final report

Project code: B.AWW.0239

Prepared by: 4c Design Ltd

Date published: September 2015

PUBLISHED BY
Meat and Livestock Australia Limited
PO BOX 1961
NORTH SYDNEY NSW 2059

Numnuts Phase 2:
Humane, Low Pain Method for 'marking' Young Ruminants

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government to support the research and development detailed in this publication.

Executive Summary

Why the work was done (what was the problem)

Castration and tail dockingremain important husbandry procedures for sheep in Australia, but Both result in distress to the animals through associated pain.

'Elastrator' constrictor rings, the most widely used methodology for castration and tail docking, cause notable and sustained pain and discomfort to young lambs. A substantial body of scientific evidence demonstrates that the methodology is ineffective in meeting the modern standards of animal welfare (Mellor and Stafford, 2000).

Thusfar market attempts to administer pain relieving drugs conjoined with the application of constrictor rings have, in practice, failed. While the administration of an anaesthetic or non-steroidal anti-inflammatory drug (NSAID) is technically demonstrable under controlled conditions (Coetzee, 2012), it is too cumbersome and risky (due to neele stick injuries) to apply in practice.

Consumer pressure focussing upon animal welfare is building, demonstrated by the increasing number of examples of campaigns initiated by animated consumer groups e.g. Animals Australia, RSPCA Australia and PETA, which are influencing broader consumer behaviour and buying patterns. Campaigns concerning eggs, , and the welfare of dairy cattle, chickens and pigs have led to changed codes of practice and legislation. As a result consumer behaviour is increasingly migrating towards products that have some form of explicit animal welfare promise labelling even if this carries with it a pricing premium. It is possible that developments in government legislation may follow.

How it was done

This project (Numnuts Phase 2) continued towards a practical solution to incorporate ringing simultaneously with the application of local anaesthetic.

A series of increasingly refined working prototypes devices were produced and trialled successfully in both Australia (CSIRO, Armidale, NSW) and the UK (MRI).

What was achieved

The aim was to achieve consistent and measurable analgesic benefits after 'marking'. Results for tail docking were particularly good and for castration show a strong trend towards effective analgesia particularly in the second and third hours after the ring being applied. . Investigations were carried out to find whether a single injection was adequate as well as the optimum needle length and volume of local anaesthetic.

What industry benefit/s will arise from the work

The outcome includes a fully ergonomic tool which can be produced in high volumes at a target price of 20-40 cents per application with minimal environmental impact. Use of the Numnuts system will permit Australian farmers to anticipate consumer and potential legislative pressures concerning animal welfare practices, and pre-empt a potential economic downturn such as the experience with mulesing.

MLA and 4c Design are negotiating a licensing deal with potential industrial partners to scale up the Numnuts technology for market availability.

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1 Background

1.1 Lamb castration and tail docking – The Issue

1.1.1 Scientific Evidence

A large body of scientific evidence from the UK and Australia indicates that current methods of castration and tail docking of lambs inflict considerable pain. The UK Farm Animal Welfare Council (FAWC) has stated that if a commercially viable and practical method for providing pain relief could be developed, it should be made mandatory.

1.1.2 Market Potential

There is a potentially extensive market opportunity within the global agricultural industry for a new technology which can enable improved castration and tail docking of lambs. This opportunity exists due to global demands from farmers, agricultural groups, veterinary scientists, animal welfare groups, emerging consumer groups and probable developments in government legislation.

1.1.3 Present Practice

A substantial body of authoritative scientific work demonstrates that the current technologies of lamb castration and tail docking are ineffective in meeting the modern standards of animal welfare (Mellor and Stafford, 2000). The most progressive mainstream technology for castration and tail docking is that of elastomer constrictor rings, which when applied, cause notable pain and discomfort to young lambs which is particualry acute 1-3 hours after application.

1.1.4 Practical Challenges

Market attempts to administer pain relieving drugs conjoined with the application of constrictor rings have not been practical in field conditions until now. While the administration of an anaesthetic or non-steroidal anti-inflammatory drug (NSAID) is technically demonstrable under controlled conditions (Coestzee, 2012) it has been too cumbersome to apply in practice. Local Anaesthetic Administration

Research conducted by the Edinburgh Veterinary School in conjunction with the Moredun Research Institute overcame the practical problems associated with administering local anaesthetic with conventional hypodermic syringes and needles by introducing the anaesthetic with a needleless device. 4c Design undertook a short feasibility project funded by Genecom in the UK in 2010 to investigate the possibility of developing the needleless injector prototype commercially. It was discovered that the manufacturing costs of the needleless injector would be too expensive to be viable, thus alternative designs and business models were explored. The design, creation and testing of these alternative products is the focus of the present project.

1.1.5 Potential Interest

A new device which castrates/tail docks effectively and can be applied quickly with minimal pain would receive rapid uptake from the first world farming communities.. Further, the realisation of such a technology could make pain-free castration and docking part of regional agricultural law.

1.1.6 Potential Market

The international market for this technology is significant. Combining Australia, New Zealand and the EU represents a potential market for up to 225 million units per annum. Even a small portion of this market retains significant commercial potential.

1.2 Previous work – Numnuts Phase 1

4c Design, Moredun Research Institute, CSIRO and the MLA began working to improve lamb castration and tail docking technologies in 2013 (4c Design, 2014). A new device was developed and tested to prove the concept that it could castrate/tail dock effectively and could be applied quickly, in addition to reducing animal discomfort.

Two castration pilot studies were conducted with small groups of lambs.

1.2.1 Animal Trials

Pilot 1 - CSIRO Armidale in October 2013

Six lambs were castrated using the novel constriction noose (no anaesthetic injection) to confirm the efficacy of castration using these new devices. The scrotums of the test lambs fell off within 37 days, the same time period as the control lamb, castrated by a conventional elastrator ring.

Pilot 2 - Dec 3/4th 2013 at CSIRO

30 Male lambs were used for the main pilot study. 40 prototype noose/injector devices were manufactured as well as an injector tool that delivered local anaesthetic in addition to applying an elastrator ring. The novel devices were applied and the behavioural responses of the lambs were recorded by an experienced behavioural study observer over a 4 hour period.

1.2.2 Phase 1 (previous project) Results and Recommendations

The Numnuts device that delivered local anaesthetic resulted in significantly fewer pain related behaviours during the first hour after application in comparison to the controls who were castrated using conventional elastrator rings. The first hour is when the behavioural studies show the highest levels of pain in the controls and is when lignocaine is most effective.

The results of Phase 1 generted the poof of concept evidence that the ‘numnuts approach’ should deliver the benefits sought. Therefore it was recommended that the project proceed to Phase 2, which has now been completed and is described in this report.

2 Project Objectives

2.1.1 Design Development & Refinement

The devices produced for the phase 1 prototype trials were early prototypes prepared using rapid prototyping techniques only suitable for less than hundred devices. To engineer a product that can be produced in very high volumes a large amount of design development and refinement must be carried out so that its function and the use of the materials can be made as efficient as possible. An objective was to develop the applicator device to further increase the efficiency when producing >2000 units.

2.1.2 Efficacy in lambs

Trials carried out to establish if the device is effective at removing tails and at delivering pain relief. Establishing the impact of anaesthetic volume and needle length on efficacy for castration and tail docking.

2.1.3 Commercial

The aim was to protect the IP generated via patents and trademarking so that the work could be published allowing the farming community a ‘low level’ awareness that a new product will be available in a few years. Once the manufacturing and business cases are better understood preliminary conversations can be held with potential manufacturing/licensing partners e.g. latex specialists, veterinary device makers and drug companies that supply local anaesthetic.

3 Methodology

3.1 Prototype Design and Development

3.1.1 Concept Evaluation and Selection

A series of increasingly refined working prototypes were produced and trialled successfully in both Australia (CSIRO, Armidale, NSW) and the UK (MRI) confirming the efficacy of the overall approach for both castration and tail docking. Optimum needle length and volume of local anaesthetic have been investigated to discover consistent and measurable analgesic benefits within an acceptable time cycle during the overall 'marking' process.

The outcome includes a fully ergonomic design engineering approach with minimal environmental impact, achieved by utilising materials that can be produced in high volumes at a target price of 20-40 cents per application.

3.1.2 Next stage (Phase 3) Preparation

MLA and 4c Design have prepared proposals and are negotiating with potential industrial partners with a view to licencing the technology to take the Numnuts to the commercial market.

The aim of phase 3 will be:-

1. To build upon the engineering and animal trials development from Phases 0, 1 and 2 to conclude with a small batch of immediate pre-volume production Numnuts devices and to test the overall Numnuts system at a series of farm-level trial to produce robust, statistically reliable results demonstrating, without ambiguity, the efficacy of the Numnuts approach to reliving animal pain;
2. To detail the engineering design, tooling design, bills of materials and all technical documentation required to create a licence package for transfer to a suitably experienced and resourced manufacturer, including the management and knowledge capture arrangements for the IP created across the development of the Numnuts system;
3. To prepare and complete all the relevant contractual and legal documentation. To have letters of intent in place with appropriate third parties to cover manufacture, supply, distribution, marketing and sale of the Numnuts system on to the Australian market.

The conclusion of phase 3 would be to have formal licence agreements the qualified and selected manufacturers and distributors. The aim would then be to launch 3-6 months prior to the Austrilian marking season.

Sheep farming in the UK is different, both in terms of farm scale and farm practice. Whilst the animal husbandry principles remain the same there are many differences in application reflecting custom, practice and legislation. Therefore a full commercialisation plan to suit the vagaries of the UK market requires further research, with the supply of local anaesthetic and distribution arrangements likely to be significant issues.

Other European markets will follow. Whilst these fall within the broad rules of the European Commission, the other 26 country markets are extremely varied in scale and level of sophistication of farming and animal husbandry practice.

3.2 Animal Trials

3.2.1 Tail Docking and Dose Response – MRI, April 2014

The small scale trials carried out during Phase 1 focused on castration. As the intention of the project was to develop a tool capable of carrying out tail docking as well as castration it was necessary to test the efficacy of applying local anaesthetic using the prototype for tail docking during Phase 2.

The trials were carried out at MRI where the Numnuts noose prototype (as described in the Phase 1 report (4c Design, 2014)) was used to perform tail docking on 60 animals.

Pain related behaviours and postures were classified at 5 minute intervals for 37 time points over 3 hours and 5 minutes. The first observation was made 5 minutes after tail docking. A single observer blinded to the treatments classified behaviours / postures of all lambs.

Cohorts 2, 3 and 5 were removed from the pens before 3 hours and 5 minutes of video was captured for all lambs. Cohorts 2, 4, 5, 6 and 8 were fed during the video surveillance period. Data were log transformed to normalize the distribution of residuals. The effects of cohort (when significant) and treatment were fitted. Statistical analyses of results by hour were not performed as data distributions could not be normalised by transformation.

The report (MRI, 2014) provides full details of the methodology used in this trial.

3.2.2 Dose Response Castration – CSIRO, November/December 2014

This trial was designed to provide evidence to address the following questions:

- How far should the needle penetrate into the scrotal neck to provide analgesia, and ensure the risk of failed injection is minimised?
- What volume of Local Anaesthetic should be delivered?

A blinded controlled randomized block study was carried out during November and December 2014 at CSIRO. Ninety-nine entire male lambs, of apparent good health, were included in the study. Pain related behaviours and postures in lambs undergoing ring castration were analysed using video footage. Nine combinations of needle penetration (6 mm; 8 mm and 10 mm) and dose volume (0.75 mL; 1.5 mL and 3.0 mL) of Lignocaine 2% were compared. Nine replicates in each treatment combination were compared against nine replicates of ring castration and nine of sham handled animals.

The assessment of behaviour post treatment was divided into active pain avoidance behaviour and postural behaviour. The active pain avoidance behaviour assessment took place for one minute, every 5 minutes for the first hour post-procedures. The postural behaviours were classified every 15 minutes for 4 hours from the time of castration. All behaviour assessments were conducted from the video recordings and carried out by a single staff member trained in categorising behaviours, blinded to treatments.

Statistical analysis was carried out using the R statistical package. Data which were normally distributed or that could be transformed to satisfy normal distribution the data were evaluated using the analysis of variance (ANOVA) method. Where data could not be transformed to satisfy normal distribution, χ^2 comparisons of proportions of postural observations considered abnormal between treatments were used, or the Wilcoxon rank-sum test, where data were counts of active pain avoidance behaviours.

The report (CSIRO, 2015) provides full details of the methodology used in this trial.

3.2.3 Numnuts Mk 7 Tool Prototype Trial – MRI, April 2015

The efficacy of local anaesthetic (LA) injection (1.5 mL 2% lignocaine) via the Numnuts Mk 7 prototype tool into a single location on the tail of ewe lambs and scrotum of ram lambs was examined in 80 2 to 4-week old, Greyface cross Texel lambs housed in pens (8 by 5 metres) with concrete floors at Moredun Research Institute.

The study was conducted in 7 cohorts over 2 days in April 2015. Lambs were subjected to one of the following procedures:

- Handling alone (Sham);
- Tail docking and LA injected into a single location using the Numnuts tool;
- Castration and LA injected into a single location using the Numnuts tool;
- Castration using the Numnuts tool and LA injected into both spermatic cords using a conventional needle.

The responses of the lambs were videoed for analysis of active pain avoidance behaviours in the first hour following the procedures and for postural behaviours for up to 3 hours (range 2h 10 min to 3 h) following the procedures.

Postures were classified at 5 minute intervals for the first hour and at 10 minute intervals in second and third hour. Individual types of active pain related behaviours were classified every 5 minutes for the first hour and were summed to give a total count of active pain behaviours.

Most of the data for the first hour were suitable for analysis without transformation. The change in postures over time was analysed in a repeated measures model. The change in active pain related behaviours over time during the first hour was also analysed in a repeated measures model.

The report (CSIRO, 2015) provides full details of the methodology used in this trial.

4 Results

4.1 Prototype Numnuts approach - Design and Development

4.1.1 The starting point - Numnuts Phase 1 (previous project)

Under Numnuts Phase 1 (2012-13, reporting February 2014) a new device was developed and tested to prove the concept that it castrates/tail docks effectively and can be applied quickly, in addition to reducing animal discomfort. Two successful castration pilot studies were conducted in small groups of lambs.

The model opposite shows the general concept used for the field trials.

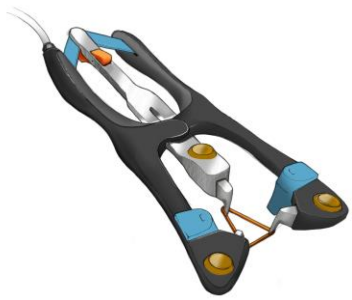
The concept made use of the fact that there was a removable part - the injector - which was removed from the animal after the lassoo had been tightened and the injection administered. This meant that the needle was not left with the animal. However, the clamp and latex tube was to be left with the animal as the constriction takes place and when the appendage fell off this would be left in the field. While this was similar to the current setup (where the rubber ring is left in the field) the additional plastic part could have caused environmental concerns.

Whilst it could be possible to make use of a biodegradable / compostable plastic which would mean that the plastic would reasonably rapidly break down into non-toxic substances, environmental concerns outlined above, coupled to the complexity of the 'on-board' device and the challenge of manufacturing down to an acceptable price, focussed design attention towards the development of a tool that automates the process of castration and anaesthesia. The objective was to keep all the complexity within the tool itself, leaving the disposable latex band as simple and hence as cheap as possible.

This would also ensure that the process is as simple and efficient as possible from the farmers' perspective, perhaps not only addressing the anaesthesia concerns, but also weaknesses in the current, cheap and readily available 'Elastrator' application tool.

Design attention under Numnuts Phase 1 therefore anticipated the development of a tool-based approach focussing upon automating much of the injection and ejection process to happened in a single and quick operation for the user.

An artistic impression of how the tool could look with more development to reduce size, increase ergonomics and improve function was provided at the conclusion of this phase of development (Phase 1).



4.1.2 Tool Development Numnuts Phase 2 (this project)

The enduring requirement was to simulate the precision supplied by a qualified veterinarian through individual treatment with repeatability, together with optimised application for both tail and scrotum through a single point injection using a single device. Device design and development under this project therefore focussed upon developing a tool-based system. The development of the tool itself comprises two fundamental aspects:-

- An ergonomic mechanical applicator for the 'Elastrator' band;

- A fluid handling device for injecting local anaesthetic.

Each aspect was exhaustively modelled and trialled in the laboratory, workshop and on the farm, by creating both physical models and CAD (Computer-Aided-Design).

4.1.3 Ergonomic mechanical ring applicator

A review of the standard, long established 'Elastrator' tool, whilst 'cheap and cheerful' for its intended purpose, identified a number of shortcomings:-

- Relatively light-weight construction with large tolerances, meaning imprecision in operation;
- A large force required to hold open whilst fixing rings to tail and scrotum (200N)
- An un-natural twist of the forearm through 90º required to operate.

Attention therefore focussed upon addressing these shortcomings:-

- The mechanism was carefully engineered to include an over-centre motion such that the force required to maintain in the fully open position with a latex ring attached is much reduced for the operator;
- The new tool is designed with a view to volume manufacture to a higher standard of precision. This will be required in the fluid handling device, to deliver, reliable precise placing of local anaesthetic into the animal;
- The opening motion has been turned through 90º hence providing a much more natural motion for the operator, reducing the risk of repetitive strain injury for the operator, and with resultant reduced risk of liability upon the employer, especially where very large number of lambs are processed in one batch.

4.1.4 Fluid handling device for injecting local anaesthetic

Whilst the veterinary tool for supplying fluids to an animal is a syringe operated manually by a qualified practitioner the project sought to automate this action by reducing to a minimum the number of variables for use by a semi-skilled operator. The Phase 1 Numnuts device provided this by employing a fuel bulb with fixed length syringe needle.

However combining the mechanical application with simultaneous local anaesthetic injection on to a tool demanded a fundamental design approach. The fluid injection requirement sought to optimise four potentially exclusive requirements:-

1. Single point injection into the scrotum to dull pain in two parallel nerves;
2. Depth of local anaesthetic placement to achieve the optimal effect for the above;
3. The same depth of local anesthetic placement in the tail as in the scrotum in order to simplify tool for use for both operations in the same manner;
4. The optimum volume of local anaesthetic to achieve successful results for both tail and scrotum.

The principal design criteria started with the point of deposition of the local anaesthetic within the animal tissue for both sites; tail and scrotum.

Working back from from this our considerations included:-

a) The position of a syringe needle relative to the 'Elastrator' ring i.e. the LA should be deposited on the cortal side of the ring;
b) The (acuteness of) angle of the needle required to avoid collision with bone in the tail, and potential blockage with bone fragments or other tissue debris;
c) The depth of needle required to:-
    i. Avoid hitting the bone in the tail but penetrate to a sufficient depth to either penetrate the nerve or deposit LA sufficiently close to affect the nerve;

ii. Penetrate the scrotum sufficiently to influence both nerves but not to protrude through the rear of the scrotum;

d) The depth of needle measured from the surface of the animal's skin to the optimum point of deposition of the LA to cover both sites;

e) The length of needle between the animal's skin and its point of exit from the safe (to the operator) housing on the tool;

f) The length of needle required to retract fully and safely into the tool for recharge;

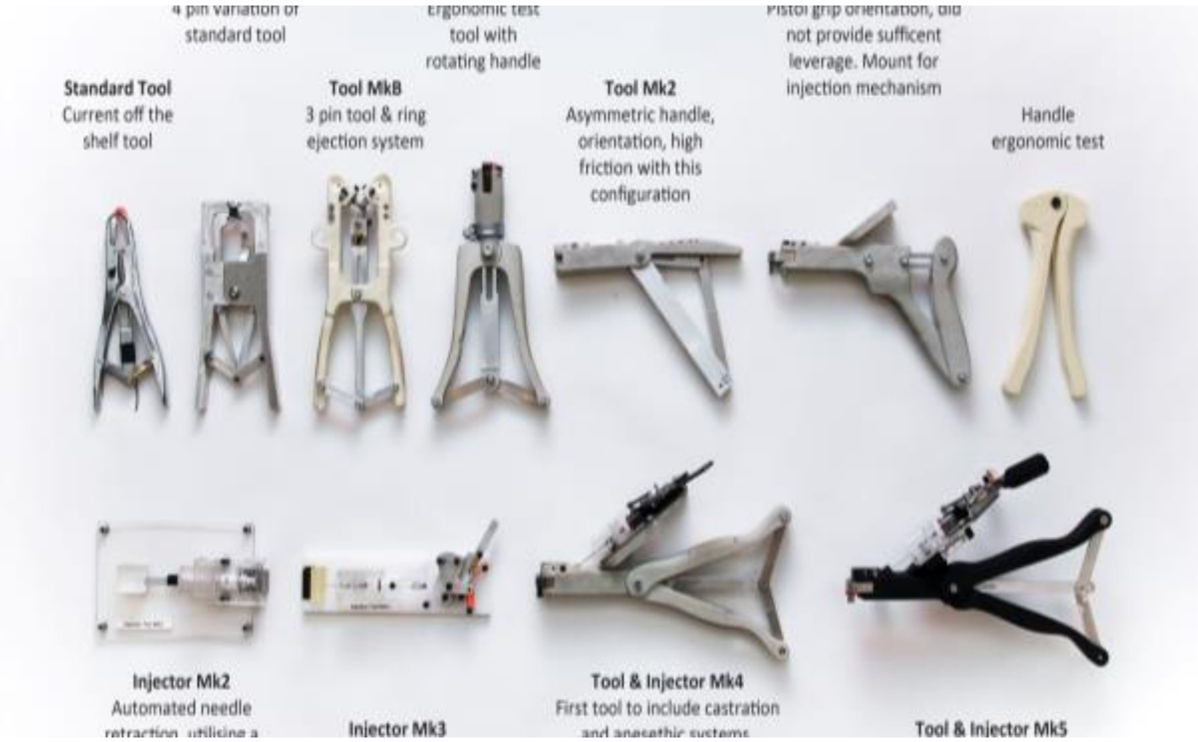
g) Combining d), e) and f) the overall length of needle required from which its engineering design characteristics could be determined i.e. resistance to bending optimised with minimal size and cross-sectional area.

The design development of the injector mechanism progressed from utilising a standard clinical syringe mounted upon increasingly refined carriages on further developed mechanments of the ring applicators, towards a unitary solution utilising a standard 100ml pharmaceutical PET bottle mounted on a completely new design of single action, quadruple function, fluid handling module. In operation easing tension on the mechanical applicator binds the ring to the animal's appendage where it acts as a 'jig' to locate the tool positively for precise positioning of the injection point on each animal and on each appendage.

4.1.5 Design development evolution

The evolution of the design development progressed through several iterations, with many model systems and sub-systems produced to test elements. Various marks of evolution were trialed live with animals at the various trials described elsewhere. The current evolution 'Mk 9' has been trialled successfully on animals.

Pictorially the design evolution is laid out thus:



Sub-system and tool evolution

Prototype Mk6 with model injector

Tool and model applicator Mk7

Mk7 tool used extensively in animal trials April 2015

Tool design and development evolution

The current Mk9 tool complete

4.2 Animal Trials

4.2.1 Tail Docking and Dose Response – MRI, April 2014

The aim of this trial was to investigate the efficacy of injecting local anaesthetic (LA) using the Numnuts prototype for alleviating the pain behaviours associated with tail docking.

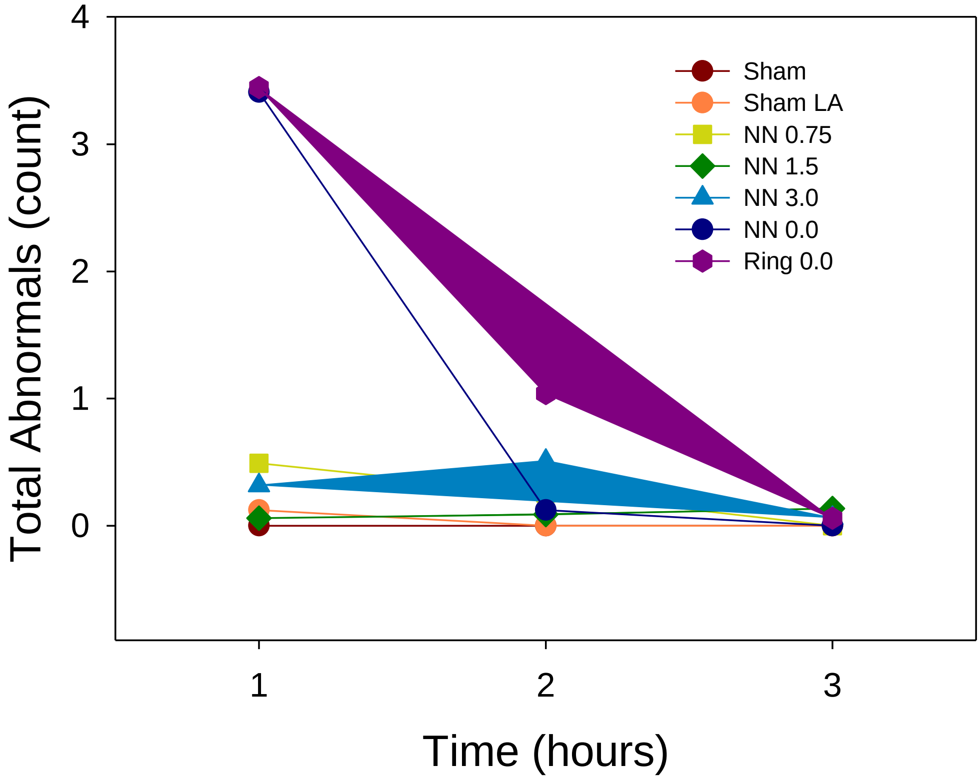


Figure 1: Total count of abnormal behaviours for different treatments: Sham (no treatment), Sham LA (no treatment and LA injection), NN 0.75 – 3.0 (Numnuts prototype with LA dosage varying from 0.75ml to 3.0ml); Ring 0.0 (constrictor ring without LA)

As shown in Figure 1: Total count of abnormal behaviours for different treatments: Sham (no treatment), Sham LA (no treatment and LA injection), NN 0.75 – 3.0 (Numnuts prototype with LA dosage varying from 0.75ml to 3.0ml); Ring 0.0 (constrictor ring without LA)Figure 1, there was a significant effect of treatment on pain related behaviours ($P < 0.001$). There were no pain related behaviours observed in sham or sham LA groups. There were no significant differences between doses of LA in Numnuts (NN) treatments receiving LA. There were significantly fewer pain related behaviours in NN + LA treatments than in NN without LA and Ring with LA treatments. NN without LA did not differ from Ring without LA. The effect of dosage volume was also investigated by varying the dose from 0.75ml LA to 3.0ml LA.

Almost all pain related behaviours occurred in the first hour. No pain related behaviours were seen at 5 minutes in NN + LA treatments whereas pain related behaviours were already occurring in Ring and NN without LA treatments at this time point.

It was concluded that LA was effective within 5 minutes of injection in providing pain relief. There was no evidence of a dose response to LA for alleviation of pain related behaviours.

The key conclusion from this trial was that local anaesthesia works for tail docking.

The report (MRI, 2014) provides full details of the analysis and results of this trial.

4.2.2 Dose Response Castration – CSIRO, December 2014

The aim of this trial was to investigate response to varying the dose volume of LA and to discover the optimal needle penetration depth.

The assessment of behaviour post treatment was divided into active pain avoidance behaviour and postural behaviour. There were no significant study day or pen interactions.

Assessment of active pain avoidance behaviours showed that ‘sham’ differed significantly from all treatments. The combined results shown in Table 1: Mean active pain avoidance over the first hour post treatment (backtransformed) show that behaviour assessment was unable to identify statistically significant differences between the remaining treatments. However, 3.0 mL Lignocaine 2% at 10 mm needle depth tended to show fewer active pain avoidance behaviours than castrate in the first 20 minute period post treatment while 0.75 mL Lignocaine 2% at 6 mm needle depth tended to show greater active pain avoidance than castrate in the second and third 20 minute periods post treatment.

Table 1: Mean active pain avoidance over the first hour post treatment (backtransformed)

	6mm	8mm	10mm
0.75mL	15.73*	9.52	8.48
1.5mL	8.36	9.70	10.77
3.0mL	7.75	8.64	7.11

* Trending towards being significantly greater than castrate (P<0.1)

Assessment of postural behaviour also showed that ‘sham’ differed significantly from the other treatments. The combined data are shown in Table 2: Mean total abnormal postures over four hours post treatment. The data for total abnormal behaviours in the first hour post treatment could not be normalised, so were analysed by χ^2 test. The data were then partitioned by observation post castration (one every 15 minutes), to investigate the possibility that early effects may be wearing off over the one-hour period. At observation 1 1.5 mL lignocaine 2% at both 8mm and 10 mm needle depths tended to show less abnormal postures than castrate; while 3 mL Lignocaine 2% at 6mm needle depth had a significantly lower proportion of abnormal observations than castrate. At observations 2 and 3 no significant differences between treatments was observed, although at 10 mm needle depth, 1.5 mL Lignocaine 2% appeared to provide a lower proportion of abnormal postures than either 0.75 mL or 3.0 mL. At observation 4, 0.75 mL Lignocaine 2% at 6 mm needle depth provided a significantly lower proportion of abnormal postures than castrate.

Table 2: Mean total abnormal postures over four hours post treatment

	6mm	8mm	10mm
0.75mL	8.00 (1.56)	6.11 (1.56)#	6.89 (1.56)
1.5mL	7.67 (1.56)	7.00 (1.56)	5.56 (1.56)*
3.0mL	7.67 (1.56)	8.44 (1.56)	7.22 (1.56)

* Significantly less than castrate (P<0.05)

Trending towards being significantly less than castrate (P<0.1)

Although the results of this study did not generate clear statistical differences, this is likely to be a result of the small number of replicates in each group and the small number of observations taken from each animal. The results do indicate that the delivery of Lignocaine 2% at the time of castration can alleviate pain related behaviours. In particular, the higher volumes (1.5 mL and 3 mL), delivered at 8 or 10 mm needle depth tended to reduce the number of abnormal postures, and 1.5 mL appears to give a more favourable outcome than 3 mL.

The key recommendation from this study was to proceed with a needle depth of 8-10 mm and a volume of 1.5 mL Lignocaine 2%.

The report (CSIRO, 2015) provides full details of the analysis and results of this trial.

4.2.3 Addtional Analysis – CSIRO, December 2014

The dose by needle length study undertaken at CSIRO in November 2014 was reanalysed in July 2015 for any further indication of efficacy of LA delivered to the midline of the scrotum.

When all lambs in the 3 groups receiving LA (0.75mL, 1.5mL and 3 mL) were combined **there was a tendency (P = 0.088) for abnormal postures in the first hour to be less in the combined LA groups than in the Castrate (0 mL LA) positive control.**

Other indicators of efficacy were not significant. There was no evidence of an interaction between LA dose and needle length.

4.2.4 Numnuts Mk 7 Tool Prototype Trial – MRI, April 2015

The aim of this trial was to investigate the efficacy of using the Numnuts tool to apply LA during tail docking of ewe lambs and castration of ram lambs. The delivery of 1.5 mL local anaesthetic via the Numnuts device at the time of tail docking abolished abnormal behaviours and signs of pain in ewe lambs as shown in Figure 2.

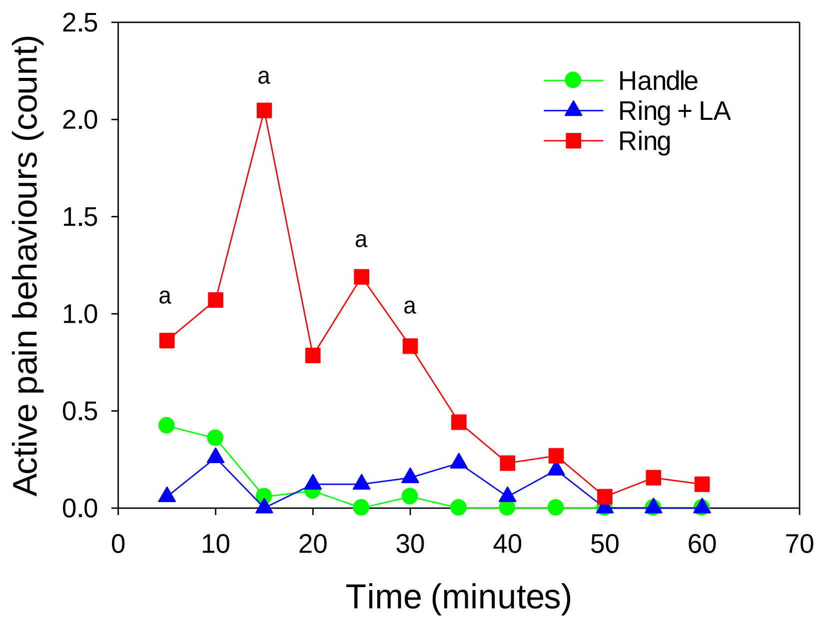


Figure 2: Active pain behaviours over time in tail docked ewe lambs comparing handling only (sham); ring docking with LA applied using the Numnuts tool and ring docking using the Numnuts tool without LA

Delivery via the Numnuts device at the time of castration significantly reduced abnormal postures in hours 2 and 3 and reduced the sum of abnormal standing and the sum of abnormal postures across the 3 hours of observation as shown in Figure 3. Lambs receiving the dose of LA split between the cords exhibited less abnormal lying in the first hour, fewer total abnormal postures in hour 1 and a reduced count of abnormal standing and total abnormal postures across the 3 hours of observation.

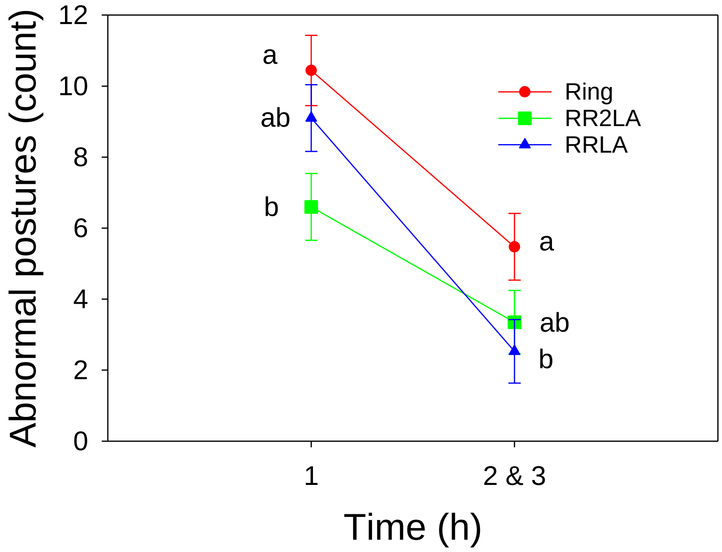


Figure 3: Abnormal postures over time in ram lambs comparing castration without LA (red); castration with LA applied using the Numnuts tool (blue) and castration with the LA dose split between cords (green)

Figure 4 compares the pain behaviours of ram lambs to castration without LA, with LA applied using the Numnuts device and with a split dose of LA to each spermatic cord applied using a conventional needle. Although LA injection using the Numnuts device reduced abnormal postures, as shown in Figure 3, it did not significantly reduce pain related behaviours during the first hour.

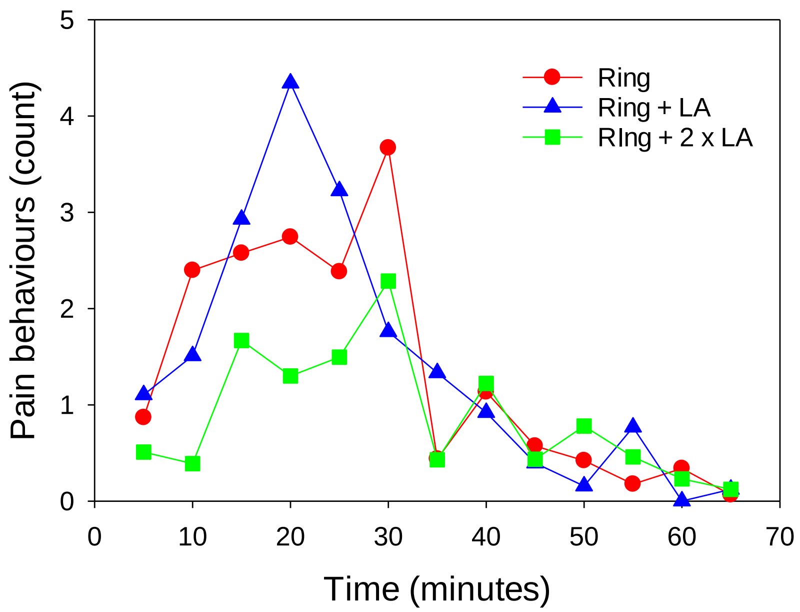


Figure 4: Active pain behaviours over time in ram lambs comparing castration without LA (red); castration with LA applied using the Numnuts tool (blue) and castration with the LA dose split between cords (green)

The results also show only modest benefit of the injection of LA into both spermatic cords. The lack of a more marked benefit by this procedure suggests that either the dose or type of LA used in this experiment may be suboptimal for effective analgesia for ring castration in the older lambs used in this experiment.

The observation of modest benefits from LA administration via the Numnuts device in hours 2 and 3 but not in the first hour suggests that diffusion of LA from the single injection site in the midline of the scrotum may be slow to occur.

The key conclusions from this trial were as follows:

- The Numnuts device proved highly effective for alleviating the pain of tail docking;
- Further investigation is required into the efficacy of injecting LA into the midline of the scrotum;
- Further investigation is required into the dose of LA needed for effective analgesia in lambs in the age bracket 4 -12 weeks.

The report (CSIRO, 2015) provides full details of the analysis and results of this trial.

5 Discussion

5.1 Outcomes in the wider context

5.1.1 Inferences and insights from the data relative to previous research

The research and animal trials carried out in the Phase 1 project demonstrated that the Numnuts device was capable of effectively castrating lambs and could be applied quickly. The full results of this project are reported in (4c Design, 2014).

The body of work carried out in Phase 2 has additionally demonstrated the efficacy of the Numnuts device for tail docking. In particular, the animal trials carried out in April 2015 proved the Numnuts tool to be highly effective in alleviating the pain responses of lambs to the procedure of tail docking.

The results of the December 2014 animal trials demonstrated that injection of Lignocaine 2% by the Numnuts device at the time of castration does reduce pain related behaviours. This had not been previously proven at a statistically significant level. Due to the small replicate numbers this study did not generate statistically significant differences in the variables we were investigating, namely dose volume and needle penetration. Nonetheless, the study indicated that a needle depth of 8-10 mm and a volume of 1.5 mL Lignocaine 2% were most favourable and these have therefore been incorporated into our development.

5.1.2 Practical implications for industry

Between 10-12 years ago the Australian wool and sheep-meat industry suffered a major economic blow as a result of international direct animal action activity highlighting mulesing. The industry took some time to recover once a remedy to the practice had been implemented.

Farmers and the scientific community have increasingly recognised that animals experience pain, acute and chronic, during some husbandry procedures, including 'marking'. A number of animal behavioural studies conducted over the past 25-30 years have proved conclusively that this is the case, and that the experience of acute pain as a result of 'marking' has a detrimental impact upon the animals' growth and development to some degree.

Animal welfare is an increasing consumer concern in the western world. The very negative impact of the anti-mulesing action on the economic welfare of Australian farmers has been a salutary lesson on assuming that consumer pressure does not bear directly upon income. Numnuts is therefore an approach to pre-emp the known pain impact of 'marking' by introducing local anaesthetic to alleviate pain simultaneously.

The use of 'Elastrator' rings for 'marking' lambs is the most popular methodlogy on Australian farms, employed by the vast majority of sheep farmers. 'Elastrator' rings have been in use popular use for 50 or more years. Hence maintain the basic methodology has significant attractions. Numnuts achieves this but with very significant improvements to the welfare of animals included.

5.1.3 Unanswered questions/additional research recommended

The latest set of animal trials carried out in April 2015 produced clear evidence that the Numnuts device is highly effective for alleviating the pain of tail docking, however, the trials were less conclusive regarding castration. Key recommendations from this study are that further investigation is carried out into the efficacy of single point injection of LA into the midline of the scrotum and also into the dose of LA required for effective analgesia in lambs in the age bracket 4 -12 weeks.

5.1.4 What could have been improved in the project delivery (what worked, what didn't)

The standout positive from the delivery of this project is the highly effective and collaborative working environment and ethos that has developed within the team. This is despite team members coming from several different organisations and being based on different sides of the world. Lines of communication are always open and we believe that the high levels of motivation, honesty and positivity within the team have made a major contribution to the project's success.

Certain elements of the delivery of the animal trials have not worked quite as well as expected. As noted in Section 4.2.2, the Dose Response trial did not produce statistically significant results. We believe this was at least in part due to the small number of replicates and we intend to improve our experimental design to avoid this problem in the future. A second issue with the animal trials has been the length of time, several months, needed to complete video analysis. This has had an impact on progression with tool design and development. As a result, we have discussed alternative approaches to analysing animal behaviour with the veterinary scientists and will apply these to future trials.

5.2 Outcomes against Project Objectives

5.2.1 Design Development & Refinement

1. *Reduce the environmental impact of the product (degradability of parts)*

The decision to fundamentally re-configure the approach to removing the technology from the device and placing it upon the tool means that the disposable element carried by the animal until ischaemia remains a standard latex ring, a very widely used and accepted farming product.

2. *Reduce the size, whilst achieving a similar improved level of ease of application*

As above.

3. *Move to more representative engineering materials that can be produced in high volumes*

Moving the technology to the tool means that standard engineering materials may be used throughout.

4. *Understand latex or alternative production techniques and how to engineer the ball bearing 'click to be sure' feature*

See 1 above - this approach has been superceded by the revised approach

5. *Needle safety for the user*

The design of the tool has two specific features in order to achieve this objective:-

i. The needle is entirely concealed within the tool until the operator explicitly moves it forward into the 'fire' position;

ii. The tool is specifically designed for two handed operation requiring the operator to remove his/her hand from the needle area BEFORE operating the needle advance and fire mechanism, which are simultaneous.

6. Target manufacturing cost per ring (in volume) <$AUD 25cents

The re-configuration of the approach, described in 1 above, moves the device on to the tool. The Numnuts SYSTEM comprises an applicator tool (patent applied for) designed for multiple use on the farm over many years, loaded by standard 'Elastrator' rings together with an disposable/returnable - refillable-remanufacturable (like ink cartridges) multiple dosage local anaesthetic cartridge (patent applied for) with built in needle. The target cost to the farmer of each application (tail dock or castration procedure) remains at AUD25c including LA dose and 'Elastrator' ring.

The cost of the tool is targeted at around $50, but since it is designed for multiple use over many years the cost per procedure will be minimal, and amortized over time. It may be expected that large volume users of the Numnuts system may be offered tools at no cost to them, depending upon the ultimate business model adopted.

7. Develop a Prototype applicator device.

The Numnuts tool described above has evolved through a series of developmental prototypes, with various marks being used in animal trials and work progressed. The current prototype is deemed Mk 9 and incorporated most of the features which will be incorporated in the ultimate production version. Five Mk9 tools with accompanying field kits including supplies of Elastrator rings have been produced for further animal trials use and demonstration. These have been distributed to MLA, CSIRO FD McMaster Laboratory, Armidale, Moredun Research Institute, and 4c Design retain two for further development work.

5.2.2 Lambs

1. Trial to discover if the device in its current form is effective for inducing ischemic death of the tail and for reduced pain associated with tail docking

Trial results from April 2015 carried out at Moredun Research Institute and interpreted by CSIRO FD McMaster Laboratory confirm conclusively that Numnuts configured to deliver 1.5ml of lignocaine 2% through a 12mm exposed needle length reduce the pain response in lambs to a minimal level.

2. Data to establish the best volume of anaesthetic to use for 6-10 week old lambs?

The Dose Response Castration trial carried out in December 2014 indicates that the most favourable dosage volume is 1.5 mL Lignocaine 2%. However, this study also recommended that further investigation is carried out into the dose required for effective analgesia in lambs in the age bracket 4 -12 weeks.

3. Data to establish the optimum needle length

The Dose Response Castration trial carried out in December 2014 recommended an optimum needle depth of 8-10 mm. During the MRI trail in April 2015 12mm was used and no miss injectotions or needle hitting the bone incidents were discovered.

4. Detailed knowledge of the analgesic benefits of tail docking and castration with the Numnuts device

Tail

Trial results from April 2015 confirm conclusively that tail docking carried out using the Numnuts device delivering 1.5mL Lignocaine 2% is highly effective in reducing pain response behaviours in lambs to a minimal level.

Castration

The results of the December 2014 trials showed that delivery of Lignocaine 2% at the time of castration results do indicate that the delivery of Lignocaine 2% at the time of castration does alleviate pain related behaviours and recommended a dose volume of 1.5 mL. Subsequent trials in April 2015 demonstrated modest benefits from analgesia using the Numnuts device in hours 2 and 3 after castration. Injection of LA into a single location was not proven to have a benefit within the first hour and for this reason the study recommended further investigation into the efficacy of the single location injection and into the dose volume required for effective analgesia in older lambs.

5. Quantitative assessment of the logistics and time taken for use of the device in the field

Representative logistics and time data was obtained from one medium sized sheep farm in New South Wales. The indications obtained were as follows:-

Item	Measure	Volume
Lamb marking	No. per day	350-500
Lamb marking crew	No. of people involved	2
Lamb marking cradles	No. of cradles per marking session	1
Activities involved at marking per lamb	Picking up	1
	Put lamb into cradle	1
	Ear tags	1
	Vaccinations	2
	Ring tail	1
	Ring purse	1/2
	Fly treatment	1
	Tip lamb from cradle	1
Mob size	Ewes and lambs	50-200
Lamb population to be marked	Per farm, per year	2000
Joining period	Plan for 2015	25 Apr - 31 May
Marking period	Plan for 2015	28 Oct - 7 Nov
Vaccine reservoir	Doses per pack	250
Needle change	No. of doses per needle	200 - 250
Ear tagging gun	Tagging magazine	50
Additional time per procedure	Numnuts injection sub-procedure	1 - 2 sec

Assumptions

Assume working day = 8 hours

Assume marking station set up and break down time = 2 hours

Assume mustering and dispersal time = 2 hours

Rates

Time available for marking at station = 8 -2 -2 = 4 hours = 240 minutes = 14,400 seconds

No. of lambs to be marked, vaccinated, ear tagged etc. = 500 (maximum)

Time available per lamb for whole procedure at marking station = 28.8 sec.

It is concluded therefore that the additional action of pressing the injector bottle on the Numnuts tool will not incur any noticeable time penalty within the overall marking/tagging procedure.

Conclusions/Recommendations

5.3 Practical application

This project has developed a unique approach to the simultaneous application of 'Elastrator' rings and local anaesthetic for tail docking and castration of lambs.

5.3.1 Tail docking

The results from the series of animal trials conducted during the project have proven beyond doubt that the configuration of the device alleviates pain immediately following ring application for tail docking.

5.3.2 Castration

In the case of castration the results are less clear particularly over the initial hour following ring application. Several reasons <u>may</u> be individually or collectively responsible for these initially ambiguous results. These <u>could</u> include:-

- Needle position relative to the 'Elastrator' ring;
- Movement of the ring following removal of the tool from the animal's appendage i.e slipping back over the area of injection of local anaesthetic, thus 'chasing' the deposited local anaesthetic back through the animal's tissue to the distal side of the ring;
- Volume of local anesthetic marginally insufficient to deliver desired results.
- The LA is not diffusing through the tissue to the nerves quickly enough

5.4 Further R&D

As noted in Section 4.2.3 above, in order to confirm the overall approach to castration via a single point injection follow-on R&D is required to:-

- Further investigate the efficacy of injecting LA into the midline of the scrotum;
- Further investigate the dose of LA needed for effective analgesia in lambs in the age bracket 4 -12 weeks.

5.5 Steps to adoption by the red meat industry for its future benefit

Given the growing groundswell of consumer pressure in Australia (and elsewhere) for welfare-assured animal products, and in the growing interest by supermarkets and the supply chain to respond to this sentiment the development and progress of Numnuts sytem to widespread availability to the market on commercially agreeable terms should be continued at pace. The following activities are recommended, to be carried out to the greatest realistic extent in parallel:-

1. Complete the R&D as outlined above;
2. Maintain the pursuit of the two patent applications and other formal intellectual property secured
3. 'Bottom out' discussions to gauge and ascertain interest in commercial participation currently underway with pharmaceutical companies in Australia;
4. Re-enter discussions with selected instrument makers to the agricultural industry to establish willingness to participate and pricing terms.
5. Continue to develop the business plan for Numnuts NewCo with variations in parallel with discussions with interested potential investors in order to expedite the delivery of the Numnuts system to the market.

6 Key Messages

6.1 Value proposition and benefits to the Australian red meat industry

Stakeholder issues which Numnuts will help to solve:-

6.1.1 Farmers

Numnuts provides the a viable solution for farmers to a long-identified animal welfare issue that is leading to consumer resistance to sheep products. It is a one-shot tool and consumables combining LA at critical position with castration/tail docking. Numnuts delivers:-

- Reduced animal discomfort;
- Improved animal health;
- No significant operational penalty with traditional marking techniques;
- Can be applied quickly within bundle of activities at same time as marking;
- Meets incoming consumer/supermarket QA labelling focussing upon improved animal welfare.

6.1.2 Veterinary community

Numnuts provides a viable on-farm answer to an animal welfare issue identified many years ago by the veterinary profession. Numnuts also offers the opportunity of increased business income for practicing vets. Numnuts therefore:-

- Fulfils veterinary recommendations;
- Potential for additional income margin via increased volume of LA sold through prescription.

6.1.3 Agricultural supply distributors

Numnuts provides a fresh, new product line with a significant tail of consumables thus providing better margins at no significant extra cost. Benefits are:-

- New product range
- Increased margins c.f. current tool and rings

6.1.4 Agricultural Contractors

The ergonomic design of the Numnuts tool will reduce operator fatigue over a full shift thereby providing improved operative satisfaction. As industry codes of practice and operational requirements develop Numnuts will provide compliance with new industry norms.

6.1.5 Meat processing and packing industry

Numnuts therefore offers the industry a stake in delivering a higher value, higher margin product demanded by consumers.

6.1.6 Supermarkets

Numnuts offers supermarkets the opportunity to differentiate animal-friendly products further through quality-assured labelling:-

- Addresses positively the growth of welfare conscious consumer markets;
- Supports the opportunity to raise prices for premium quality-assured products;

- Products which are defensible to animal welfare activists claims.

6.1.7 Legislators

The commercial availability of Numnuts as a practical, on-farm solution, permits legislators to respond to professional advice received over many years regarding animal welfare.

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