

AWI Breech Strike R&D Technical Update
Maritime Museum, Sydney
20th August 2014

Troy Laboratories
Australia Pty Ltd



The Genesis of an idea

- Where ? – Germany May 2005
- Why ? – Jet lag enabled me to tune into a EU Parliament summary
- What? – Debate relating to the humane raising of production animals, initially focusing on the pig industry (Implementation 2012) and then other production areas (Implementation 2013)
- The Problem – How to achieve pain alleviated production from animals that is:
 - EASY
 - EFFECTIVE
 - AFFORDABLE
 - SAFE



WHO IS TROY Laboratories Australia ?

- We are an Australian Veterinary Pharmaceutical Manufacturer
- Company formed in 1959
- Company privately owned by one family
- Based in Glendenning in a purpose built facility that is registered with the APVMA to make gels, creams, tablets, powders, liquids and sterile injections
- We started as a generic manufacturer but now R&D is the key to our future to achieve our vision (QUALITY, AFFORDABLE & INNOVATIVE PRODUCTS)



Routine Sheep Procedures on Farm that can cause pain



Castration



Tail docking

Pain

- A welfare issue that is now being regulated in NZ and EU
- It interferes with healing
- Hypertension
- Immunosuppression
- Mothering
- Hypothermia

The Problem

- How do we provide a product that:
 - That effectively achieves effective pain management for essential animal husbandry operations
 - That is easy to use and safe for the operator and animal
 - That is affordable
 - Ensures graziers can provide their quality products to the total world market



Meloxicam Buccal Formulation

ILIUM[®] BUCCALGESIC OTM

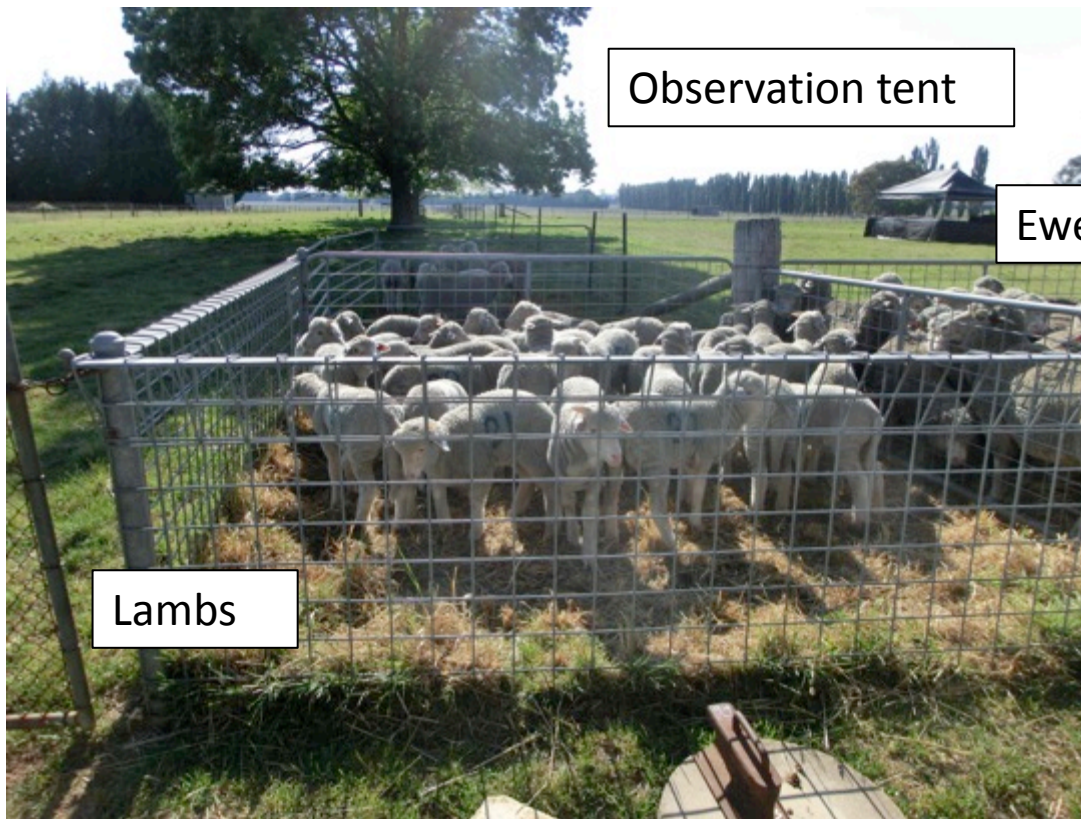
- Troy Laboratories Australia have developed a buccal formulation for oral trans mucosal (OTM) absorption
 - Cattle and sheep
 - Contains 10 mg meloxicam/ml
 - Is sticky so it adheres to the mucous membrane of the the mouth
 - Is applied into the sulcus between the molar teeth and the inside of the cheek



- ✓ It removes OH&S issues that comes with needles and syringes

Field Efficacy Study in Lambs

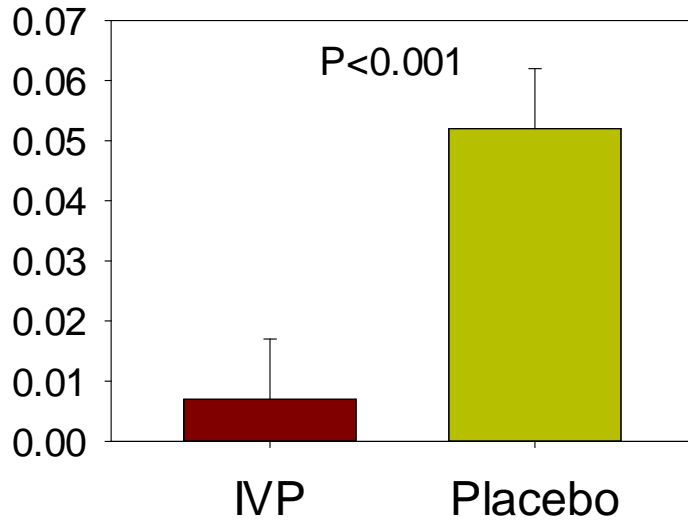
- A blinded, controlled, randomized block design study with detailed observed individual behavioural and physiological pain indicators



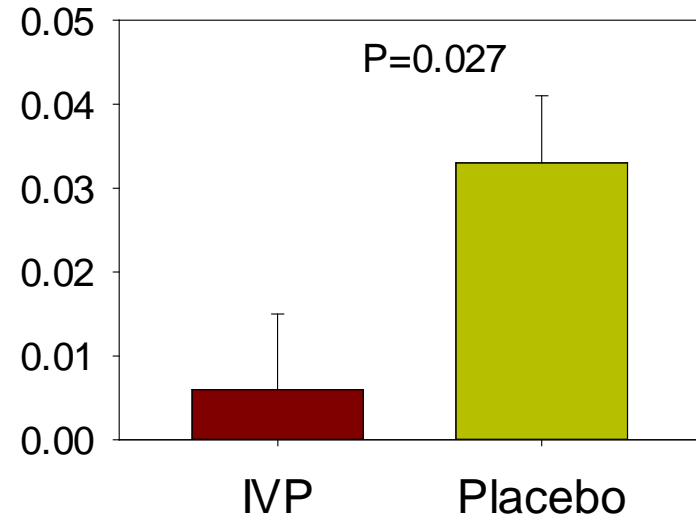
- ✓ 60 male lambs
- ✓ 7 – 10 weeks old
- ✓ On their mothers
- ✓ Divided into 2 groups:
 - 1) placebo treated
 - 2) meloxicam OTM treated at 1mg/kg BW

Results: 8 Hours Post Treatment and Procedure

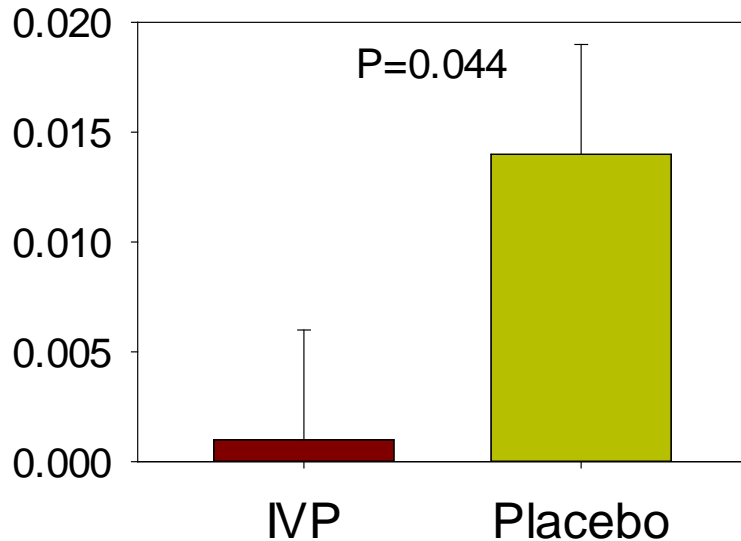
Total Abnormal Behaviours



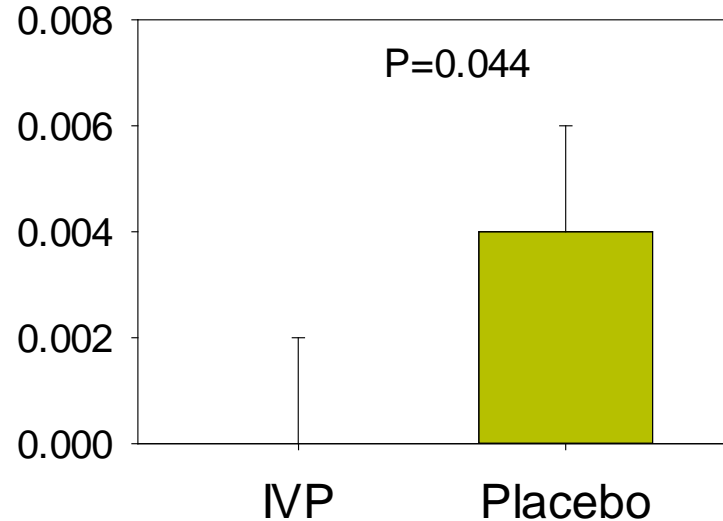
Standing hunched



Standing Stretched

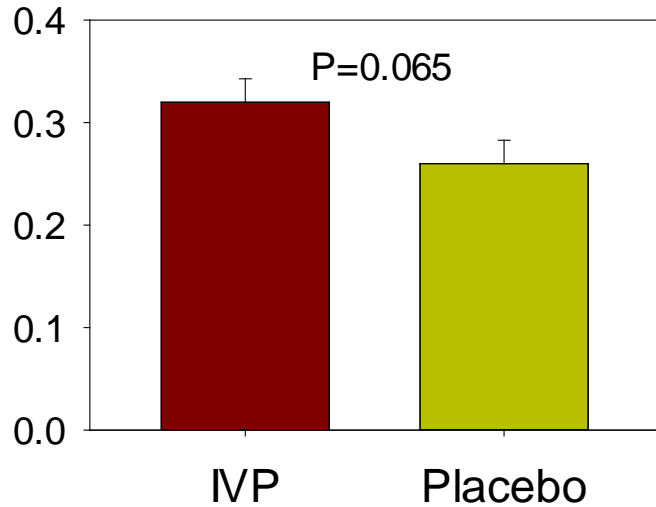


Walking Stiff

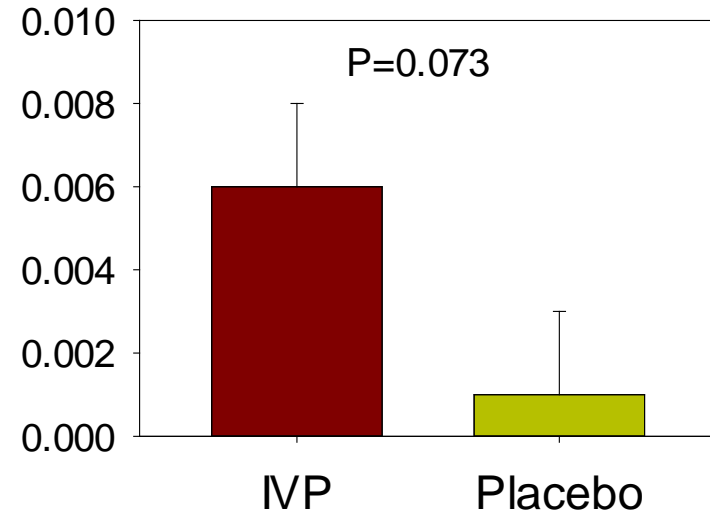


Results: 8 Hours Post Treatment and Procedure

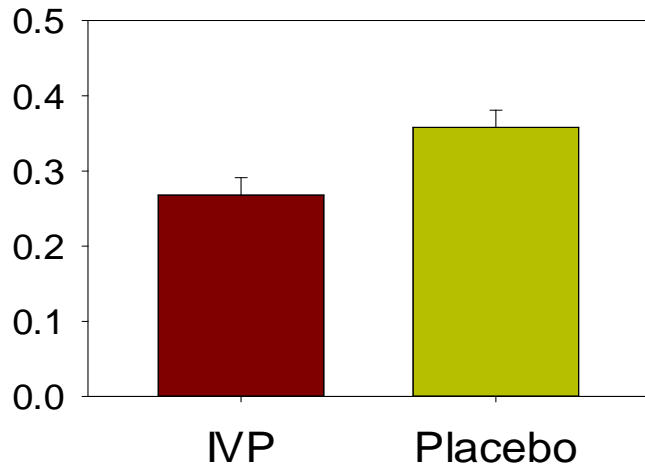
Grazing



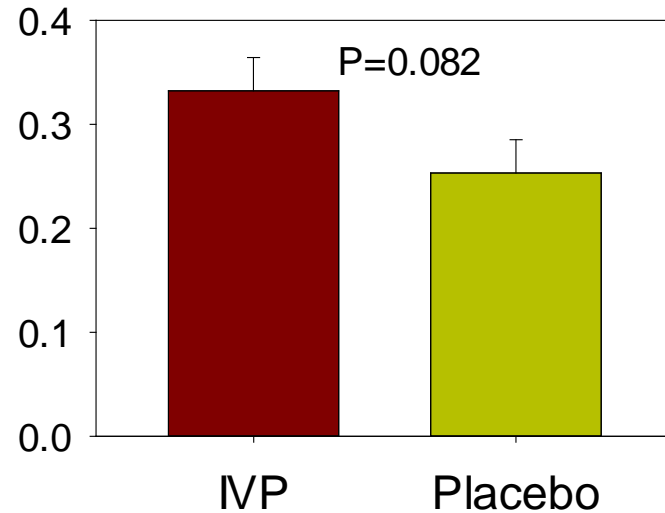
Suckling



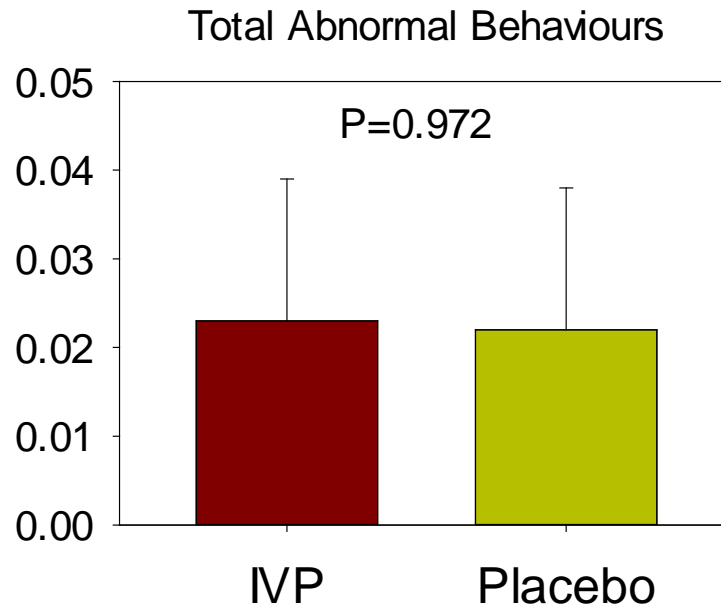
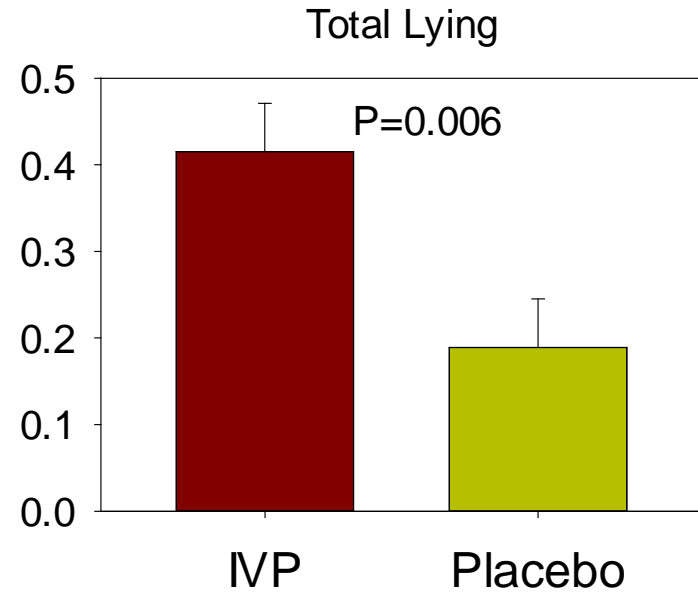
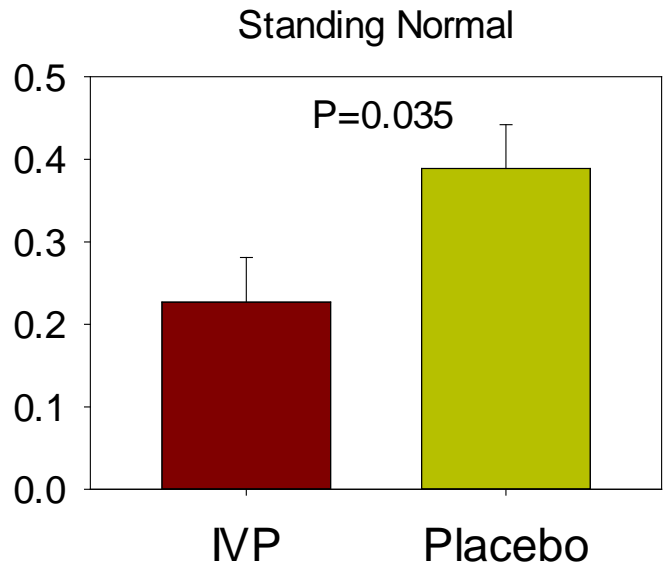
Standing Normal



Total Lying



Results: 24 Hours Post Treatment and Procedure



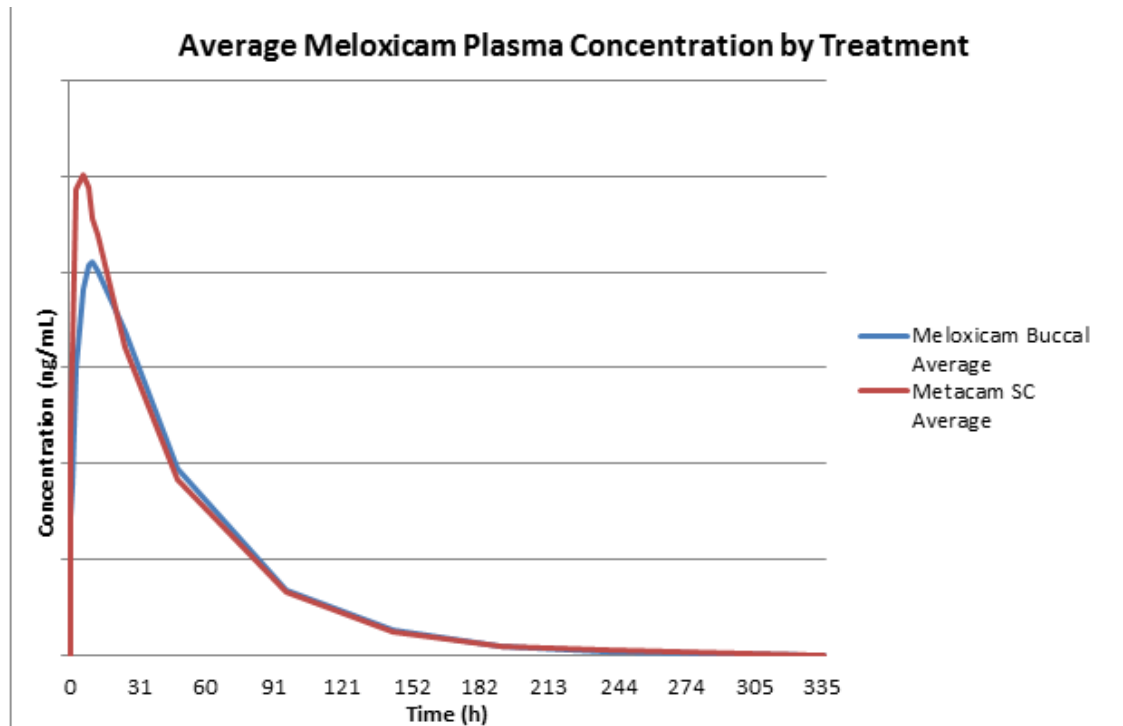
Conclusions

ILIUM[®] BUCCALGESIC OTM

- ✓ 1.0 mg meloxicam/ kg provided considerable analgesic benefits to lambs undergoing castration and tail docking
- ✓ was safe in young lambs when used as recommended under field conditions in Australia
- ✓ is a valuable tool in providing pain relief to lambs
- ✓ OH&S: safer for the operator
No needles

Introducing Buccalgesic

- A low volume gel is administered to the Buccal cavity
- The product contains 10mg/ml Meloxicam , and can have Xylazine added to it to shorten the time to achieve pain management
- The gel behaves like an intramuscular delivered drug



Average T_{max} by Treatment		
Buccal	8.9 h	
SC	5.2 h	

SC, Sub Cutaneous



ILUM BUCCALGESIC

- Fiona Cotter from Troy Laboratories has advised that recent research has confirmed Meloxicam can be used as a pain and inflammation management treatment in sheep.
- Meloxicam is administered to sheep by the buccal method (Meloxicam is placed in the sheep's mouth between the teeth and inner cheek lining) where the drug is quickly absorbed. High serum levels of Meloxicam are reached within 8 minutes of being administered.
- The research has shown that Meloxicam administered at the maximum proposed dose rate of 1 mg Meloxicam per kg bodyweight has no detectable residues of the drug in any tissue matrix from (and inclusive of) day 10 onwards post treatment.

ILIUM BUCCALGESSIC

- It is stained to ensure that double dosing does not occur
- There are no needles on farm
- It has been proven to work by quality third party scientists (CSIRO publication in Australian Veterinary Journal pending)
- It has been shown to be very effective in significantly reducing pain
- It will be AFFORADABLE
- It will be delivered to the market with MRL and ESI information
- The product will be entering the market in November 2014 for cattle, 1-2 years for sheep





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Australian
Wool Innovation
Limited

2008