# Maggot debridement therapy with *Lucilia cuprina*: a comparison with conventional debridement in diabetic foot ulcers

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## ABSTRACT

This is prospective case–control study of more than 18 months performed to assess the effectiveness of maggot debridement therapy (MDT) with the sterile larvae of *Lucilia cuprina* (a tropical blowfly maggot) for the treatment of diabetic foot ulcers. Literature thus far has only reported results with the temperate maggot, *Lucilia sericata*. This study documents outcome in diabetic foot wounds treated with maggot debridement versus those treated by conventional debridement alone. In this series of 29 patients treated with MDT, 14 wounds were healed, 11 were unhealed and 4 were classified under others. The control group treated by conventional debridement had 30 patients of which 18 wounds were healed, 11 unhealed and 1 classified under others. There was no significant difference in outcome between the two groups. The conclusion that can be made from this study is that MDT with *L. cuprina* is as effective as conventional debridement in the treatment of diabetic foot ulcers. It would be a feasible alternative to those at high risk for surgery or for those who refuse surgery.

**Key words:** *Lucilia cuprina* • Maggot debridement therapy

## INTRODUCTION

Maggot debridement therapy (MDT) has and is being used extensively in the United Kingdom (UK) and the United States of America, where sterile maggots are commercially available. It has been used as one of the modalities for the treatment of infected diabetic foot ulcers. The species used in these temperate climates is the blowfly *Lucilia sericata*. Here, in Malaysia, being a country with tropical weather, we have the tropical blowfly *Lucilia cuprina,* instead of *L. sericata*. MDT with *L. cuprina* to our knowledge has never been published. It has been tried once before here in Malaysia on 12 patients with diabetic foot wounds at the Lumut Naval Hospital (1). Two patients in this study had

### Key Points

- MDT is as effective as conventional debridement in treating diabetic foot ulcers.
- MDT with *L. cuprina* has similar results to that with *L. sericata*
- maggot debridement therapy (MDT) has and is being used extensively in the United Kingdom (UK) and the United States of America, where sterile maggots are commercially available
- it has been used as one of the modalities for the treatment of infected diabetic foot ulcers

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**Key Points**

- our study objective was to compare MDT with L. cuprina and conventional debridement for the treatment of infected diabetic foot ulcers
- our hypothesis is that MDT is as effective as conventional debridement in the treatment of infected diabetic foot ulcers

MDT discontinued. The other ten had their wounds heal satisfactorily. This was a descriptive study. We have tried to build on this by conducting a prospective non randomised case–control study to prove that MDT with *L. cuprina* is as effective as conventional debridement in the treatment of infected diabetic foot ulcers.

### Study objective and hypothesis

Our study objective was to compare MDT with *L. cuprina* and conventional debridement for the treatment of infected diabetic foot ulcers. At this time of writing, no trials, to the best of our knowledge, have been published with regards to the clinical use of *L. cuprina*.

Our hypothesis is that MDT is as effective as conventional debridement in the treatment of infected diabetic foot ulcers.

## MATERIALS AND METHODS

### Study design

This is a prospective case–control study that compares two treatment outcomes for diabetic foot ulcers – conventional debridement and MDT. This study was approved by the Clinical Research Centre of the Ministry of Health Malaysia. Ethics approval was granted to the Institute of Medical Research, Malaysia (IMR) for the use of *L. cuprina* in clinical trials.

### Inclusion and exclusion criteria

#### *Inclusion criteria*

All patients aged 35–70 years, who were admitted to the orthopaedics wards in the Kuala Lumpur General Hospital (HKL) for infected diabetic foot wounds (below ankle) from December 2005 to May 2007 requiring redebridement or non urgent primary debridement, were treated with either MDT or conventional debridement. Each patient needing such debridement was offered MDT as a form of treatment. Antibiotics were given as indicated by the presence of sepsis (spiking temperature, raised total whites) or the presence of cellulitis. Because of the limited supply of sterile maggots, only a maximum of two patients were on the therapy at any one time. Both groups had foot wounds graded at the onset using the University of Texas Diabetic Foot Classification System.

#### *Exclusion criteria*

Patients with the following were excluded:

1. Gangrenous wounds
2. Necrotising fasciitis
3. Abscesses
4. Wounds with exposed viable bones
5. Wounds with exposed viable tendons
6. Wounds that are profusely bleeding
7. Ischaemic wounds [ankle-brachial systolic index (ABSI) of less than 0·75 (moderate ischaemia)]
8. Patients who have entomophobia

Patients selected for and agreeable to MDT were asked to sign an informed consent form. Thereafter, therapy was initiated within the next 2 days. We required some time for our entomology colleagues from IMR to prepare the maggots.

### Transport of maggots

The maggots were transported in a sterile vial in a cooler box at 4°C. As the Institute for Medical Research is located just next to the HKL, maintaining the temperature during transport was not a problem.

### Wound dressing and treatment

For the study group, the maggots were applied directly onto the wound with a sterile spatula. Around ten maggots were needed for every 1 $cm^2$ of wound surface. The wound was then covered with light gauze and then the entire wound was sealed with OpSite™ (Smith & Nephew, Mull, UK). Some small fenestrations were made in the OpSite dressing to allow drainage of fluid. A gamgee was placed over this to absorb the fluid. Then, the entire foot was loosely bandaged with a crepe bandage. The crepe bandage and gamgee were changed as necessary before the washout, that is if the dressing had become soaked. A washout of the wound was performed after 48 hours of application of maggots. This was performed using normal saline. Maggots were reapplied after that if needed. If no change was noticed after three consecutive applications then MDT was abandoned and debridement was carried out as needed. All patients were converted to subcutaneous insulin during the duration of treatment.

For the control group, wound dressing was performed daily with normal saline only and the necessary surgical debridement and desloughing was performed as indicated. All patients were converted to subcutaneous insulin during the duration of treatment.

### Outcome measurements

We devised our own wound outcome scoring system, one for the MDT group and one for the

**Table 1** Outcome classification for the MDT group

| Grades | Subgrades | Outcome |
|---|---|---|
| Healed | 1A | Suitable for SSG, flap coverage or for self-healing |
| | 1B | Debridement + SSG/flap coverage at same setting |
| | 1C | Assisted debridement (debridement in between – to remove necrotic tendons or exposed bone) |
| Unhealed | 2 | Surgical debridement (MDT abandoned) |
| | 3A | Minor amputation (below ankle) |
| | 3B | Major amputation (above ankle) |
| Others | 4 | Others (patient withdrawal, discontinuation, death, etc.) |

MDT, maggot debridement therapy; SD, surgical debridement; SSG, split skin grafting.

control group. Each group has three grades: healed, unhealed and others. Outcome for the study group categorised into four subgrades was measured as a final outcome after treatment as in Table 1.

Outcome for the control group (conventional debridement) categorised into three subgrades was measured as a final outcome after treatment as in Table 2.

### Evaluation

Both the study and control groups had their foot ulcers graded according to the University of Texas Medical Branch (UTMB) grading (2). Treatment was considered complete once healing had taken place. Healing was defined as the wound/ulcer being suitable enough for split skin grafting (SSG), flap coverage or self-healing as judged clinically. Ulcers that were found suitable for desloughing and SSG or flap coverage at the same setting were also considered as healed.

The following variables from both groups were also compared:

1. Haemoglobin count
2. Average blood sugars – calculated as the average dextrostix during the entire duration of treatment
3. Ankle brachial systolic index – taken from the affected limb
4. Serum albumin
5. White cell count
6. Neuropathy – tested using a 10 g Semme's monofilament
7. Age
8. Wound swab before treatment
9. Number of debridements
10. Length of ward stay

**Table 2** Outcome classification for the control group

| Grades | Subgrades | Outcome |
|---|---|---|
| Healed | 1 | Suitable for split skin grafting, flap coverage or self-healing |
| Unhealed | 3A | Minor amputation (below ankle) |
| | 3B | Major amputation (above ankle) |
| Others | 4 | Others (patient withdrawal, discontinuation, death, etc.) |

## RESULTS

A total of 29 patients were treated with MDT. There were 18 males and 11 females, with ages ranging from 30·0 to 75·0 years, with an average age of 56·6 years. Four patients from the study group prematurely stopped treatment with MDT. Of these four patients, two stopped because of pain, one took an 'at own risk' discharge to seek treatment elsewhere and one more patient had the MDT-treated ulcer debrided surgically as he went for a drainage of an abscess on the contralateral leg.

A total of 30 controls were treated. There were 20 males and 10 females, with ages ranging from 32·0 to 82·5 years, with an average age of 55·6 years. Of the control group, one patient took an 'at own risk' discharge. At the end of the study period, 25 cases and 29 controls were analysed. The demographic data of the sample analysed are summarised in Tables 3 and 4.

All the variables were analysed with Microsoft Excel 2003 (Microsoft Corp). The Fisher's exact test was used for all the discreet variables, and all the continuous variables were analysed using the Student's *t* test. The results have been divided into two tables – one for the continuous variables (Table 3) and one for the discreet variables (Table 4). These tables display the distribution of data as well as the two-tailed *P* value after analysis.

Based on our results, we can conclude that maggot-assisted debridement is comparable to conventional debridement in the treatment of diabetic foot ulcers in terms of outcome. There was no significant difference noted in outcome between the MDT group and the conventional debridement group. There was, however, a significant difference in the length of ward stay between the two groups.

### Key Points

- based on our results, we can conclude that maggot-assisted debridement is comparable to conventional debridement in the treatment of diabetic foot ulcers in terms of outcome

**Key Points**

- various dressing methods have been described in the literature, but the important principle is that the dressing must be permeable
- this is because oxygen exchange can occur between the wound and surrounding environment and also fluid can drain out of the wound
- maggot debrided wounds are heavily exudative

**Table 3** Results of analysis of the continuous variables*

| Continuous variables | MDT | SD | *P* |
|---|---|---|---|
| Age (years) | | | |
| Mean | 55·3 | 55·3 | >0·05 |
| Range | 30·0–69·2 | 32·0–82·5 | |
| Length of stay in ward (days) | | | |
| Mean | 12·5 | 19·8 | 0·01 |
| Range | 2·0–32·0 | 3·0–47·0 | |
| Serum albumin (g/dL) | | | |
| Mean | 35·4 | 37·4 | >0·05 |
| Range | 24·0–44·0 | 24·0–46·0 | |
| White cell count ($\times 10^9$) | | | |
| Mean | 10·6 | 10·8 | >0·05 |
| Range | 7·6–17·6 | 7·5–18·0 | |
| Haemoglobin (g%) | | | |
| Mean | 10·0 | 10·8 | >0·05 |
| Range | 7·7–13·7 | 8·6–13·7 | |
| Average blood sugars (mmol/l) | | | |
| Mean | 11·1 | 9·8 | >0·05 |
| Range | 6·5–17·3 | 6·5–15·8 | |
| ABSI | | | |
| Mean | 1·0 | 1·1 | >0·05 |
| Range | 0·81–1·86 | 0·90–1·50 | |

MDT, maggot debridement therapy; SD, surgical debridement; ABSI, ankle-brachial systolic index.
*The only significant difference was noted in the length of ward stay.

**Table 4** Results of analysis of the discreet variables*

| Discreet variables | MDT | SD | *P* |
|---|---|---|---|
| UTMB class 1B | | | |
| Healed | 4 | 6 | >0·05 |
| Unhealed | 0 | 2 | |
| UTMB class 2B | | | |
| Healed | 8 | 4 | >0·05 |
| Unhealed | 8 | 4 | |
| UTMB class 3B | | | |
| Healed | 2 | 8 | >0·05 |
| Unhealed | 3 | 5 | |
| Neuropathy | | | |
| Yes | 11 | 10 | >0·05 |
| No | 14 | 19 | |
| Amputation (major and minor) | | | |
| Yes | 5 | 11 | >0·05 |
| No | 20 | 18 | |
| Amputation subtypes | | | |
| Major (above ankle) | 1 | 6 | >0·05 |
| Minor (below ankle) | 4 | 5 | |
| Antibiotic usage | | | |
| Yes | 24 | 28 | >0·05 |
| No | 1 | 1 | |
| Outcome | | | |
| Healed | 14 | 18 | >0·05 |
| Unhealed | 11 | 11 | |

MDT, maggot debridement therapy; SD, surgical debridement; UTMB, University of Texas Medical Branch.
*There was no significant difference in the outcome (healed versus unhealed).

### Wound swab results

Wound swab results were varied and were difficult to quantify. In the study group, 11 patients had mixed growth, 7 had no growth and 7 had growth. None had methicillin-resistant *Staphylococcus aureus* (MRSA). The organisms isolated were *Bacillus* sp., *Streptococcus* group B, *Escherichia coli*, *Klebsiella* sp., *Pseudomonas aeuriginosa*, *Bacteroides fragilis* and *S. aureus* (two patients). In the control group, 12 patients had mixed growth, 6 had no growth and 11 had growth. None had MRSA. The organisms isolated were *Enterobacter* sp., *Streptococcus* group B, *E. coli*, *Klebsiella* sp. (two patients), *P. aeuriginosa* (three patients), *Proteus* sp. (two patients) and *S. aureus* (two patients).

## DISCUSSION

MDT is defined as the use of sterile maggots for the debridement of wounds in humans. Other prerequisites are that the treatment has to be hypoallergenic, non invasive and effective.

MDT has been used for the treatment of pressure ulcers (3,4), burns (5,6), venous stasis ulcers (7), osteomyelitis (8), diabetic foot ulcers (9–10), MRSA-infected wounds (10), debridement of infected surgical wounds (13) and even chronic, non healing ulcers (14,15). It is contraindicated for use in wounds that need urgent debridement, for example in necrotising fasciitis, abscesses as well as in wounds that are haemorrhagic (lest the maggots drown).

Maggots can be applied either directly to the wound or in commercially available bio-bags (7,16). These bio-bags are not available here in Malaysia, and thus, our use of free-range maggots, that is maggots applied directly onto the wound.

Various dressing methods have been described in the literature (3,8,9,15,17), but the important principle is that the dressing must be permeable. This is so that oxygen exchange can occur between the wound and surrounding environment and also fluid can drain out of the wound. Maggot debrided wounds are heavily exudative. Much care has been taken by some authors by meticulously sealing the edges of the wound with a hydrocolloid dressing followed by a muslin cloth taped down to the dressing,

followed by an absorbent pad on top of that. The dressing is usually changed every 48–72 hours. This is because the maggots become far less active after the first 48 hours and serve no useful purpose in the wound after that. Our method of wound dressing in this study was one that was modified, so that it is relatively cheap and can be performed in any Ministry of Health hospital in Malaysia as the dressing material is readily available in all such hospitals.

As the use of *L. cuprina* for MDT has not yet been published, an interesting question is whether *L. cuprina* and *L. sericata* are similar or just as effective. Secretions collected from the larvae of the greenbottle fly *L. sericata* showed the presence of small antibacterial factors within the larval secretions, active against a range of bacteria, including the MRSA (17) and to a lesser extent the Gram-negative *Pseudomonas aeruginosa* (19,20). It has been postulated that different components in their secretions are responsible for its antibacterial effects against different bacteria (20). Three compounds have been isolated and identified: *p*-hydroxybenzoic acid (molecular weight 138 Da), *p*-hydroxyphenylacetic acid (molecular weight 152 Da) and octahydrodipyrrolo [1, 2-a; 1′, 2′-d] pyrazine-5, 10-dione (molecular weight 194 Da). All three molecules showed antibacterial activity, and the effect was even more pronounced when these molecules were tested in combination and caused lysis of these bacteria. It has been shown that *L. cuprina* and *L. sericata* larvae share the same proteases. *L. cuprina* also has been shown to have similar wound healing secretions (18).

There is a theoretical danger of allergy to maggot protein, but this has not been reported in the literature. The danger of myasis (infestation by fly larvae) within human tissue has not been reported with the blowfly species. There has been a report of a cutaneous infestation of *L. sericata* (21). However, there have been no such reports with *L. cuprina* in Malaysia (22). Another issue is that the larvae of the *L. species* have *Proteus mirabilis* as their gut commensals (23) and thus, they may not be effective against all *Proteus* species. None of the patients in our study group had their wounds infected with *Proteus* spp. so an inference on its effectiveness cannot be made on this from our data.

The most commonly mentioned disadvantage of larval therapy is the negative perception with which it is regarded by both patients and practitioners (24,25). Although the so-called 'yuk factor' of its clinical appearance has been frequently reported in case studies, there is little evidence to suggest that patients refuse larval therapy when it is offered (26). In our experience, we had an overwhelming response with many patients asking for MDT. Many had to be turned down as they were not suitable and some as we could not cope logistically.

### Sterilisation of maggots

It was reported in 1933 that for successful larval therapy, the maggots should be free of bacteria before being placed into wounds (27). An early sterilisation technique was to wash fresh fly eggs in a dilute solution of sodium hypochlorite, rinse in sterile water, then agitate the eggs in 4% formaldehyde (8). The eggs were then rinsed and placed on sterile meat-agar media for development. Our colleagues from the IMR tried this unsuccessfully. Official literature about the sterilisation process is almost non existent as the processes are patented. Below is a summary of the sterilisation process used by IMR (patent pending at the time of writing) for the preparation of maggots.

A piece of fresh cow liver (1·5 g) in a Petri dish is placed inside the adult *L. cuprina* cage for egg laying. The liver with eggs were then transferred into a plastic container and covered with netting to prevent the maggots from escaping. Maggots are incubated for 60 hours on the liver. About 40–50 maggots of second instar stage are removed and placed into a glass vial and covered with a net. The maggots are then washed with sterile distilled water at least three times until the debris from gut content is cleared. The maggots are then starved overnight. After this, they are washed with 1:1 ratio of chlorhexidine and 70% ethanol and are incubated for 5 minutes. The solution is discarded and the maggots are washed with 70% ethanol. This washing step is repeated three times until chlorhexidine had been removed. The maggots are then washed with sterile double distilled water and transferred into sterile containers. Finally, the sterile containers containing the maggots are placed inside a cold box (at 10°C) and ready for delivery. Some maggots from the final procedure were used to check for sterility by plating them directly onto culture media. Tubes showing the presence of bacterial contamination will be discarded.

## Key Points

- our method of wound dressing in this study was one that was modified, so that it is relatively cheap and can be performed in any Ministry of Health hospital in Malaysia as the dressing material is readily available in all such hospitals
- it has been shown that L. cuprina and L. sericata larvae share the same proteases. L. cuprina also has been shown to have similar wound healing secretions
- although the so called 'yuk factor' of its clinical appearance has been frequently reported in case studies,there is little evidence to suggest that patients refuse larval therapy when it is offered

**Key Points**

- several limitations are identified that may have some degree of influence on the validity of this study: small sample size, length of ward stay measurement, different personnel doing the wound dressing

### Wound outcome grading

We could not find any literature on wound outcome classification or scores that were suitable for our study. Literature related to classification and scores of diabetic foot ulcers are pertaining to the initial wound score and not to the outcome. Thus, we devised our own wound outcome scoring system, one for the study group and one for the control group (Tables 1 and 2).

### Outcome of MDT

MDT has been reported recently in the UK to have a 67% successful outcome in wound healing (28). The results in the literature are in line with this (2,4,6,8,9,11). However, these studies have been for cases with which MDT was used as a last resort, not in direct comparison to conventional treatment. Our literature search only showed two studies that compared MDT with conventional debridement. One study by Sherman (4) in 2002 compared MDT with conventional debridement for the treatment of pressure ulcers. It showed a significant difference with MDT being better in terms of the rate of healing and the formation of granulation tissue. Another by Sherman (29) in 2003 showed similar results plus a better rate in reduction in wound size in patients treated with MDT. However, eventual wound outcomes for both studies at the end were not statistically different. These studies also showed that MDT-treated patients had a shorter ward stay. This is similar to our results in terms of outcome and length of ward stay. One of Sherman's studies also showed that MDT reduced the need for amputation (30). Our study showed that the MDT-treated group had a lower overall amputation rate of 20% as compared with the surgical debridement group with a rate of 38% (Table 4). However, this was statistically not significant probably because of the small sample numbers. Larger trials are needed to confirm this.

We had quite a number of patients in HKL enquiring about MDT even before the study had begun. IMR had already established its maggot project but had not carried out any trials yet to ascertain the efficacy of *L. cuprina*. The English literature is rife with many reports on *L. sericata*, but none about *L. cuprina* with regards to its use for MDT.

### Limitations of study

Several limitations are identified that may have some degree of influence on the validity of this study. They are described below:

1. Small sample size – The numbers presented here are small. The study had just begun over a year ago and a larger series is being investigated currently. However, the statistical analyses, which were used, were suitable for the small sample size.
2. Length of ward stay measurement – The length of ward stay was measured from admission till discharge. Those whose wounds were suitable for skin grafting were discharged and given another elective admission date. Some patients stayed on for other unrelated problems. Thus, the time documented may not be truly representative of the actual time until wound healing.
3. Different personnel doing the wound dressing – One main problem we had with the application of maggots to the wound was that the dressings were performed by different health personnel. At times, we noted that there were no viable maggots on wound washout, probably because the initial dressing did not allow seepage of fluid out from the wound. This may have an effect on the length of ward stay as well.

### Other problems encountered

During the initial pretrial phase, MDT was tried on three patients upon their request. We noted that exposed tendons and bones that were still viable tended to become dry, although the rest of the wound was exudative. We are unable to explain this and it has never been documented in the literature. We do not know whether it is a particular event because of *L. cuprina*. More trials and laboratory investigations are needed to further evaluate this phenomenon.

### Patients' experience

Overall, most patients were very accepting of MDT. Very few had the feeling of the 'yuk factor'. Two of 29 patients had experienced pain during treatment, but most without neuropathy could feel the maggots crawling over the wound, rather than experience pain. One way to overcome the 'yuk' factor may be to

synthetically manufacture the antibacterial molecules secreted by the maggots for direct application onto the wound. This would indeed be a revolutionary invention as huge quantities of secretions would be needed.

## CONCLUSIONS

From the literature reviewed it can be noted that as a treatment, larval therapy offers numerous advantages including rapid wound debridement and elimination of infection, control of pain and the promotion of wound healing. Use of larval therapy has resulted in few side effects and has reduced the need for amputation (30). It is also apparent that the treatment also offers an efficient alternative to antibiotic therapy for the treatment of wounds contaminated with a variety of wound pathogens, including MRSA. Having been largely superseded by antibiotics, larval therapy has reemerged as one of the current strategies for targeting microbial resistance.

Our study with *L. cuprina* has managed to prove that therapy with these larvae is as effective as conventional debridement with regards to wound outcome. Although the numbers may look significantly different with regards to the amputation rate (20% for the MDT group and 38% for the conventional debridement group), statistical analysis showed that the difference was not significant. This could be because of the low power of our study. In the comparison studies between MDT and conventional debridement in the literature, the eventual outcome was the same, but the MDT group had better time towards healing. This is in line with our study, whereby the relevant significant difference was in the length of ward stay, but this too has its limitations as mentioned above. Some studies in the literature showed a better outcome with MDT-treated wounds. However, in these studies, MDT was used mainly as a salvage tool when almost all else had failed, which would explain the better healing outcome. Our group consisted of fairly uncomplicated diabetic foot infections with none having MRSA. Furthermore, we had not compared wound size shrinkage, the rate of necrotic tissue shrinkage and the rate of granulation tissue growth between the two groups. In our study, there was also no significant difference in the UTMB class type and outcome (healed versus unhealed).

Possible uses for *L. cuprina* larvae would be in patients with intractable wounds, those who are too ill for surgery or too high a risk for surgery or even for those who refuse surgery. However, more trials are required, probably with more difficult wounds and with further and more elaborate wound analysis to further examine the efficacy of *L. cuprina*. Overall, larval therapy facilitates the selective debridement of devitalised tissue. The treatment has the added benefit of being bactericidal while functioning in harmony with wound processes to promote healing. Larval therapy may indeed be a feasible armament in our treatment of diabetic foot ulcers.

### Key Points

- from the literature reviewed it can be noted that as a treatment, larval therapy offers numerous advantages including rapid wound debridement and elimination of infection, control of pain and the promotion of wound healing
- use of larval therapy has resulted infew side effects and has reduced the need for amputation
- having been largely superseded by antibiotics, larval therapy has reemerged as one of the current strategies for targeting microbial resistance
- larval therapy may indeed be a feasible armament in our treatment of diabetic foot ulcers

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