Recovery of chronically lame dairy cows following treatment for claw horn lesions: a randomised controlled trial


A positively controlled, randomised controlled trial (RCT) was undertaken to test recovery of cows with claw horn lesions resulting in lameness of greater than two weeks duration. Cows on seven commercial farms were mobility scored fortnightly and selected by lameness severity and chronicity. Study cows all received a therapeutic trim then random allocation of: no further treatment (trim only (TRM)), plastic shoe (TS) or plastic shoe and NSAID (TSN). Recovery was assessed by mobility score at 42 (±4) days post treatment by an observer blind to treatment group. Multivariable analysis showed no significant effect of treatment with an almost identical, low response rate to treatment across all groups (Percentage non-lame at outcome: TRM – 15 per cent, TS – 15 per cent, TSN – 16 per cent). When compared with results of a similar RCT on acutely lame cows, where response rates to treatment were substantially higher, it can be concluded that any delay in treatment is likely to reduce the rate of recovery, suggesting early identification and treatment is key. Thirty-eight per cent of animals treated in this study were lame on the contralateral limb at outcome suggesting that both hindlimbs should be examined and a preventive or if necessary a therapeutic foot trim performed when lameness is identified particularly if the duration of lameness is unknown.

Introduction
Claw horn lesions represent a significant cause of lameness in dairy cattle with sole ulcer, sole haemorrhage and white line disease accounting for the majority of the lesions found (Capion and others 2008, Cramer and others 2008). Prevention of these lesions and identification of risk factors have received some investigation in recent years, however there has been limited information available in the peer-reviewed scientific literature to guide practitioners on the most effective treatment options once lesions have occurred (Botterton and others 2012). Two randomised clinical trials conducted in Australia and New Zealand (Fyman 1997, Laven and others 2008) investigated the use of common treatments for claw horn lesions but found no significant difference between treatments at their 14-day and 100-day outcomes, respectively. In contrast, a positively controlled randomised clinical trial (RCT) carried out on newly lame dairy cows in the UK (Thomas and others 2015) found that, compared with a minimum treatment intervention of a therapeutic foot trim, the addition of an orthopaedic foot block in combination with a 3-day course of NSAID had a significant effect on recovery to soundness over a 35-day period. One notable difference between these studies was the method used to identify lame cows. In the former two studies, identification of lame cows was made by farm staff while in the latter study identification was made by the primary researcher using fortnightly mobility scoring. This is of significance as studies have shown that farmers identify and treat lame cows later in the disease process. Surveys based on mobility scoring show prevalence of lameness is around three times higher than farmer estimates (Whay and others 2003, Espejo and others 2006, Leach and others 2010) with farmers’ estimates of lameness prevalence more closely matching prevalence of cows scored as severely lame by the researchers (Leach and others 2010). This delay in recognition of milder lameness cases leads to a subsequent impact on lameness treatment, Alawneh and Stevenson (2012) found a median delay to treatment of 21 days for severely lame cows and 70 days for milder cases, Groenevelt and others (2014) found an average treatment delay of 37.7 days (range 7–126). While recent work suggests early treatment of lame cows is fundamental in promoting recovery and reducing recurrence of cases (Groenevelt and others 2014, Leach and others 2012), the
early and predominantly mild lesions seen in the UK RCT (Thomas and others 2015) may not necessarily be representative of those lame cows treated by farmers, foot trimmers and vets in the field due to delays in presentation by farm staff. In order to investigate the impact of chronicity of lameness on outcome following treatment, a further study was undertaken with the aim of filling the knowledge deficit in treatment of cows suffering more chronic and possibly more severe claw horn lesions.

Materials and methods
Study design and reporting
A prospective, positively controlled RCT with blind outcome observations was designed to test the recovery of dairy cows with claw horn lesions resulting in lameness of a greater than two weeks duration. Three different treatment protocols were tested (Table 1). The hypothesis of the study stated that the proportion of cows recovering from lameness would depend on the treatment administered.

The authors’ previous study demonstrated a 32 per cent difference in cure rate to soundness between treatment groups (56 per cent v 24 per cent; Thomas and others 2015). A power calculation suggested that treatment group sizes of 41 would detect a 30 per cent difference in recovery rate between treatments (power value of 0.8, P ≤0.05). Target group sizes of 60 were specified to allow for withdrawals and differences in treatment response rates in this study population.

The RCT was conducted under the Veterinary Surgeons Act 1966 which regulates acts of veterinary surgery in the UK. A therapeutic trim intervention was used as a positive control (i.e. no animals were untreated; see Table 1). All treatments trialled were considered ‘accepted’ practice by the industry at the time of the trial. The study protocol was approved by the University of Nottingham’s School of Veterinary Medicine and Science Ethical Review Committee. The study manuscript has been prepared in accordance with the guidelines outlined in the REFLECT statement for reporting RCTs in livestock (O’Connor and others 2010).

Herd selection
A convenience sample of seven commercial dairy farms within close proximity to the University of Nottingham was recruited.

Farms were either known to the research team or recommended by their veterinary surgeons. The farms recruited to the study were between 87 and 592 cows in size (median 147) with 305 day adjusted milk yields ranging from 6826 litres to 10670 litres (median 9062 litres). On six of the farms (farms 1, 2, 3, 4, 5 and 7) lactating cows were kept at pasture during the summer (~March–October), cubiclouse housed over the winter and milked twice daily. On one farm (farm 6) cows were continuously housed and milked on a robotic milking system. All farms undertook routine foot bathing (minimum once per week) with formaldehyde or copper sulfate for control of digital dermatitis and were visited either fortnightly (farm 7), monthly (farms 1, 2, 3, 4) or three times a year (farm 6, whole herd) by a professional hoof trimmer for routine hoof trimming. Farm 5 was visited three times a month by a professional hoof trimmer for treatments only. Additional lameness treatments were undertaken by the farmers or veterinary surgeons as required. Initial herd lameness prevalence ranged from 22 per cent to 59 per cent (median 50 per cent).

Cow selection and enrolment criteria
Beginning in December 2013, all lactating cows on each of the farms were mobility scored fortnightly using a six-point scale adapted from the DairyCo mobility scoring system (Table 2). Animals were uniquely identified by freeze-brand number. For cows with a mobility score of greater than 1, the lame leg was identified and recorded. Dry cows and youngstock were not scored. Mobility scoring was conducted by trained technicians as cows exited the parlour (farms 1, 2, 3, 4, 5 and 7) or in a passageway with a firm, level surface (farm 6). Each farm was allocated a trained technician for the duration of the study.

Animals were eligible for examination if they had at least two of the previous three mobility scores greater than 1 (lame) on the same hindleg with at least one of the scores greater than 2a (i.e. only animals with a unilateral hindlimb lameness were enrolled). Therefore cows were selected based on both chronicity and lameness severity. Cows must not have received treatment for lameness in the previous six weeks. If cows had been enrolled on the study previously, they were not eligible for re-enrolment on the same leg, however they could be selected for treatment on the opposite hindleg provided a minimum of six weeks had elapsed. Animals which had received parenteral antibiotics or anti-inflammatory treatment within the previous 14 days were excluded.

### Table 1: Treatments administered in a randomised controlled trial to test the recovery of cows with chronic claw horn lesions following different treatments

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Treatment name</th>
<th>Treatment definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (TRM)</td>
<td>Therapeutic foot trim only</td>
<td>1. Remove excess horn growth and investigate and trim out any lesions present. Remove diseased and under-run horn. As far as possible, rebalance claw height to reduce weightbearing on diseased claw (Toussaint Raven 1985)</td>
</tr>
<tr>
<td>2 (TS)</td>
<td>Therapeutic trim and plastic shoe</td>
<td>1. Therapeutic foot trim as in treatment 1. 2. Application of an orthopaedic plastic shoe* (Demotec, Niddereau, Germany) to the unaffected claw</td>
</tr>
<tr>
<td>3 (TSN)</td>
<td>Therapeutic trim, plastic shoe and NSAID</td>
<td>1. Therapeutic foot trim as in treatment 1. 2. Application of an orthopaedic plastic shoe* (Demotec, Niddereau, Germany) to the unaffected claw. 3. Administration of a three-day course of ketoprofen (Ketofen 10% solution for injection at 3 mg/kg intramuscular, Merial Animal Health, Woking, UK)</td>
</tr>
</tbody>
</table>

*Plastic shoe with weightbearing surface approximately 110 mm long, 55 mm wide and 18 mm deep. The shoe was positioned and fixed in place following the manufacturer’s instructions in an attempt to replicate normal claw placement and weight distribution.

TRM, trim only; TS, trim and shoe; TSN, trim, shoe and NSAID.

### Table 2: Mobility scoring descriptors employed in a randomised controlled trial to test the recovery of cows with chronic claw horn lesions following different treatments

<table>
<thead>
<tr>
<th>Mobility Description</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Walks with even weightbearing and rhythm on all four feet, with a flat back. Long fluid strides possible</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Steps uneven (rhythm or weightbearing or strides shortened, affected limb or limbs not immediately identifiable)</td>
<td></td>
</tr>
<tr>
<td>2a</td>
<td>Mild asymmetry in hindlimb movement. Decreased stride length on affected limb and slightly decreased stance duration with a corresponding increase in limb flight velocity on the non-affected side. Walking velocity remains normal. Back may be raised.</td>
<td></td>
</tr>
<tr>
<td>2b</td>
<td>Moderate asymmetry in hindlimb movement. Decreased stride length on affected limb and a distinct decrease in stance duration. Limb flight on the non-affected limb is correspondingly faster and the overall walking velocity is reduced. Back usually raised.</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>Severe asymmetry in hindlimb movement. Marked decrease in stride length on affected limb and very short stride duration. Limb flight on non-affected limb rapid and walking velocity reduced such that the cow cannot keep up with the healthy herd. Back raised.</td>
<td></td>
</tr>
<tr>
<td>3b</td>
<td>Minimal or non-weightbearing on affected limb. Back raised. Reluctant to walk without encouragement.</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted from the DairyCo Mobility Score system (www.dairyco.org.uk), the UK industry standard. Scores were subdivided to allow greater differentiation between levels of lameness, particularly in milder cases. Scores 2a and 2b and 3a and 3b can be amalgamated back to scores 2 and 3 in this system, respectively.
Examination of the lame foot of eligible cows was undertaken within two (±2wo) days of mobility scoring with the animal restrained in a foot trimming crush. Animals with infectious lesions (interdigital necrobacillosis or digital dermatitis) or a large interdigital growth on the lame foot were excluded. Identification of the painful claw was attempted using lateral rotation of the claw and application of hoof testers resulting in a withdrawal reflex. Each animal then received a five-stage, therapeutic trim of both claws of the foot identified as lame during mobility scoring (Table 1).

Animals where no lesions could be identified or diagnosed with substantial lesions in both claws where the cause of the lameness could not be attributed to a single claw were excluded. If the animal did not comply with or became unduly stressed by the study protocol it was excluded. Animals which failed to meet the enrolment criteria during examination were treated but were not enrolled. They could be considered again if found to be lame, providing a minimum of six weeks had elapsed since last treatment.

**Lesion classification**
Claw lesions were identified by the treatment operator during examination of the foot identified as lame during mobility scoring and placed into one of three categories;

1. sole haemorrhage or sole ulceration (SH/U): lesion or lesions composed of haemorrhage or an ulcer of the sole in any location
2. white line disease (WLD): lesion or lesions of any severity (haemorrhage through to complete separation) at any location on the white line; and
3. ‘other’ claw lesion: two or more lesions types on a single claw (e.g. SH/U and WLD) and any other claw lesion which could not be categorised as SH/U or WLD including those attributed to a single claw without visible lesions.

**Randomisation and treatment selection**
Three treatments were tested (Table 1). Treatment group 1. (‘TRM’) acted as the positive control group. A computer generated randomisation plan (randomizer.org) was created for each farm with 50 sets of 5 unique numbers per set (range 1–5). The randomised sequence was then transcribed onto cards in blocks of three (one random repetition of each treatment). The treatment group was assigned to the individual cow by selection of the next card from the holder following completion of the therapeutic trim at enrolment. The date and cow identification number were recorded on the card to prevent reuse and to allow cross-checking with data capture forms. Animals which had been enrolled were identified with a coloured band attached to each hindleg. Farmers were requested to manage enrolled cows following their normal practices and inform the researchers of any concerns between visits.

Treatments were undertaken on three of the farms (farms 5, 6 and 7) every two weeks throughout the study period. On the other four farms (farms 1, 2, 3 and 4) treatments were undertaken every four weeks. Farms 6 and 7 were treated by veterinarians (JGR and JNH respectively) while the remaining five farms (farms 1, 2, 3, 4 and 5) were treated by a fully licenced member of National Association of Cattle Foot Trimmers (AB). A research assistant (NJB) attended all visits to assist with data collection and ensure consistency in delivery of the study protocol.

**Treatment follow-up and outcome observations**
Animals were inspected at 14 (±3) days after treatment during the routine fortnightly mobility scoring session. They were eligible for retreatment if there were any concerns about their level of lameness and were excluded following retreatment. Animals which farm staff identified as failing to respond to treatment were also re-examined. Animals were re-examined after 28 (±3) days. If a plastic shoe had been applied and remained attached (TS and TSN), it was manually removed using trimming pincers and careful leverage. If the animal did not comply with or became unduly stressed by this procedure it was excluded.

The primary outcome measure was mobility score at 42 (±4) days after treatment; score was collected during the routine fortnightly mobility scoring. The observer was not aware of which leg had been treated or which treatment the animal had received.

**Additional data collected**
Body condition score (BCS) was assessed according to Edmonson and others (1989) using a scale of 1 to 5 with increments of 0.5 at the initial examination and four-week recheck/ shoe removal visit. Milk recording data were collected monthly on all farms. Animals which were sold, culled or died before the primary outcome measure were withdrawn from the study.

**Data collection and statistical analysis**
Data were captured at the time of enrolment, then transcribed and stored in a relational database (Access 2007, Microsoft Corporation, Redmond, Washington, USA) for analysis. Data for milk yield, parity and calving date were obtained directly from farm recording systems. The primary outcome measure were withdrawn from the study. Variables included at enrolment and four-week recheck (Table 1).

### Results

The proportion of successful treatments in animals which received TS and TSN were compared with animals which had received TRM for each measure of recovery. Univariable analysis of the treatment groups was carried out using a chi-squared test with $P \leq 0.05$ considered statistically significant. Data manipulation was carried out in Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington, USA) and univariable analysis was carried out in R V3.1.1 (R Core Team 2014).

Further analysis of the data set was carried out using multivariable logistic regression to account for confounding factors or clustering at the cow or farm level. Regression modelling was carried out in MLwiN V2.1 (Rasbash and others 2009) using stepwise forward selection, with $P \leq 0.05$ considered statistically significant. Single-level and two-level random effects models (case level and cow level) were fitted with treatment group forced into the model. Farm, parity, diagnosis, days in milk, BCS at enrolment, BCS four weeks after treatment, identity of technician conducting mobility score, test day milk yield, parity and calving date were obtained directly from farm recording systems. The primary outcome measure were withdrawn from the study. The proportion of successful treatments in animals which received TS and TSN were compared with animals which had received TRM for each measure of recovery. Univariable analysis of the treatment groups was carried out using a chi-squared test with $P \leq 0.05$ considered statistically significant. Data manipulation was carried out in Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington, USA) and univariable analysis was carried out in R V3.1.1 (R Core Team 2014).

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### Results

Enrolment of cows on farm 5 was suspended on April 16, 2014 at the request of the farmer due to time constraints. Enrolment of cows on farm 1 was suspended on July 1, 2014 as the protocol did not meet the expectations of the farmer. Farms 6 and 7 were recruited to the study on February 6, 2014 and July 4, 2014 respectively to replace farms 1 and 5. Enrolment of cows continued on these farms until the end of the study.

Between December 1, 2013 and January 16, 2015, 648 cows were examined after meeting the initial selection criteria. Of these 159 cases of lameness from 176 cows on the seven farms were enrolled on to the trial, 65 in group TRM, 64 in group TS
and 62 in group TSN. In total 33 cases were not available for outcome assessment, having been sold, culled, dried off or treated for other conditions and subsequently excluded (Fig 1). Of the 156 cows included in the final analysis, ten cows in the TS or TSN groups had lost their foot blocks by the four week recheck visit (6 in TS, 4 in TSN).

The number of cases in each of the three recovery outcomes is shown for each treatment group in Table 3. Of the 132 cases remaining mobility score lame (>1) 42 days after treatment, 60 (45.5 per cent) were identified as lame on the opposite leg to the leg identified as lame at enrolment. Univariable analysis using each of the recovery definitions (i. Non-lame, ii. Improved, iii. Apparent Leg-cure) identified no significant differences between the three treatment groups.

No statistically significant effect of treatment group was detected using multivariable analysis; given that the target sample size was exceeded the authors can be 80 per cent confident to detect a 27 percentage point difference in recovery between treatment groups. No further clinically relevant, statistically significant associations were identified in the data set.

Discussion
This study investigated the treatment of claw horn lesions in a cohort of cows with chronic lameness of at least two weeks duration (and often considerably longer). No difference in recovery at 42 days post treatment was found in cows treated with a plastic shoe or combination of a shoe and NSAID in addition to a therapeutic trim alone. Importantly, overall only 15 per cent of cows were non-lame at study outcome meaning response rate to treatment was very low, and almost identical between groups. When comparing these results with a similar UK RCT investigating the recovery of acutely lame cows treated for claw horn lesions (Thomas and others 2015) it is evident that delaying the time to administration of treatment had a profound effect on outcome. The study by Thomas and others (2015) followed a similar protocol, but in this instance selected acutely lame cows (<two weeks) for treatment. Cows that met the enrolment criteria all received a therapeutic foot trim followed by random allocation of a foot block, course of NSAID, combination of a foot block and course of NSAID or no further treatment. Cows in the trim, block and NSAID groups were significantly more likely to be sound at outcome and the proportion of cows which were non-lame at outcome ranged between 69 per cent (trim only) and 55 per cent (trim, block and NSAID). These response rates to treatment are substantially higher than the results reported here and provide more evidence that early identification and treatment is key to successful recovery regardless of what treatment is administered. Once lameness caused by claw horn lesions becomes chronic, it is much more difficult to treat successfully.

Whilst the studies were similar, there were small differences in study methodology. In the current study animals were treated with a plastic shoe (compared with a wooden block), outcome was at six weeks post treatment (compared with five weeks) and blocks were not reapplied if they were not present one week after application. Whilst the authors consider it unlikely, it remains possible, that the differences in results observed were in whole or in part due to these small differences in methodology.

Part of the explanation for the large difference in recovery rate seen between these two RCTs was the number of animals which were lame on the contralateral hindlimb at outcome (58 per cent (60 of 156) compared with 11 per cent (19 of 167)). If

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**FIG 1:** Diagram showing the number of animals examined, randomly allocated to treatment groups and completing the study protocol, in a randomised controlled trial investigating the treatment of chronic claw horn lesions. *Lesions ranged from mild to severe but did not include any lesions with an infectious component (e.g. lesions with secondary digital dermatitis infection). A presumptive diagnosis of ‘other’ claw horn lesion was made in four cows (1× TRM, 2× TS, 1× TSN) with no visible lesions where claw pain was present and no infectious cause was identified. SH/U, sole haemorrhage or sole ulceration; WLD, white line disease.
these animals are considered a successful treatment (all be it of that limb only) the response rate increases to 54 per cent overall, lower but at least closer to the treatment success reported by Thomas and others (2015). The authors propose two explanations for the difference in the number of animals lame on the contralateral limb between the studies. First, as many of the proposed factors leading to claw horn lesions occur at a cow level, it is reasonable to expect that changes occur in both hindlimbs, however the delay to treatment may mean this effect is magnified as bilateral lesions have had longer to develop. Alternatively the increase in loading on the contralateral limb in these more chronically (and severely) lame animals could have precipitated or exacerbated the development of more severe lesions in the other hindlimb.

The results of the present study suggest that in all but the most acute cases of lameness, both hindlimbs should be treated at the initial examination even if lameness is only evident in one limb, to reduce the likelihood of a contralateral lameness occurring in the following weeks. Where the cow is severely lame, this may present ethical issues as the cow would be required to bear all its weight on the lame leg whilst the other leg is treated. Consequently early interventions to avoid this situation are always more appropriate. Where this is not possible everything should be done to reduce the length of time the animals spends standing on the lame leg, whilst the contralateral leg is treated. Alternative tactics could include an initial treatment of the lame claw only with a repeat examination and treatment of both hindlimbs as soon as possible, or the use of crashes which remove hindlimb weight bearing during treatment providing they do not compromise the animal’s welfare. Provision of local analgesia (e. g. by intravenous regional anaesthesia) may also be considered both for the initial treatment of the affected claw and weight-bearing on the lame leg whilst trimming the contralateral foot. It is clear more studies are needed to fully investigate the development and resolution of bilateral lameness and the most successful strategies for its treatment.

Two further RCTs have been published looking at the efficacy of treatments for claw horn lesions in dairy cows. Comparisons with the first study conducted in Australia (Pyman 1997) are difficult due to differences and deficits in study design (e. g. lack of a control group and short time to outcome (14 days)). The findings of the study presented here are more directly comparable with that of Laven and others (2008) where animals identified as lame by farm staff in New Zealand received a corrective trim then were randomly allocated the addition of a plastic shoe, NSAID, a combination of a plastic shoe and NSAID or no further treatment. Both mobility score and nociceptive threshold were recorded; the authors found no statistically significant difference between the treatment groups. The prevalence and causes of lameness in animals managed under New Zealand’s more extensive management systems are different from those seen in the higher yielding, more indoor systems which predominate in the UK and Europe. Additionally as cows treated in the New Zealand study were detected by farm staff (rather than by fortnightly mobility scoring by trained technicians) it is not possible to know the duration of lameness in the cows treated in this study. That said a number of studies have shown farmers are more likely to identify cows at a later and more severe stage of lameness (Whay and others 2003, Espejo and others 2006, Leach and others 2010) and so it can be assumed these cows are likely to be chronically lame. It is noteworthy that despite these differences neither study identified differences between treatment groups which once again reinforces the importance of early intervention to provide effective treatment.

The results of this study were generated from a convenience sample of farms in close proximity to the University of Nottingham, they were not randomly drawn from the population. That said the authors have no reason to suspect that both the animals and management practices are not broadly representative of other farms across the UK.

Differences in outcome between the treatment groups in this study were not significant. It remains possible however that differences do exist but that they are less than 27 percentage points (compared with retrospective power calculation). Treatment operator differed between farms as did the technicians conducting mobility scoring; both variables were tested in the multivariable model to account for differences between operators. Farm, mobility scorer and treatment operator were correlated and could not be tested together. As the final model showed no significant differences between the farms participating in the study, the authors suppose there was no significant effect of operator or observer variability. Finally the impact of between farm differences such as this were minimised by blocking treatment group by farm (i.e. achieving similar numbers of cows in each treatment group on each farm).

Conclusions

In this RCT investigating the treatment of chronic lameness caused by claw horn lesions in dairy cows there were no differences between treatment groups. Response to treatment was poor regardless of the treatment administered. When this study is considered together with a similar UK study which treated acutely lame cows it has identified two key clinical findings. First, any delay in the time to treatment of claw horn lesions, regardless of the treatment administered, is likely to reduce the rate of recovery. This suggests that early identification and prompt effective treatment of claw horn lesions is key to their successful management. Secondly, when treating lame cows with claw horn lesions, they should be considered to have lesions on both hindlegs regardless of which leg is identified as lame. A therapeutic trim (plus additional treatment(s) as required), of the non-lame leg should consequently be implemented at the time of examination. This is particularly true if the time from the onset of lameness is unknown as the animal could be chronically lame.

In practice this suggests that all newly and mildly lame animals should be screened systematically at least fortnightly. This is unlikely to be achieved by casual observation during routine management procedures. Until automated systems for reliably screening cows for lameness become more widely available, regular and routine mobility scoring of the whole herd remains the only practical method to achieve this. Results of a recent UK study (Thomas and others 2015) suggest that using a combination of a therapeutic trim plus the addition of a foot block and course of NSAID results in the best outcome in these newly lame animals. Whilst these additional treatments offered no significant benefit outcome in this study, their use in chronically lame cows can be justified on welfare grounds alone.

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