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INTERPRETIVE SUMMARY

Evaluation of treatments for claw horn lesions in dairy cows. Thomas.

Lameness in dairy cows is a significant health and welfare problem around the world.

Diseases affecting the hoof are some of the most common problems. Thousands of animals are treated for these conditions, yet there is little research evidence on the most effective treatments. We tested four treatments in an on-farm trial. A therapeutic trim alone or in combination with either elevating the diseased digit using a glue on block, or a course of anti-inflammatories or both additional treatments. The combination of trimming, elevation of the claw and course of anti-inflammatories was most successful. We recommend its use on-farm.
EVALUATION OF TREATMENTS FOR CLAW LESIONS

Evaluation of treatments for claw horn lesions in dairy cows in a randomized controlled trial


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ABSTRACT

Lameness is one of the most significant endemic disease problems facing the dairy industry. Claw horn lesions (principally sole haemorrhage, sole ulcer and white line disease) are some of the most prevalent conditions. Despite the fact that thousands of animals are treated for these conditions every year, there is limited experimental evidence on the most effective treatment protocols.

A randomized, positively controlled clinical trial was conducted to test the recovery of newly lame cows with claw horn lesions. Animals on five farms were locomotion scored every two weeks. Cows were eligible for recruitment if they had two non-lame scores followed by a lame score and had a claw horn lesion on a single claw of a single foot.

Following a therapeutic trim, enrolled cows were randomly allocated to one of four treatments: Treatment 1 – no further treatment (positive control; ‘TRIM’), Treatment 2 – trim plus a block on the sound claw (‘TRIM/BLOCK’), Treatment 3 – trim plus a 3 day course of the non-steroidal anti-inflammatory drug (NSAID) ketoprofen (‘TRIM/NSAID’), Treatment 4 – trim plus a block plus ketoprofen (‘TRIM/BLOCK/NSAID’). The primary outcome measure was locomotion score 35 days after treatment, by an observer blind to treatment group.

Descriptive statistics suggested that treatment groups were balanced at the time of enrolment i.e. randomization was successful. Based on a sound locomotion score (Score 0) 35 days after treatment, the number of cures was 11 of 45 (24.4%) for TRIM, 14 of 39 (35.9%) for TRIM/BLOCK, 12 of 42 (28.6%) for TRIM/NSAID and 23 of 41 (56.1%) for TRIM/BLOCK/NSAID. The difference between TRIM/BLOCK/NSAID and TRIM was significant.

To test for confounding imbalances between treatment groups, logistic regression models were built with two outcomes, either sound (Score 0) or non-lame (Score 0 or 1) 35
days after treatment. Compared to TRIM, animals which received TRIM/BLOCK/NSAID
were significantly more likely to cure to a sound outcome. Farm, treatment season, lesion
diagnosis, limb affected, treatment operator and stage of lactation were included in the final
models.

Our work suggests that lameness cure is maximised with NSAID treatment in addition
to the common practices of therapeutic trimming and elevation of the diseased claw using a
block when cows are newly and predominantly mildly lame.

Key words: dairy cow, lameness, claw horn lesion, randomized clinical trial
INTRODUCTION

Lameness in dairy cattle is a significant problem in intensive dairy industries around the world, causing both production losses (Huxley, 2013) and discomfort, undermining animal welfare (Whay et al., 1997). Achieving sustainable reductions in the levels of disease on-farm, requires a combination of two approaches. Firstly, the implementation of effective farm-specific prevention strategies to decrease the rate at which new cases develop, and, secondly, early identification and prompt and effective treatment of clinical cases to reduce the duration of time over which animals are lame. While the emphasis of the majority of recent research has rightly focused on identifying risk factors for lameness and disease prevention, the treatment of animals once they become lame must not be neglected.

Sole haemorrhage, sole ulcer and white line disease (the most common claw horn lesions) are some of the most prevalent conditions causing lameness (Capion et al., 2008, Cramer et al., 2008). Despite the fact that many thousands of animals are routinely treated for these diseases, a recent systematic review of the peer reviewed literature on the prevention and treatment of foot lameness in cattle highlighted the deficit of information in this area (Potterton et al., 2012). In literature published between 2000 and 2011, no papers were identified concerned with the treatment of white line disease and only three with the treatment of sole ulcers. Of these, two were case studies (i.e. not experimental) and whilst the third was composed of primary research it assessed dietary supplementation with Biotin (Lischer et al., 2002) and is of limited use in the field. The authors concluded that virtually all the existing information on the treatment of claw horn lesions appeared to be from anecdotal reports, based on the experience and knowledge of experts working in the field. This does not mean to say that current treatment protocols are ineffective, rather it highlighted the deficit of experimental evidence on the most effective treatment i.e. those that lead to the highest cure rates in the shortest time.
An extension of the literature search described above confirms that very little primary research work has ever been published testing treatments for claw horn lesions, only two other peer reviewed papers were identified. The first describes a randomized study conducted in Australia which tested wooden blocks, rubberised shoes and padded bandages containing copper sulphate for the treatment of a variety of claw horn lesions (Pyman, 1997). Three and seven days after treatment, significantly high number of cows had recovered in the block and shoe groups compared with the bandage group; outcome assessment was limited to 14 days post treatment by which time no differences between groups were apparent. In the second, dairy cows managed under New Zealand’s extensive pasture based systems, were randomly treated with a plastic shoe and the non-steroidal anti-inflammatory drug (NSAID) Tolfenamic acid, following corrective trimming (Laven et al., 2008). The authors concluded that there were no significant differences between treatments in either nociceptive threshold or locomotion score over the 100 day outcome period. The objective of the present study was to compare four treatments for claw horn lesions in a randomized study under UK field conditions.

MATERIALS AND METHODS

Study Design and Reporting
A positively controlled, randomized clinical trial (RCT) with blind outcome observations was designed to test the recovery of dairy cows with claw horn lesions, treated using different protocols. The study hypothesis stated that the likelihood of claw horn lesion recovery depended on the treatment administered. Based on a binary primary outcome measure (lame or not lame) post treatment, a power calculation suggested that treatment group sizes of 58 would detect a 25% difference in recovery rate between treatments (power value of 0.8, $P \leq$
A difference of 25% was selected as it was considered clinically meaningful and likely to be large enough to warrant the additional cost of the treatments tested should they prove superior.

The study was positively controlled (i.e. no animals were left untreated) and conducted under the Veterinary Surgeons Act 1966, which regulates acts of veterinary surgery in the UK. The protocol was reviewed and approved by the University of Nottingham’s School of Veterinary Medicine and Science Ethical Review Committee prior to study instigation.

The study manuscript has been prepared in accordance with the guidelines outlined in the REFLECT statement for reporting randomized controlled trials in livestock (O’Connor et al., 2010).

**Herd Selection**

A convenience sample of five commercial dairy farms was recruited in the East Midlands area of the UK, within close proximity to the University of Nottingham. To be eligible for enrolment, farms were required to have a herd lameness prevalence of above 20% at the start of the study and be undertaking routine measures to control digital dermatitis at the herd level (e.g. regular foot bathing). Farms were either known to the trial coordinators or were recruited through their veterinary surgeons’ who were asked to nominate clients they considered met the criteria and would be willing to participate. A short list of suggested farms were approached and visited to discuss the trial and to assess their lameness prevalence. Following an introductory phone call, one farm elected not to participate as they considered the trial would interfere with their day to day farm management.

The five farms were between 187 and 353 (median 241) cows in size with 305-d adjusted milk yields ranging from 7,394 to 11,579L (median 10,381L). Three of the farms
(Farms 2, 4 and 5) housed lactating cows continuously, the other two farms managed cows at
pasture during the summer (~March – October) and in housing over winter. On all farms,
lactating cows were accommodated in stalls with mats, mattresses or waterbeds. Two farms
(Farms 2 and 4) milked cows in an automatic milking system, the remaining farms milked
cows in conventional parlours, two times daily. All walkways and standing areas were
concrete on all farms except Farm 2 which had rubber matting throughout and Farm 3 which
had rubber matting at the feed face of the high yielding group. All farms undertook routine
foot trimming, although scheduling ranged from as required to weekly sessions; two farms
(Farms 1 and 2) used an external professional foot trimmer, on the other farms trimming was
conducted by farm staff. All the farm routines were that lame cows were treated as soon as
they were identified or at weekly or fortnightly routine health sessions, depending on disease
severity and staff availability. Farmers were advised to continue their normal procedures for
identifying and treating lame cows throughout the study period.

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**Cow Selection and Enrolment Criteria**

Beginning in December 2011, locomotion scoring of all cows in the lactating herd was
undertaken at fortnightly intervals, by trained experienced observers (HT, GMP, NJB), as
cows exited the milking parlour (Farms 1, 3 and 5) or in a passageway with a firm, level
surface (Farms 2 & 4). All animals in all herds were uniquely identified by freeze brand,
which was used to distinguish individual cows. Dry cows and young stock were not scored.
Cows were scored on a 6 point scale adapted from the Great Britain industry standard scoring
system (Table 1); for animals considered lame (> 1), the lame limb was identified and
recorded.

Animals were considered for enrolment if they presented with a new case of lameness
in a single hind limb i.e. two successive non-lame scores (0 or 1) followed by a lame score (>
Animals were excluded if they had received treatment for lameness in the same foot within 120 days, treatment for lameness in another foot within 90 days or had completed a course of parenteral antibiotics or NSAIDs within the previous 14 days.

Selected cows were examined within 48 hours of the locomotion scoring. Animals were assessed for body condition score (BCS) according to Edmonson et al. (1989) using a scale of 1-5 with increments of 0.5. The lame foot was inspected with the animal restrained in a foot trimming crush. Animals were excluded if they were diagnosed with interdigital necrobacillosis, active digital dermatitis (an M1, M2 or M4.1 lesion (Berry et al., 2012)), substantial inter-digital hyperplasia or a significant hock lesion. Identification of the painful claw was attempted by lateral rotation of the claw resulting in a withdrawal reflex and the application of hoof testers. Each animal received a therapeutic trim of the whole foot (i.e. both claws) consisting of a standard trim, investigation and trimming out of any lesions identified, removal of diseased and under-run horn and rebalancing the claw height to reduce weight bearing on the diseased claw (Toussaint Raven, 2002). Animals were excluded from the study where lesions were identified in both claws i.e. only animals with a claw horn lesion(s) on one claw of a single lame hind leg were eligible for inclusion.

Animals which did not meet these enrolment criteria were treated but not enrolled. They took no further part in the study, but they could be considered again in the future providing the minimum lag periods since treatment had elapsed. Animals could only be enrolled onto the study once; if they presented with lameness on the same or a different leg in the future they were excluded.

**Lesion Classification**

Claw lesions identified during examination of the feet of enrolled animals were classified into one of three groups:
1. Sole haemorrhage / sole ulceration (SH/U): Lesion(s) composed of haemorrhage or an ulcer of the sole in any location

2. White line disease (WLD): Lesion(s) of any severity (haemorrhage through to complete separation) at any location on the white line

3. Other claw horn lesion: Any other claw horn lesion(s) that could not be categorised as SH/U or WLD or two or more different lesions on the same claw (e.g. SH/U and WLD)

### Randomization and Treatments Administered

Enrolled animals were randomly allocated to one of four treatment groups (Table 2), using a computer generated randomization plan (www.randomization.com, work conducted by HT) created in blocks of four, with each of the four treatment groups included once in each block.

Randomization was further blocked by farm and lesion type (SH/U, WLD or ‘Other’), to ensure approximate temporal matching of equal numbers of cows with each diagnosis within each study farm. Group 1 (Therapeutic trim only; ‘TRIM’) was considered the positive control group. Following completion of the therapeutic trim, animals were allocated to treatment group by drawing consecutively numbered cards from a card index box which had the treatment written on the reverse side.

Drawing of the randomization cards and administration of treatments were conducted by trained veterinary surgeons familiar with the treatment of lame cows and predominantly undertaken by a single operator (HT) with vacation cover (SA, OM, JH and JR). Operators administering treatments were not blind to the treatment administered. Enrolled animals were identified with a leg band on both hind limbs. Farmers were asked to continue managing them in accordance with normal farm management practices but were requested not to treat them for lameness and to notify the researcher if they felt that further intervention was necessary. Farmers were not blind to treatment group, whilst they were not provided with a
list of treatments administered, the presence of a therapeutic blocks could be observed and
treatment with NSAID was recorded in their medicine records.

Treatment Follow Up and Outcome Observations

Animals were re-examined eight days (± 3 days) after treatment. If a foot block had been
applied as part of the treatment protocol (Treatment 2 (‘TRIM/BLOCK’) and Treatment 4
(TRIM/BLOCK/NSAID’)) and it was no longer present, it was reapplied. If their locomotion
score had deteriorated from that at the time of enrolment, animals were retreated.

Animals in groups TRIM/BLOCK and TRIM/BLOCK/NSAID were re-examined for
a second time, 28 days (± 3 days) after treatment. If the block was still present, it was
manually removed using trimming pincers and careful leverage. This was the only action
undertaken at this time point i.e. no additional treatment(s) were administered.

The primary outcome measure, locomotion score 35 days (± 4 days) after treatment,
was conducted by an independent observer (GMP) blind to treatment group. That observer
collected outcome scores with cows walking in isolation, on a firm level surface. For animals
considered lame (> 1), the lame limb was identified and recorded. Following the blind
outcome score animals were body conditioned scored using the method previously described
and the treated limb was elevated and examined for digital dermatitis and any other
conditions.

Additional Data Collected

Data on parity, monthly milk yield and calving date were collated from farm records.
Animals which were sold, culled or died before assessment of the primary outcome measure
were recorded and withdrawn from the study.
Data Collation and Statistical Analysis

Data collected for each cow at each visit were recorded onto data capture forms and then transcribed and stored in a relational database (Access 2007, Microsoft Corporation). Data analysis was conducted in Minitab 16 (Minitab Inc.). Data were audited for validity and spurious records using entry rules set up in the database and by manually scanning for outlying data following sorting within each data category. For analysis locomotion scores 2a and 2b, and 3a and 3b were amalgamated to 2 and 3 respectively.

Differences between treatment groups at the time of enrolment were assessed by analysis of variance (days in milk and last recorded monthly yield) and using the Kruskal-Wallis test (lameness score at treatment, body condition score at treatment and parity).

A successful treatment at study outcome (35 days after treatment) was defined as either: i. a sound locomotion score (Score 0) or ii. a non-lame score (Score 0 or 1). The proportions of successful treatments in animals which received TRIM/BLOCK, TRIM/NSAID (Treatment group 3) and TRIM/BLOCK/NSAID were each compared to TRIM using the $\chi^2$ test. A Bonferroni corrected $P$ value was calculated to account for multiple comparisons; the significance probability was set at $P \leq 0.05$ for a two tailed test.

To test for confounding effects in the results, a multivariable analysis was conducted. Logistic regression models were built in MLwiN (Version 2.1, Centre for Multilevel Modelling, University of Bristol), with the same outcomes described above: i. a sound locomotion score (Score 0) 35 days after treatment and ii. a non-lame score (Score 0 or 1) 35 days after treatment. Farm and treatment were forced into the models as categorical fixed effects. Other variables and plausible interactions were investigated by forwards selection, for inclusion stepwise. Variables were eliminated from the model based on the Wald test if $P \leq 0.05$. Variables tested included parity (1, 2, 3, $\geq 4$), days in milk, calving season (winter, spring, summer, autumn), season of treatment, locomotion score at treatment, lame leg at
treatment, BCS at treatment and outcome, lesion classification (SH/U, WLD, Other), active
DD at outcome (Yes/No), retreatment required at 8 day recheck visit (Yes/No), reapplication
of block required at eight day recheck visit (Yes/No), treatment operator (principal operator
(HT) or ‘other’ operators (SA, OM, JH, JR)) and milk yield at the last two monthly
recordings. DIM was tested as a linear mean centred variable, a categorical variable in 30 d
increments, and as a non-linear variable; $e^{-0.065 * \text{DIM}}$ (Silvestre et al., 2006).

To assess fit, model predictions were compared to the observed data in groups
stratified by categorical variables in the model, such as treatment group. Predictions were
generated by simulation. The models were deemed adequate if observed values were within
95% confidence intervals of prediction.

RESULTS

Study Inclusions

Between the 10th of January 2012 and the 31st January 2013 a total of 512 cows met the initial
selection criteria and were examined. Enrolment of cows on Farm 3 was suspended on the
24th of April 2012 due to the very low numbers of animals which were becoming eligible for
enrolment (i.e. the number of new cases of lameness had dropped substantially from the start
of the study). Farm 5 was recruited as a replacement; enrolment began on the 17th of July
2012 and continued to the end of the study. Selection of cows on Farm 3 recommenced on the
16th of November 2012 and continued to the end of the study. Of the selected and examined
cows, 183 met all of the inclusion criteria and were enrolled into the RCT. The remaining 329
animals were not enrolled for the following reasons: 227 (68.9%) had a lesion on both claws;
27 (8.2%) had no visible lesion on either claw and no painful claw could be identified; two
(0.6%) were no longer lame, 41 (12.5%) had active digital dermatitis, three (0.9%) had
interdigital necrobacillosis, one (0.3%) had an inter-digital hyperplasia, six (1.8%) had a hock
lesion, 14 (4.3%) had been treated by farm staff and eight (2.4%) were not compliant with
the study protocol.

The number of cows allocated to each of the treatment groups by lesion diagnosis and
farm is outlined in Table 3. In total 47 cows received TRIM, 46 TRIM/BLOCK, 45
TRIM/NSAID and 45 TRIM/BLOCK/NSAID. Of the enrolled cows, 171 (93.4%) presented
with a locomotion score of 2 and 12 (6.6%) with a score of 3.

**Study Exclusions**

Sixteen enrolled cows were withdrawn before the primary outcome was assessed. One
animal (Fm 1, TRIM/NSAID) was culled; five animals (Fm 2, TRIM/BLOCK x2; Fm 4,
TRIM/BLOCK/NSAID; Fm 5, TRIM/BLOCK x1 & TRIM/BLOCK/NSAID x1) were
withdrawn for non-compliance with the study protocol after enrolment (e.g. becoming unduly
stressed or repeated collapsing in the crush); four animals (Fm 2, TRIM/NSAID x1 &
TRIM/BLOCK/NSAID x1; Fm 4, TRIM/BLOCK x1 & TRIM/BLOCK/NSAID x1) were
retreated by the farmer without informing the researcher and six animals (Fm 1,
TRIM/BLOCK x1 & TRIM/NSAID x1; Fm 2, TRIM/BLOCK; Fm 4, TRIM x1 &
TRIM/NSAID x1; Fm 5, TRIM) were lost to the study or were unavailable for reassessment
for other reasons (e.g. moved to a distant location or incorrectly identified). Of the remaining
167 enrolled animals, six animals (Fm 1, TRIM x1 & TRIM/BLOCK x1; Fm 2,
TRIM/BLOCK x1 & TRIM/NSAID x1) required retreatment at the eight day recheck visit. Two received additional trimming,
two had their foot block removed and repositioned, one was treated for digital dermatitis with
topical oxytetracycline spray (Alamycin aerosol 3.58% w/w cutaneous spray solution,
Norbrook) and one received treatment for a hock lesion by cleaning and the application of
topical oxytetracycline spray. Seventeen animals that received TRIM/BLOCK (seven animals)
and TRIM/BLOCK/NSAID (10 animals) required the reapplication of a foot block at the eight day recheck visit because it was no longer present. One hundred and forty four cows were treated by the principal operator (HT) and 23 cows were treated by other operators (SA, JR, JH or OM).

Descriptive Results and Univariate Analysis

The parity, days in milk, last recorded milk yield and body condition score and lameness score at treatment of enrolled cows by treatment group are outlined in Table 4. Differences between groups were not significant.

The locomotion scores of enrolled cows at outcome, 35 days after treatment, are outlined in Table 5. Based on a sound score (Score 0) the number (and percentage) of successful treatments was 11 of 45 (24.4%) for TRIM, 14 of 39 (35.9%) for TRIM/BLOCK, 12 of 42 (28.6%) for TRIM/NSAID and 23 of 41 (56.1%) for TRIM/BLOCK/NSAID. The difference between TRIM/BLOCK/NSAID and TRIM was significant (Bonferroni corrected $P = 0.01$).

Based on a non-lame score (Score 0 or 1), the number (and proportion) of successful treatment was 31 of 45 (68.8%) for TRIM, 28 of 39 (71.8%) for TRIM/BLOCK, 32 of 42 (76.2%) for TRIM/NSAID and 35 of 41 (85.3%) for TRIM/BLOCK/NSAID. The differences between groups were not significant.

Of the lame animals 35 days after treatment, the number (and proportion) of animals lame on the leg that was treated at enrolment was eight of 14 (57.1%) for TRIM, four of 11 (36.4%) for TRIM/BLOCK, five of 10 (50%) for TRIM/NSAID and five of six (83.3%) for TRIM/BLOCK/NSAID.

Logistic Regression Analysis
Of the enrolled cows, 85 and 66 had missing milk recording records in the preceding one and two months respectively. Milk recording records in the two months preceding treatment were tested in models based on subsets of the dataset with no missing records. Eight animals had missing records for DIM and were discarded.

Model fit to the data was acceptable, and results of the logistic regression models are outlined in Table 6. In the first model testing cure to outcome i. (Score 0), animals in the TRIM/BLOCK/NSAID group were significantly more likely to cure compared to cows in the TRIM group ($P \leq 0.05$). Cows treated on Farm 5, compared to other study farms, and treatments in Spring and Autumn, compared to treatments in winter, were less likely to cure.

In the second model testing cure to outcome ii. (Score 0 or 1), treatment group was not significant, however there was a trend for animals in the TRIM/BLOCK/NSAID group to be more likely to cure compared to cows in the TRIM group (odds ratio 3.2, 95% CI 0.9-11.3). Cows with ‘Other’ lesions had lower odds of cure compared to cows treated for SH/U and animals treated by ‘Other’ operators were less likely to cure than those treated by the principal operator.

In both models, animals treated on the left hind limb were more likely to cure (compared to those treated for lameness on the right hind limb) and cows were more likely to recover when treated in early lactation with exponential decay in the relationship with time after calving.

**DISCUSSION**

In this study, lame cows treated for a claw horn lesion in a single claw of a single leg recovered at different rates depending on the treatment administered. Cows treated with a therapeutic trim, block and NSAIDs were more likely to recover to a sound locomotion score than those treated with a therapeutic trim alone.
One of the surprising findings from our study was how small the differences in treatment success were between therapeutic trim and the application of a block to the sound claw and therapeutic trim alone. Only when a NSAID was added to the block and trim were significant differences in outcome seen. The application of a block to the sound claw as a treatment for lameness is a common practice around the world. In a recent review of text books and grey literature (e.g. reports and control plans) (Potterton et al., 2012), 85% of sources advocated their use for claw horn lesion. Behind a therapeutic trim, therapeutic blocks were the next most common treatment option described. Similarly in a recent survey of UK dairy farmers over 90% reported using blocks and 70% considered trim and block an effective treatment for claw horn lesions (Horseman et al., 2013).

The aetiology of claw horn lesions has not been fully elucidated; whatever the underlying cause, compression of the sole corium leads to vascular compromise, ischaemia, haemorrhage and ultimately interruption of keratogenesis and the development of lesions. The application of a block to the sound claw is thought to reduce load bearing and hence compression of the corium in the diseased claw and allow the compromised tissues to heal. It is noteworthy that only marginal, non-significant differences in cure rates were observed following the administration of NSAID without a block or a block without NSAID. This suggests that reduction in load bearing and NSAID action were synergistic in this study. We propose two hypotheses for this observation. Firstly the NSAID could be having a direct effect at the corium, reducing inflammation and assisting the corium to heal if loading is reduced by a block. Alternatively it seems credible that blocks may cause some discomfort following application, this may modify behaviour (e.g. changing lying or feeding time) or cause a redistribution of weight bearing between the claws and limbs leading to a reduction in the rate of healing of the diseased claw. Administration of a NSAID in combination with a block may mitigate these possible changes. Our results provide some circumstantial evidence
of this effect. At outcome (35 days after treatment), six, seven and five cows were lame on
the contralateral hind leg in the TRIM, TRIM/BLOCK and TRIM/NSAID groups
respectively, this compares to just one cow in the TRIM/BLOCK/NSAID group. Lame cows
in the TRIM, TRIM/BLOCK and TRIM/NSAID groups may have increased loading on the
contralateral hind limb predisposing it to lesion progression and lameness. Cows in the
TRIM/BLOCK/NSAID group may have been comfortable to bear weight evenly on the lame
limb, whilst at the same time the block allowed the diseased claw to heal. Further work is
required to confirm our findings and better understand the mechanisms of action and benefits
of different treatment options in cows with claw horn lesions.

Our results disagree with those reported by Laven et al (2008), who saw no difference
in outcomes between lame cows with claw horn lesions treated with blocks and the NSAID
tolfenamic acid in addition to a therapeutic trim alone. Whilst the study designs are not
directly comparable they have a range of similarities making comparisons between outcomes
legitimate. The differences in outcome observed could be due to differences in case selection
(identified by an external observer as soon as lame vs identified by farm staff and therefore
likely to be more chronically lame), management system (more intensive predominantly
housed vs more extensive predominantly pasture based), cow type (predominantly higher
yielding Holstein type vs predominantly lower yielding Friesian and Jersey type) or other
unidentified factors.

The study population recruited to this RCT was a convenience sample. That said we have no
reason to suspect that it was not broadly representative of both cow and farm types common
in the UK (all be it that two of the study farms used automatic milking systems). Enrolled
cows selected from this population were predominantly newly and mildly lame. A previous
study reported a median lag of 65 days between when cows can first be identified as lame by
an external observer and when they were identified for treatment by farmers (Leach et al., 2012). This may be because, as recent work suggests, many farmers do not identify or refer to milder cases as ‘lame’ (i.e. score 2 in this study). It appears they reserve the term ‘lame’ for more severe cases (i.e. score 3 in this study) (Horseman et al., 2014). Consequently if farmers do not consider that milder cases are ‘lame’ it stands to reason that they would not necessarily be considered for treatment. In our study, animals were locomotion scored every two weeks and treated as soon as they became identifiably lame. The period of time which could have elapsed between animals first becoming lame and being treated ranged between two and 16 days (fortnightly locomotion scoring plus lag to treatment visit). The majority of cows (93%) presented with the mildest lameness classification (Score 2). This population was selected firstly because we considered it ethically questionable to identify and then knowingly leave lame animals for a number of weeks before they were treated and secondly because we believe that these are the animals which the industry should be targeting for treatment. Readers should note that our study population, and consequently our results, may not reflect the cases which many farmers routinely identify and present for treatment and at this stage it is not possible to say whether our results are generalisable to more severe and / or chronic cases managed in different farm systems. Further studies are needed to replicate this type of clinical trial to test treatment protocols in more chronically and severely lame animals, providing this work does not encourage or condone delayed treatment on-farm.

A range of other variables were significant in the final models (i.e. they significantly impacted on cure), including farm, limb treated, days in milk, season of treatment, diagnosis and operator. Of note, cure rates to soundness on one farm (Farm 5) were significantly worse than on other study farms. Despite identical case selection criteria, an unidentified factor(s) significantly affected outcome following all treatments on this unit. Clinically, it is important that farms with poor cure rates are identified and the reasons for poor responses are explored.
to limit the impacts of this painful disease on health and welfare. It is also interesting to note that cows were more likely to recover from lameness when treated in early lactation and that there was an exponential decay in the relationship with time after calving. Whilst animals were not enrolled until at least 120 days had elapsed since their last treatment on the same limb, the reduction in treatment success could reflect lower recovery rates in feet with more chronic lesions from previous lameness events. Finally, the reasons for the difference in cure rates between left and right limbs is unclear, it could reflect an operator bias based on the relative ease of trimming left and right feet, depending on the dominant hand of the worker.

Logistically, this was a complex, expensive and time consuming study protocol to conduct; this may explain why so few of these studies have been conducted previously. The low proportion of cows which met all the selection criteria was particularly challenging, over 500 animals had to be examined and trimmed to enrol 183 cows. The principal reason, making up nearly 70% of exclusion, were animals with lesions on both claws, i.e. even if the claw causing the lameness was obvious, large numbers of animals had mild lesions on the contralateral claw. Whilst in practice, therapeutic blocks are often applied to claws with visible but mild lesions we felt it important that this was not the case in a RCT. The use of blocks as part of treatment also necessitated an additional crush restraint intervention to remove blocks from treatment groups which had received them. We considered this necessary firstly to blind treatment group from the outcome observer and secondly because work suggests that cows alter their gait whilst walking on blocks (Higginson Cutler, 2012). Workers wishing to undertake studies such as this may wish to consider their selection criteria, case definitions and study methodology carefully to avoid some of the logistical problems we encountered.

The study of lameness treatment protocols has lagged behind that of similarly important endemic diseases such as mastitis and infertility. In these fields clinical decision
making is based on a plethora of research studies which have tested different treatments and
identified the most effective protocols. It is incumbent on the industry and research
community to find ways of ensuring that more studies such as this are conducted to provide a
robust evidence base to support the effective treatments of this prevalent, costly and painful
endemic disease.

CONCLUSIONS

In the RCT described here, dairy cows with claw horn lesions treated with a therapeutic trim,
a foot block on the sound claw and a three day course of the NSAID Ketoprofen were most
likely to be sound five weeks post treatment. Our work suggests that cows benefit from
NSAID treatment in addition to the common practices of therapeutic trimming and elevation
of the diseased claw using a foot block even when they are newly and mildly lame.

ACKNOWLEDGEMENTS

The work reported here was funded by DairyCo (www.dairyco.org.uk / www.ahdb.org.uk) a
levy funded, not for profit organisation working on behalf of British dairy farmers and a
division of the Agriculture and Horticulture Development Board.
REFERENCES


Table 1. Locomotion scoring descriptors employed in a randomized clinical trial to test the recovery of dairy cows from claw horn lesions

<table>
<thead>
<tr>
<th>Locomotion Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Walks with even weight bearing and rhythm on all four feet, with a flat back. Long fluid strides possible.</td>
</tr>
<tr>
<td>1</td>
<td>Steps uneven (rhythm or weight bearing or strides shortened; affected limb or limbs not immediately identifiable).</td>
</tr>
<tr>
<td>2a</td>
<td>Mild asymmetry in hind-limb 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>
</tr>
<tr>
<td>2b</td>
<td>Moderate asymmetry in hind-limb 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>
</tr>
<tr>
<td>3a</td>
<td>Severe asymmetry in hind-limb movement. Marked decrease in stride length on affected limb and very short stance duration. Limb flight on non-affected limb rapid and walking velocity reduced such that cannot keep up with healthy herd. Back raised.</td>
</tr>
<tr>
<td>3b</td>
<td>Minimal or non-weight bearing on affected limb. Back raised. Reluctant to walk without encouragement.</td>
</tr>
</tbody>
</table>

1Adapted from the DairyCo Mobility Score system, the GB industry standard. Scores 2a and 2b and 3a and 3b can be amalgamated back to scores 2 and 3 in this system respectively.
Table 2. Treatment administered in a randomized clinical trial designed to test the recovery of dairy cows from claw horn lesions

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Treatment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ('TRIM')</td>
<td>Therapeutic trim only (Positive control group)</td>
<td>1. Therapeutic trim applicable to the lesion</td>
</tr>
<tr>
<td>2 ('TRIM/BLOCK')</td>
<td>Therapeutic trim plus foot block</td>
<td>1. Therapeutic trim applicable to the lesion 2. Application of a foot block(^1) (Demotec 95, Demotec) to the unaffected claw</td>
</tr>
<tr>
<td>3 ('TRIM/NSAID')</td>
<td>Therapeutic trim plus NSAID</td>
<td>1. Therapeutic trim applicable to the lesion 2. Administration of a three day course of ketoprofen (Ketodale 100mg/ml, Richter Pharma AG) administered by deep intramuscular injection at 3mg ketoprofen / kg bodyweight</td>
</tr>
<tr>
<td>4 ('TRIM/BLOCK/NSAID')</td>
<td>Therapeutic trim plus foot block plus NSAID</td>
<td>1. Therapeutic trim applicable to the lesion 2. Application of a foot block (Demotec 95, Demotec) to the unaffected claw 3. Administration of a three day course of ketoprofen (Ketodale 100mg/ml, Richter Pharma AG) administered by deep intramuscular injection at 3mg ketoprofen / kg bodyweight</td>
</tr>
</tbody>
</table>

\(^1\)Approximately 110mm long, 55mm wide and 23mm deep. The block was positioned based on the experience of the worker in an attempt to replicate ‘normal’ claw placement and weight distribution. Where necessary the block was positioned towards the heel (away from the toe) to ensure weight was borne on the flat of the block.
Table 3. Number of cows allocated to each of 4 treatment groups by lesion diagnosis and farm in a randomized clinical trial designed to test the recovery of dairy cows from claw horn lesions

<table>
<thead>
<tr>
<th>Farm ID</th>
<th>Sole Haemorrhage / Ulcer</th>
<th>White Line Disease</th>
<th>‘Other’ Lesion (^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T</td>
<td>T/B</td>
<td>T/N</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>Grand</td>
<td>83</td>
<td>36</td>
<td>64</td>
</tr>
</tbody>
</table>

\(^1\)Predominantly a combination of both sole haemorrhage / ulcer and white line disease
Treatment Group: T – Therapeutic trim only; T/B – Therapeutic trim plus block on the sound claw; T/N – Therapeutic trim plus 3d course of NSAID; T/B/N – Therapeutic trim plus block plus NSAID
Table 4 Descriptive statistics of animals in each of 4 treatment groups in a randomized clinical trial designed to test the recovery of dairy cows from claw horn lesions

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>TRIM</th>
<th>TRIM/BLOCK</th>
<th>TRIM/NSAID</th>
<th>TRIM/BLOCK/NSAID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parity (Median (Interquartile range))</td>
<td>3 (2-4)</td>
<td>3 (2-4)</td>
<td>3 (2-3)</td>
<td>2.5 (2-3)</td>
</tr>
<tr>
<td>Days in milk (Mean (SE))</td>
<td>205 (126)</td>
<td>180 (111)</td>
<td>168 (100)</td>
<td>182 (102)</td>
</tr>
<tr>
<td>Last recorded milk yield (Mean (SE))</td>
<td>36.2 (10.8)</td>
<td>37.4 (10.8)</td>
<td>43.1 (9.1)</td>
<td>37.6 (9.4)</td>
</tr>
<tr>
<td>Body condition score at treatment (Median (Interquartile range))</td>
<td>3 (2.5-3)</td>
<td>3 (2.5-3)</td>
<td>2.5 (2.5 – 3.375)</td>
<td>2.5 (2.5 – 3.5)</td>
</tr>
<tr>
<td>Lameness Score at treatment (Median (Interquartile range))</td>
<td>2 (2-2)</td>
<td>2 (2-2)</td>
<td>2 (2-2)</td>
<td>2 (2-2)</td>
</tr>
</tbody>
</table>

1 Differences between treatment groups were not significant

2 TRIM – Therapeutic trim only; TRIM/BLOCK – Therapeutic trim plus block on the sound claw; TRIM/NSAID – Therapeutic trim plus 3d course of NSAID; TRIM/BLOCK/NSAID – Therapeutic trim plus block plus NSAID
Table 5. Locomotion score 35 days after treatment in dairy cows recruited to a randomized clinical trial designed to test recovery from claw horn lesions

<table>
<thead>
<tr>
<th>Treatment</th>
<th>0(^1)</th>
<th>1(^1)</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIM(^2) (n=45)</td>
<td>11 (24.4%)</td>
<td>20 (44.4%)</td>
<td>14 (31.1%)</td>
<td>0</td>
</tr>
<tr>
<td>TRIM/BLOCK (n=39)</td>
<td>14 (35.9%)</td>
<td>14 (35.9%)</td>
<td>10 (25.6%)</td>
<td>1 (2.6%)</td>
</tr>
<tr>
<td>TRIM/NSAID (n=42)</td>
<td>12 (28.6%)</td>
<td>20 (47.6%)</td>
<td>10 (23.8%)</td>
<td>0</td>
</tr>
<tr>
<td>TRIM/BLOCK/NSAID (n=41)</td>
<td>23 (56.1%)</td>
<td>12 (29.3%)</td>
<td>6 (14.6%)</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^1\)Score 0 = Sound; Scores 0 & 1 = Non-lame

\(^2\)TRIM – Therapeutic trim only; TRIM/BLOCK – Therapeutic trim plus block on the sound claw;

TRIM/NSAID – Therapeutic trim plus 3d course of NSAID; TRIM/BLOCK/NSAID – Therapeutic trim plus block plus NSAID
Table 6. Outcomes from logistic regression models in a randomized clinical trial designed to test the recovery of dairy cows from claw horn lesions (odds ratio scale unless shown otherwise)

<table>
<thead>
<tr>
<th>Model term</th>
<th>Outcome i. Sound locomotion score (Score 0) 35 days after treatment</th>
<th>Outcome ii. Non-lame locomotion score (Score 0 or 1) 35 days after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio</td>
<td>2.5%</td>
</tr>
<tr>
<td>Intercept</td>
<td>-1.08</td>
<td>-2.14</td>
</tr>
<tr>
<td>TRIM$^1$</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>TRIM/BLOCK$^1$</td>
<td>2.1</td>
<td>0.8</td>
</tr>
<tr>
<td>TRIM/NSAID$^1$</td>
<td>1.2</td>
<td>0.4</td>
</tr>
<tr>
<td>TRIM/BLOCK/NSAID$^1$</td>
<td>6.4*</td>
<td>2.4</td>
</tr>
<tr>
<td>Farm 1</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Farm 2</td>
<td>0.6</td>
<td>0.2</td>
</tr>
<tr>
<td>Farm 3</td>
<td>1.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Farm 4</td>
<td>1.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Farm 5</td>
<td>0.1*</td>
<td>0.0</td>
</tr>
<tr>
<td>Right hind limb</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>Left hind limb</td>
<td>4.8*</td>
<td></td>
</tr>
<tr>
<td>e^{-0.185 * DIM} (logit scale)</td>
<td>8.5*</td>
<td></td>
</tr>
<tr>
<td>Winter treated²</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Spring treated²</td>
<td>0.2*</td>
<td></td>
</tr>
<tr>
<td>Summer treated²</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Autumn treated²</td>
<td>0.1*</td>
<td></td>
</tr>
<tr>
<td>Sole ulcer / haemorrhage</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>White line disease</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>‘Other’ lesion(s)</td>
<td>0.3*</td>
<td></td>
</tr>
<tr>
<td>Principal Treatment</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Operator (HT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Other’ Treatment</td>
<td>0.3*</td>
<td></td>
</tr>
</tbody>
</table>

* * P ≤ 0.05

1TRIM – Therapeutic trim only; TRIM/BLOCK – Therapeutic trim plus block on the sound claw;
2TRIM/NSAID – Therapeutic trim plus 3d course of NSAID; TRIM/BLOCK/NSAID – Therapeutic trim plus block plus NSAID
3Spring – March, April and May; Summer – June, July and August; Autumn – September, October and November; Winter – December, January and February