the resulting seals were stiff and hard, making them a risk for pressure injury.					
Surgical cyanoacrylate	Dermabond by Ethicon, Bridgewater, NJ; Swiftset by Medtronic, Minneapolis, MN; SkinStitch Medical Products, Massena, NY	making them a risk for pressure injury.					
Contact adhesive	Glue Dots; Germantown, WI						
Glue gun	Model GR-50; Parker Manufacturing; Worcester, MA						
Heat sealers/welders							
Industrial calibratable heat sealer	PW7016 by Packworld; Nazareth, PA	Industrial heat sealers produced the high temperatures necessary to weld all tested polyester fabrics. Hand-held impulse heat sealers were capable of welding polypropylene					
Impulse heat sealers	8" Heat Sealer by Metronics, Los Angeles, CA; KF- 150CST by Fairly Odd Treasures, Harrisburg, NC	and polyethylene, but not polyester. Household irons, like the open flame, could not achieve the controllable and					

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#### TABLE 1 (Continued)

Products	Manufacturer and model	Comments		
Electric Irons	Assortment of curling irons, soldiering irons, wood burning irons, clothing irons	reproducible heat necessary to produce a good, consistent weld.		
Open flame				
Closure devices				
Dialysis membrane clips	Thermo Fisher Scientific; Waltham, MA	Clips were simple and inexpensive, but their hard, bulky structure posed a significant risk of pressure injury. Tying the bags with suture was successful when the tie was		
Ostomy bag clips	Hollister Incorporated; Libertyville, IL	woven into the collar to prevent it from slipping off.		
Nylon suture, size 0	Ethicon; Bridgewater, NJ			



**FIGURE 2** Adding a polyethylene or polypropylene collar onto the polyester net bag. The polyethylene or polypropylene collar must first be welded onto the net fabric before folding and welding the fabric into its final form as a bag. The plastic film can be allowed to extend beyond the polyester net fabric as a "collar" (A), without or with a zipper lock (B), or the plastic film can be cut to size so that it is nothing more than an inner lining within the neck of the net bag (C).

**FIGURE 3** Method for constructing net bags with two different plastics. Polyester net was cut twice as long as the finished bag (A) before adding the strip of polyethylene or polypropylene film (B) with a heat-sealer. The material was folded in half to align the top edges, and the sides of the materials were then heat-sealed (C), creating a net bag with a plastic collar, liner or zipper-lock, as described in the text.

within the bag could feed and mature to their maximum size and strength within the bag. Once satiated, larvae instinctively and with powerful urgency seek to pupariate away from the food source. Post-feeding larvae would exploit any weakness of the seal and pry it open to permit escape. Each net bag was incubated within a 120-mL specimen vial. Larvae that successfully pried open the sealed net bags were found crawling within the vial, outside the bag. This assay was monitored for at least 5 days or until the first larva was seen crawling freely within the vial, as the purpose of this assay was to identify failurefree seal integrity.

#### 2.3.3 | Sterilization durability assay

As the goal was to identify simple and inexpensive manufacturing methods, the only methods of sterilization tested in this investigation were steam sterilization (30 min at 124°C in a Tuttnauer EZ 10; Hauppauge, New York) and chemical sterilization by immersion in 0.525% sodium hypochlorite for 30 min. For the containment bags to successfully pass the sterilization assay, neither their form, fit, function nor appearance could be altered by the sterilization process. These samples themselves were not tested for microbiological sterility, but both sterilization methods were validated with 14-day aerobic and anaerobic cultures as being effective at killing  $\geq 10^6$  organisms.

#### 2.3.4 | Analysis of assay results

Each sealing method was tested in triplicate, checked once or twice daily, and the number of escapees was recorded. Seal integrity and durability were assessed qualitatively by observing the extent of maggot escapes. If maggots escaped from two or more of the three bags, then the performance of that sealing method was considered to be very poor (1+/4+). If maggots escaped from only one or none of the triplicate bags, then the seal was considered to be acceptable, and the method would be retested in another round of triplicate samples, up to a total of three sets of triplicate samples. If there were no escapes from any of the three sets of triplicate samples, then the seal performance was deemed to be very good (4+/4+). Bonds that were inconsistently welded or not durable were rated 2+/4+. Seals that were nearly always complete and durable were rated 3+/4+. In addition, qualitative assessments were made concerning the relative ease of use and cost of each sealing method, relative to the other methods tested.

#### 3 | RESULTS

The standard method for sealing polyester net maggot dressings is to use an ultrasonic welder or an industrial heat sealer with controllable temperature, pressure and/or welding time. The polyester net maggot containment bags constructed in this fashion were simple to produce, worked well and passed all performance assays (Figure 1). The polyester net fabrics could not be sealed at all with the inexpensive hand-actuated impulse heat sealers.

The less expensive hand-actuated impulse heat sealers were able to weld polyethylene (2–6 mil or 0.0508–0.1524 mm) and polypropylene (2–4 mil or 0.0508–0.1016 mm) plastic films very easily and effectively.

When polyethylene or polypropylene was welded as a collar to the polyester net bags (requiring the industrial heat sealer to make that weld), the low-heat hand-actuated impulse sealers easily and reliably welded the maggot containment bags at the level of the plastic collar (Figure 2A).

Polypropylene-collared bags withstood low-temperature steam sterilization, but the polyethylene-collared bags did not. Bags with polyethylene-collars (or polyethylene lining) only withstood the sodium hypochlorite method of sterilization. Creating a polypropylene collar with a zipper lock yielded a net containment bag that could be steam-sterilized, filled with medicinal larvae, and easily sealed by pressing the male and female sides of the zipper shut, thereby locking them without the need for any special equipment at all (Figure 2B).

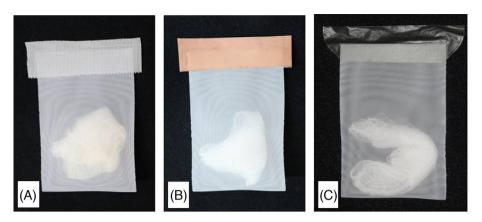
In subsequent iterations of the poly-collared net bags, the collars were trimmed such that only the portion of polyethylene or polypropylene bonded to the inside of the polyester net remained, thereby effectively creating an inner lining of the plastic film at the neck of the polyester net containment bag. The low-heat impulse heat sealers successfully welded these containment bags, too, at the level of the polypropylene or polyester inner lining (Figure 2C).

Welding nylon stockings into bags required very high temperatures, so hand-actuated impulse heat sealers were ineffective. It was possible to secure them by tying them closed with surgical sutures.

Sealing the net bags with fabric or zinc oxide medical tapes, or with transparent membrane dressings (polyurethane membranes coated with acrylic adhesive), worked reasonably well as long as those tapes were extended beyond, or securely folded over, the edges of the net bag (Figure 4). Liquid adhesive between the two layers of taped fabric did not appreciably improve the bond. An effective bond formed only where the two layers of tape or transparent membrane dressing from the opposing sides of the net bag extended beyond the edges of the bag and touched each other, adhesive to adhesive.

Pressure sensitive glue (Glue Dots, Germantown, WI) bonded to the polyester net fabric well enough to create secure seals for the bags, but within the retail market, this adhesive could not be sourced in shapes or sizes that would be practical to apply as a bag sealant.





**FIGURE 4** Strong adhesive tape provided an adequate seal as long as the tape extended beyond the edges of the bag and was applied firmly to itself, adhesive side to adhesive side. Fabric tape was folded over the net bag, extending beyond the edges, and pressed firmly together to seal the bag, before trimming the excess border (A). Zinc oxide tape (B) and transparent membrane dressings (C) worked equally well to seal the polyester net bags.

Most other methods of sealing the net bags were less effective in containing maggots, time-consuming to construct or had other drawbacks, as described in Table 1.

#### 4 | DISCUSSION

With the increasing prevalence of non-healing wounds and the increasing popularity of maggot therapy worldwide, more and more clinicians are discovering the utility of maggot therapy.<sup>19</sup> Dressings that confine the medicinal maggots to the wound bed are generally quite affordable, and this type of maggot therapy is now readily available in dozens of countries. Dressings that completely contain the maggots so that the maggots do not need to be handled directly are more labour-intensive and more costly to produce,<sup>120</sup> thereby hindering their availability around the world. Arguably, free-range maggots debride wounds more efficiently than contained maggots.<sup>6,13,48</sup> But there are some clinical situations that are better treated with contained maggots than free-range maggots, such as when the wound in need of debridement is near a sensitive piece of anatomy (i.e., eye, rectum, ostomy) or has insufficient bordering tissue upon which to build and secure cage-like confinement dressing.<sup>17</sup> Containment dressings may also help to overcome some of the psychological drawbacks of maggot therapy (personal correspondence), if these dressings can minimize the fears and disgust that prevent some therapists and patients from accepting maggot therapy.<sup>17,122–130</sup>

This study was undertaken to identify methods that would simplify the production and reduce the costs of netted maggot containment bags, thereby making bagged maggots more affordable and available, especially in resource-strapped regions. To that end, this research succeeded. In fact, not only are some of the simple maggot containment bags suitable for manufacturers, but they could even be used by local pharmacists or end-users (wound care clinicians) in situations where only free-range maggots, not bagged maggots, are available.

Heat sealing proved to be the simplest and most reliable method for sealing the polyester net fabric that commonly comprises maggot containment bags. However, the high melting point of that fabric requires industrial heat sealers to weld the two opposing mesh fabric sides shut. Expensive industrial heat sealers are the most common method used by maggot producers to seal maggots into net bags. Lower cost hand-actuated impulse heat sealers did not produce sufficiently high temperatures to weld the polyester or nylon materials tested, but low-cost alternative methods were identified that could substitute for the expensive industrial heat sealers.

A consistently secure seal was possible by adding a polypropylene or polyethylene collar to the unsealed fourth side of the bag, either extending beyond the polyester margins of the bag or only lining a strip on the inside of the bag around its opening. Fabrication of these modified polyester bags still required the use of an industrial heat sealer to achieve the high temperatures required for fusing polyester with polyethylene or polypropylene.

Both collar plastics have melting points lower than that of polyester, and lower than that attained by handactuated impulse heat sealers. Thus, the producer of medicinal maggots or the pharmacist and clinician at the point of care could fill these net bags with maggots and easily seal the containment bags with a low-cost, lowtemperature hand-actuated impulse heat sealer. Polypropylene has the advantage over polyethylene in that its melting point is higher than that required for steam sterilization (124°C). This allows bags fitted with a polypropylene collar to be autoclaved to use. For care settings where electricity is not easily available or where convenience and speed are of the essence, this design can be further refined by pre-manufacturing bags fitted with a polypropylene zipper lock collar that can be sealed by hand, without any additional equipment at all.

#### TABLE 2 Comparison of most successful sealing methods and materials tested.

Sealing method tested	Ease <sup>a</sup>	Efficacy <sup>b</sup>	Cost <sup>c</sup>	Availability <sup>d</sup>
Heat sealing equipment				
Industrial (controllable high-heat) sealer/PES	++++	++++	\$\$\$\$	++
Table-top pulse sealer/PES	+	0	\$	++++
Table-top pulse sealer/PET	++++	++++	\$	++++
Hand-held sealers/PET	+++	++++	\$	++++
Table-top pulse sealer/PP	++++	++++	\$	++++
Hand-held sealers/PP	+++	++++	\$	++++
Tapes				
Tape (fabric)	++++	++++	\$	++++
Tape (zinc oxide)	++++	+++	\$	++++
Transparent membrane dressing	++++	++++	\$	++++
Other				
Zipperlock snap	++++	+++	\$\$	++
Suture tie on nylon stocking	++++	+++	\$	++++

*Note:* Comparisons are qualitatively indicated with "+" except for cost, which is qualitatively compared with the symbol "\$." The material sealed was a polyester (PES) net, unless otherwise noted as 6 mil (0.1524 mm) polyethylene (PET), or 4 mil (0.1016 mm) polypropylene (PP).

<sup>a</sup>+ requires much experience, patience and/or time; ++ Requires moderate amount of training or experience; +++ requires minimal training or practice; ++ ++ No special training or skill required.

 $^{b}$ + incomplete bond; ++ inconsistent bond or non-durable bond; +++ usually a good strong bond, but not always; ++++ consistently solid and durable bond.

<sup>c</sup>\$ less than USD 30; \$\$ USD 30–100; \$\$\$ USD 100–1000; \$\$\$\$ USD 1000–10 000.

 $^{d}$ + available only from specialty <u>sources</u> or suppliers; ++ available in some medical facilities or could be ordered; +++ available in any medical facility, easily ordered online; ++++ usually available in home or neighbourhood store.

A few other bag sealing methods were found to be effective (Table 2), but for reasons of relative ease, cost, availability or reproducibility, they were not preferred methods. All of the sealing methods were tested on polyester net bags because this is the most readily available fabric mesh with the pore sizes and pore densities necessary to create effective maggot containment bags. Other woven fabrics or a polypropylene net film might seal quite easily, but they were not as readily available on a retail market, and would have had to be custom ordered or converted.

The major shortcoming of this work is its lack of clinical data. We have used laboratory models of debridement efficacy—namely, digestion of beef liver—instead of placing these bags on actual patients. A few patients with life- or limb-threatening wounds have been treated with these containment bags, but no controlled clinical studies have yet been conducted. Therefore, we can make no claims about the effects of these specific bag sealing methods on the debridement efficacy or safety of these maggot containment dressings. The most successful containment bag designs (Table 2) used materials with demonstrated biocompatibility. Of course, these are issues that would need to be demonstrated during or before clinical trials of these maggot containment bags. Still, for the individual clinician trying to save a life or limb without the advantage of clinical trials or commercially available maggot containment bags, it is hoped that the methods of sealing and testing improvised bags, as described in this study, will be of some assistance.

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The other shortcoming with this study is that it did not include evaluations of gas or gamma-irradiation methods for sterilization. This was intentional, because these two sterilization methods are generally more expensive than steam or liquid chemical sterilization and require specialized equipment or facilities. Because we were searching for the least expensive methods for creating containment dressings, we did not evaluate the impact of these relatively expensive sterilization procedures. That said, based on our prior experience with gas and gamma sterilization of maggot confinement dressings, we do not expect that these sterilization methods would alter the fit, form or function of the containment dressings and sealing methods described in this study.

To summarize, in an ideal world, the process of sealing the maggots within the containment bag would be done at the site of maggot production, where good manufacturing practices (GMP) and validation of terminal sterilization could be assured.<sup>135</sup> If the manufacturer cannot afford an industrial heat sealer, some of the

successful methods identified in this study may provide lower-cost alternatives to produce bagged maggots within the maggot production laboratory. If the maggot production laboratory cannot provide bagged maggots under any circumstances, and if the end-user requires that the maggots be sealed within pouches, then some of the alternatives described in this study may be used by the therapist to transfer the medicinal maggots into a netted pouch and then seal that pouch either in the pharmacy, the clinic, or at the bedside. Finally, it is hoped that this series of experiments will help investigators evaluate other bag construction and sealing methods of their own using the seal integrity assay and bond strength and durability assay described in detail.

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#### **CONFLICT OF INTEREST STATEMENT**

Dr. Sherman discloses that, when this research was initiated, he was co-founder and Laboratory Director of Monarch Labs, a company that produced and distributed medicinal maggots in the United States. Dr. Sherman subsequently retired from, and divested from, Monarch Labs; he is no longer the owner, shareholder or employee of any wound care company. Dr. Sherman is the Director of the not-for-profit BioTherapeutics, Education and Research (BTER) Foundation, whose mission is to advance health care through education and research in biotherapy. To minimize conflicts of interest, he accepts no remuneration for the administrative, research, teaching, patient care or other services that he performs for this charity and its clients. To further minimize conflicts of interest, Dr. Sherman earns his living by working in an unrelated field: as an HIV/AIDS physician for the Health Care Agency of Orange County, California. Dr. Stadler is the director of MedMagLabs, a Similitude Pty Ltd. business aiming to supply medicinal maggots in Australia and elsewhere, particularly in low-and middle-income countries and compromised healthcare settings. The technology described in this publication is likely to

facilitate low-cost delivery of maggot therapy services in such markets.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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