The efficacy of maggot debridement therapy – a review of comparative clinical trials

Kian Zarchi, Gregor BE Jemec

ABSTRACT
Over the last decade, maggot debridement therapy (MDT) has been recognized by many clinicians as a potential adjunct to conventional therapy, and many patients with non healing, chronic ulcers have been treated. Numerous case reports and case series have described the successful use of MDT in a variety of ulcers. However, comparative clinical trials and in particular randomized controlled trials investigating the efficacy of MDT are sparse. A systematic search in the literature showed three randomized clinical trials and five non randomized studies evaluating the efficacy of sterile Lucilia sericata applied on ulcers with various aetiologies. Of these, seven studies had debridement and/or healing as an outcome variable. When evaluating maggots as debriding agents, the studies report MDT as being significantly more effective than hydrogel or a mixture of conventional therapy modalities, including hydrocolloid, hydrogel and saline moistened gauze. However, the design of the studies was suboptimal, with important differences in the use of other therapies, such as compression, that may influence both debridement and healing between the compared groups, as well as inappropriately short follow-up times. The quality of the studies therefore makes it difficult to conclude that MDT shortens healing time. The poor quality of the data used for evaluating the efficacy of MDT highlights the need for more and better designed investigations.

Key words: Biosurgery • Chronic ulcer • Debridement • Larval therapy • Maggot debridement therapy

INTRODUCTION
Debridement is an established procedure in wound management. It is thought to reduce the risk of infection and to promote wound healing through the removal of foreign debris and devitalized or contaminated tissue. However, there is a striking paucity of clinical evidence supporting its efficacy when dealing with sloughy and necrotic wounds (1–4). There are a number of existing methods for debridement of chronic wounds, such as mechanical, surgical, autolytic and enzymatic. Each of these techniques has associated disadvantages, such as limited efficacy, need for anaesthesia, pain and mechanical damage to the underlying healthy tissue. Maggot debridement therapy (MDT) is a technique that has attracted some attention recently. Throughout history, MDT has been used in wound healing by various cultures, including Mayan, Burmese and Chinese and among Australian Aborigines (5). In 1557, Ambroise Paré, chief surgeon to Charles IX and Henri III, reported myiasis in the suppurative wounds of soldiers on the battlefield of St. Quentin (6,7). In 1829, Baron Dominique-Jean Larrey, surgeon
Key Points

- the rising incidence of antibiotic resistance in the 1990s raised renewed interest in MDT
- the contrast with the number of published controlled clinical trials is striking; accordingly, we reviewed the available comparative clinical trials to assess the evidence base and efficacy of MDT
- a systematic electronic literature search of comparative clinical trials was carried out in Medline and Cochrane library
- trials had to include debridement and/or healing as an outcome variable

...in chief with the Napoleonic army, discovered the property of enhancement of granulation tissue and shortening of the healing process in wounds infected by maggots (8). However, the first clinical application of maggot therapy is credited to J.F. Zacharias and J. Jones, Confederate medical officers during the American Civil War (9). Later, during World War I, William Baer, professor of orthopaedic surgery, who is considered to be the founder of the modern maggot therapy, noted that maggots assisted the healing process of two soldiers with compound femur fracture as well as abdominal and scrotal wounds (10). Baer refined the technique by using sterile maggots to prevent maggot-induced infections, a technique gradually popularized across North America and Europe during the 1930s. With the introduction of antibiotics in 1940s and the development of better surgical debridement and anaesthesia techniques, the popularity of maggot therapy gradually declined and became largely forgotten. However, the rising incidence of antibiotic resistance in the 1990s raised renewed interest in MDT. In the last decade, many patients with non healing, chronic ulcers have been treated with maggots, leading to MDT being recognized by many clinicians as an adjunct to conventional therapy.

Numerous case series and case reports have described successful use of MDT among a variety of ulcers, including necrotizing fasciitis, perineal gangrene, post-surgical wound infections and burns (11–13). The contrast with the number of published controlled clinical trials is striking; accordingly, we reviewed the available comparative clinical trials to assess the evidence base and efficacy of MDT.

RESULTS

Randomized controlled trials

Between 2004 and 2007, a multicentre, randomized, controlled, single-blinded, open trial was conducted to investigate the efficacy of MDT compared with standard autolytic debridement technique, using hydrogel (Purlon; Coloplast Humlebaek, Denmark) (16). A total of 267 patients with at least one venous or mixed venous and arterial ulcers (ankle brachial pressure index (ABPI) > 0.60) with an area of 5 cm² or less with at least 25% coverage of slough or necrotic tissue were randomized to receive loose larvae, bagged larvae or hydrogel. Randomization was performed using permuted blocks with stratification by trial centre and ulcer area. Sterile L. sericata were applied loose or bagged on ulcers allocated to receive larvae therapy for 3–4 days, which could be repeated if additional larval therapy was assessed as necessary by the attending nurses.

Patients in the control group received hydrogel covered with knitted viscose dressings as well as compression, depending on the ABPI and patient tolerance. The randomized treatment was applied in the debridement phase, which ended either when debridement was achieved according to the assessment of the attending nurses or when treatment was stopped before debridement because of, for example, patient request, which was classified as withdrawal. Debridement was defined as a cosmetically clean wound and was additionally assessed by masked independent...
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<td>Wayman et al. (17)</td>
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<td>Sherman (21)</td>
<td>2002</td>
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<td>Pressure ulcers</td>
<td>67 (in debridement and wound healing analysis), 103 (in adverse event analysis)</td>
<td>MDT versus ‘conventional therapy’</td>
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<td>NCT</td>
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<td>Proportion of healed ulcers</td>
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HRQoL, health-related quality of life; MDT, maggot debridement therapy; NCT, non randomized clinical trials; RCT, randomized clinical trials.
Key Points

- The authors found no evidence that debridement with loose or bagged larvae reduced the time of healing on venous leg ulcers.
- However, time to debridement differed significantly between the groups.

assessors using digital photographs. Assessment of the efficacy of debridement was conducted blindly. In the post-debridement phase, patients received a standard knitted viscose dressing with or without compression. The follow-up period was 6–12 months.

Of the 180 patients allocated to receive loose or bagged larvae, 10 did not receive the allocated treatment because of death, hospital admission, ulcer improvement or refusal to receive MDT. Of the remaining 170 patients, 75 (44%) withdrew from the treatment because of various reasons, such as increased slough (38 patients), patient request (10 patients) and adverse treatment reaction (14 patients).

Of the 87 patients allocated to receive hydrogel, nine did not receive the allocated treatment, and of the remaining 78 patients, 34 (44%) withdrew because of various reasons, such as increased slough (16 patients), patient request (5 patients) and adverse treatment reaction (7 patients).

The authors found no evidence that debridement with loose or bagged larvae reduced the time of healing of venous leg ulcers, compared with hydrogel. The median time to heal in the combined larvae and in the hydrogel group was 236 (95% CI: 147–292) and 245 days (95% CI: 166 to upper limit not estimable), respectively. However, time to debridement differed significantly between the groups. The median time to debridement was shorter with loose larvae (14 days, 95% CI: 10–17) than with bagged larvae (28 days, 95% CI: 13–55) and hydrogel (72 days, 95% CI: 56–131). The difference between loose and bagged larvae was not statistically significant.

In total, 340 adverse events were reported in 131 patients. Of these 13.8% were classified as serious, corresponding to 14.6% events with loose larvae, 13.5% with bagged larvae and 13.5% with hydrogel. More patients in the combined larvae group experienced one or more adverse events than patients in the hydrogel group (51.7% versus 43.7%), but this difference was not statistically significant.

Although significantly more pain was reported by patients in both larvae groups than the hydrogel group, the authors found no evidence of a difference in health-related quality of life between the groups.

In 2000, Wayman et al. reported the results of a randomized, controlled trial evaluating the cost effectiveness of larval therapy (17). A total of 12 patients with sloughy venous leg ulcer, deemed to require debridement, were randomized to receive MDT or hydrogel (Intrasite gel; Smith & Nephew, London, UK). Patients were excluded if there was evidence of arterial insufficiency or if the patient had undergone previous failed therapy. The two groups were comparable in terms of age, sex, ulcer size and duration. The proportion of ulcer covered with slough in the MDT and hydrogel group was reported as 95% and 100%, respectively. Loose sterile L. sericata were applied to ulcers allocated to receive larvae therapy for a maximum of 72 hours. All patients were reviewed every 72 hours until debridement had occurred or for a maximum of 1 month. The outcome measures for effectiveness were whether debridement had occurred within the month and the time to debridement. Ulcers were considered debrided where the percentage surface area of slough was less than 5%. The authors reported that debridement occurred more rapidly in the MDT group, where patients required only one application of larvae. In the hydrogel group, debridement was achieved in only two patients within the month. The authors also reported that the median number of patient visits was 19 in the hydrogel group compared with 3 in the MDT group, but no references were made to the actual time to debridement.

In 2000, Markevich et al. reported the results of a randomized, controlled trial evaluating the efficacy of MDT compared with hydrogel conducted among patients with diabetic foot ulcers (results available in abstract form only) (18). The authors identified diabetic neuropathy as the primary aetiology but did not make further references to inclusion and exclusion criteria. One hundred and forty patients were randomized to receive MDT (unknown whether loose or bagged) for 72 hours or hydrogel (unknown type). The authors reported the duration of the trial to be 30 months, while the follow-up was only 10 days. Despite the short follow-up, the proportion of completely healed ulcers was chosen as the primary outcome. In the MDT group, 7% (5/70) achieved complete healing, compared with 3% (2/70) in the hydrogel group. This difference was not statistically significant. However, reduction of more than 50% in wound area was achieved in 51% of patients (36/70) compared with 27% (19/70).
in the hydrogel group, suggesting a significant difference in the two methods (Table 2).

Non randomized controlled trials
In 2005, Armstrong et al. reported the results of a non randomized, unblinded, open, retrospective review of patients with neuroischaemic diabetic foot ulcers who had been treated with either MDT or conventional therapy (19). Medical records were reviewed of non ambulatory diabetic wound patients who had a peripheral vascular disease, with at least 6 months of reliable follow-up data and who received MDT. Thirty patients met the inclusion criteria. Their data were compared with 30 age- and sex-matched control patients receiving contemporary standard wound care at the same institution. The authors reported that both groups were treated in a standardized manner according to the protocol and were followed in a high-risk diabetic foot clinic, but made no further references to the treatment modalities that they referred to as conventional therapy. In total, 27 patients (45%) healed during the 6-month review, where healing was defined as complete epithelialization. The proportion of patients healing in the MDT was 57% compared with 33% in the conventional therapy group. This difference was not statistically significant. Among the healed patients, time to heal in the maggot group was 18.5 ± 4.8 weeks versus 22.4 ± 4.4 weeks in the conventional group. The authors also reported significantly more antibiotic-free days during the 6 months of follow-up in patients who received MDT (127 ± 30 days versus 82 ± 42 days).

In 2002, Sherman reported the results of a non randomized, unblinded, open, retrospective review of cases aimed at evaluating the efficacy of MDT in patients with pressure ulcers (20). Medical records were evaluated of 103 patients with 145 pressure ulcers who were referred to maggot therapy between 1990 and 1995. In total, 61 ulcers in 50 patients received MDT, while 84 ulcers in 70 patients did not receive maggot therapy. Fifty-one patients did not receive MDT on any wound. MDT was not administrated to these patients because of various reasons: the patient’s doctor did not consent to maggot therapy (11 patients), the wound improved during baseline observation with conventional therapy alone (8 patients), the patients (2 cases) or their decision-making surrogates (2 cases), did not consent to therapy and patients were discharged, died or lost to follow-up (24 cases), before they could be treated. No reason was documented in four cases. Loose sterile L. sericata were applied for two 48-hour cycles per week. Conventional therapies included topical antimicrobial therapy (35%), acemannan hydrogel (10%), chemical debriding agents (8%), wet to dry dressings (8%), hydrocolloids and calcium alginites (6%), growth factors (4%) and multiple combinations of non surgical treatments (12%). Of the conventionally treated group, 17% received bedside or intra-operative surgical debridement. Evaluation of debridement and wound healing was carried out using digitalized images and tracings. Some wounds were excluded from the efficacy analysis, e.g. because of complex non planar topography, being photographed without the scale markers and follow-up shorter than 2 weeks. The efficacy analysis comprised 70% (43/61) of the wounds receiving MDT and 59% (43/84) of the wounds receiving conventional therapy. Ulcers in the MDT group were 60% larger, and maggot-treated patients were more often diabetic with spinal cord injuries and with higher average serum albumin. Otherwise there were no significant differences between the two treatment groups. The author reported that 80% (95% CI: 65–95) of maggot-treated wounds were completely debrided after 4–8 weeks, while complete debridement occurred in 48% (95% CI: 26–70) of wounds in the conventional therapy. Percentages of wounds that completely healed within 12 weeks for the MDT and conventional therapy group were 39% and 21%, respectively. This difference was not statistically significant. The average time until ulcers completely healed was 12 weeks (95% CI: 8–19) in the MDT group compared with 13.4 weeks (95% CI: 7–17) in the conventional therapy group. Pain complaints were reported in 4% of the maggot-treated patients.

In 2002, Sherman reported the results of a non randomized, unblinded, open, case review attempting to evaluate the efficacy of MDT on diabetic foot and leg ulcers (21). Between 1990 and 1995, 26 patients with diabetic foot and leg ulcers were evaluated as candidates for MDT. Of these, eight were excluded because of the lack of sufficient baseline data. Of the 20 wounds on the remaining 18 patients, six wounds were treated only with conventional therapy, six wounds were treated with maggot...
Table 2 Baseline characteristics of patients in the included studies

<table>
<thead>
<tr>
<th>Trials</th>
<th>Groups</th>
<th>Mean age (years)</th>
<th>Ulcer size (cm²)</th>
<th>Proportion of ulcer covered with slough</th>
<th>Ulcer duration (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dumville et al. (16) (venous or mixed arterial and venous ulcers)</td>
<td>MDT (loose)</td>
<td>74.1 (SD: 12.9)</td>
<td>Median12.2 (range: 0.6–174.9)</td>
<td>‘At least 25% covered by slough or necrotic tissue’</td>
<td>9.0 (Range: 1.0 – 240.0)</td>
</tr>
<tr>
<td></td>
<td>MDT (bagged)</td>
<td>73.5 (SD: 12.2)</td>
<td>Median17.3 (range: 1.8–197.9)</td>
<td>‘At least 25% covered by slough or necrotic tissue’</td>
<td>6.9 (Range: 1.0 – 204.0)</td>
</tr>
<tr>
<td></td>
<td>Control (hydrogel)</td>
<td>74.3 (SD: 12.8)</td>
<td>Median 12.2 (range: 1.0–116.8)</td>
<td>‘At least 25% covered by slough or necrotic tissue’</td>
<td>8.0 (Range: 1.0 – 372.0)</td>
</tr>
<tr>
<td>Markevich et al. (18) (diabetic foot ulcers)</td>
<td>MDT</td>
<td>53.6 (SD: 15.4)</td>
<td>14.9</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Control (hydrogel)</td>
<td>53.6 (SD: 15.4)</td>
<td>15.1</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Wayman et al. (17) (venous leg ulcers)</td>
<td>MDT</td>
<td>58 (48–72)</td>
<td>18 (13–25)</td>
<td>100% (80–100)</td>
<td>5 (2–8)</td>
</tr>
<tr>
<td>Armstrong et al. (19) (diabetic foot ulcers)</td>
<td>Control (hydrogel)</td>
<td>54 (40–75)</td>
<td>16 (14–22)</td>
<td>95% (80–100)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Sherman (20) (diabetic foot ulcers)</td>
<td>Control (conventional therapy)</td>
<td>72.7 (SD: 6.8)</td>
<td>12.4 (SD: 6.7)</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>MDT</td>
<td>63 (range: 53–74)</td>
<td>13.3 (range: 0.9–42)</td>
<td>Not reported</td>
<td>38% (range: 0–90)</td>
</tr>
<tr>
<td></td>
<td>Control (conventional therapy)</td>
<td>68 (range: 53–82)</td>
<td>6.3 (range: 0.5–15.5)</td>
<td>44% (range: 0–100)</td>
<td>9 (40, weeks, range: 4–312)</td>
</tr>
<tr>
<td>Sherman (21) (pressure ulcers)</td>
<td>MDT</td>
<td>62 (range: 26–85)</td>
<td>22.1 (range: 15.7–28.4)</td>
<td>31% (95% CI: 21–41)</td>
<td>8.3 (37 weeks, range: 5–207)</td>
</tr>
<tr>
<td></td>
<td>Control (conventional therapy)</td>
<td>66 (range: 32–91)</td>
<td>14.0 (range: 9.7–18.2)</td>
<td>34% (95% CI: 23–45)</td>
<td>7.6 (34 weeks, range: 4–208)</td>
</tr>
<tr>
<td>Sherman et al. (22) (pressure ulcers)</td>
<td>MDT</td>
<td>58 (range: 44–68)</td>
<td>13.8 (range: 4.8–30.0)</td>
<td>0–25%; five patients 51–100%; three patients</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Control (conventional therapy)</td>
<td>The same patients as in the MDT group</td>
<td>The same patients as in the MDT group</td>
<td>22% worsening during conventional therapy was reported, baseline data not specified</td>
<td>Not reported</td>
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MDT, maggot debridement therapy; SD, standard deviation.
therapy, and eight wounds were treated with conventional therapy first followed by MDT. For the six wounds not treated with MDT, one patient underwent a below-knee amputation before maggot therapy was initiated, and in four patients consent to therapy was not given by the patient or the spouse. Conventional therapy included dry dressing or saline-moistened gauze (four wounds), topical antimicrobials (three wounds), acemannan hydrogel (one wound), hydrocolloid (one wound), unspecified multiple non surgical modalities (two wounds) and bedside surgical debridement (three wounds).

MDT was administrated by applying loose sterile _L. sericata_ to the wound for cycles of about 48 hours. One or two cycles were applied each week. The authors reported that a 50% reduction in necrotic surface area was reached after 9 days of MDT, whereas conventionally treated wounds did not reach that stage until Day 29. This difference was statistically significant. Within 4 weeks maggots-treated wounds were completely debrided, whereas wounds treated with conventional therapy for an average of 5 weeks were still covered with necrotic tissue over 33% of their surface. MDT was also associated with hastened growth of granulation tissue, resulting in 56% surface area coverage with granulation tissue within 4 weeks of treatment (19% at the baseline), whereas 15% of coverage with granulation tissue was reached in the conventional therapy group (18% at the baseline). The average time to wound closure in the maggot-treated group was 15 weeks (95% CI: 3–26) compared with 18 weeks (95% CI: 2–33) in the conventionally treated group. Two maggot-treated patients complained of pain during therapy, but the pain was not severe enough to cause cessation of treatment. The authors reported that the same two patients complained of pain during conventional dressing changes.

In 1995, Sherman _et al._ reported the results of a case review aimed at evaluating the efficacy of MDT on pressure ulcers among spinal cord patients (22). Among 20 spinal injured patients with pressure ulcers treated with maggots, eight were followed for 3–4 weeks before MDT, thereby limiting the study group to eight patients. These patients were followed while receiving conventional therapy, prescribed by their primary care teams. Conventional treatment modalities included thrice daily sterile normal saline (two patients), 0-5% sodium hypochloride (two patients), povidone iodine dressings (two patients), topical antimicrobial ointment (one patient) and knitted cellulose acetate impregnated with petrolatum emulsion (one patient). Patients were then treated with loose sterile _L. sericata_. Ulcers were evaluated visually and photographically every week, by an unblinded investigator. The authors reported that of ulcers with a 20% or larger necrotic base, none had debrided more than 50% during the 3–4 weeks before MDT. All such ulcers were reported completely debrided within 1–2 weeks after the initiation of MDT. The average change in ulcer surface area before MDT was an increase of 22% per week, whereas a decrease of 22% per week was reported after the initiation of MDT. No complications resulted from the MDT.

**DISCUSSION**

In recent years, it has been claimed that MDT should be recognized as an effective alternative to the conventional debridement methods. In this review, we undertook an investigation to determine whether the existing evidence in the literature supports such a claim.

When evaluating therapy modalities in wound management, a variety of outcome measures, including infection rate, duration of hospital admission, post-operative complications, cost effectiveness and impact on the quality of life can provide valuable information. In this review, we aimed to evaluate the efficacy of maggots as debriding agents and solely focused on their impact on debridement and healing rate.

Controlled trials, and in particular randomized controlled trials investigating the efficacy of MDT, are sparse. A systematic search in the literature showed three RCTs and five non randomized clinical trials (NCTs) evaluating the efficacy of sterile _L. sericata_ applied to ulcers with various aetiologies. Of these, seven trials had debridement and/or healing as an outcome variable. Effectiveness of maggots as debriding agents was investigated in two RCTs and four NCTs, all suggesting MDT as being more effective than hydrogel and more efficient than a mixture of conventional therapy modalities including hydrocolloid, hydrogel and saline moistened gauze. However, the

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**Key Points**

- when evaluating therapy modalities in wound management, a variety of outcome measures, including infection rate, duration of hospital admission, post-operative complications, cost effectiveness and impact on the quality of life can provide valuable information
- In this review, we aimed to evaluate the efficacy of maggots as debriding agents and solely focused on their impact on debridement and healing rate
quality of data in studies describing MDT is poor and the conclusions may therefore be questioned. The questionable quality of these trials is due to the following reasons: very short follow-up, limited number of patients, unclear inclusion and exclusion criteria, lack of clarity regarding whether treatment in the control group was administrated adequately, lack of blinding of outcome assessors and lack of randomization.

The study of Dumville et al. is the only randomized clinical trial, following patients for longer than 1 month. Follow-up longer than 1 month must be considered as mandatory when outcome variables include time to heal. In the study of Wayman et al., the authors primarily focused on the cost effectiveness of the therapy and followed patients for a maximum of 1 month, while the follow-up was only 10 days in the study of Markevich et al. Although, the study of Dumville et al. had an appropriate follow-up, the authors conducted the study on patients with venous or mixed venous and arterial ulcers (ABPI > 0-6) in whom compression must be regarded as the cornerstone of treatment. Reviewing the baseline data shows that 70% of patients treated with hydrogel received high compression compared with 53% in the MDT group. The dataset was therefore skewed, and their conclusion regarding MDT’s impact on healing time must therefore be questioned. Unfortunately, the remaining studies have limited value if any definitive conclusion is to be drawn, although they can play an important role in showing some tendencies. The studies of Sherman et al. and Armstrong et al. are subject to marked selection bias. Conclusions drawn by comparing MDT with conventional therapy among patients, who were referred to MDT because of inadequate therapeutic response to conventional methods, must be questioned.

Accepting the premise that debridement is a prerequisite for healing, it is therefore difficult to draw the conclusion, that there is evidence suggesting that MDT shortens time to heal. The studies highlight the need for more and better designed investigations in this area with standardized outcome variables that allow comparison across different studies similarly to studies of surgical techniques elsewhere.

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