

ENVIRONMENT

Title: Feasibility of Transdermal, Needleless Injection Device for Prevention of Pork Carcass Defects - **NPB #01-146**

Investigator: Joseph G. Sebranek

Institution: Iowa State University

Co-Investigators: Brad Thacker, Terry Houser, and Tom Baas

Abstract

A needle-free transdermal injection device was evaluated for effectiveness of vaccine delivery and for injection site lesions. A total of 96 pigs were vaccinated for pseudorabies virus (PRV) and for *Mycoplasma hyopneumonia* (*M.hyo.*). Pigs were divided into three groups; the first group served as unvaccinated controls, the second group was vaccinated with conventional hypodermic needles, and a third group was vaccinated with a needle-free, air powered injection device.

Pigs were tattooed on the neck to mark the injection sites. Blood samples were collected from the pigs at 11-13 days and 23-25 days following injection and the serological response was measured. Injection sites were collected at slaughter and dissected to evaluate tissue damage.

The results showed that both injection methods produced similar serological response in the vaccinated pigs and both were significantly greater than the controls. The injection site examinations have shown no lesions in any of the pigs.

The results show the needle-free, transdermal injection device to be effective and safe. Elimination of needles will prevent residual needle fragments in carcasses and associated carcass defects from injection site lesions.

Introduction

Pork carcass defects resulting from intra-muscular injection of vaccines and antibodies are a well-recognized problem in the meat industry. Problems of abscesses and muscle damage are result of injections, but a more serious problem to the meat industry is the presence of broken needles and needle fragments. Needle fragments are not easily identified by metal detectors due to; alloy compositions of the needles, fragment size, and orientation to the detector. Needle fragments in pork carcasses, are identified by metal detectors in less than 10% of the cases, where they are present. Thus, the potential exposure of consumers to metal fragments in pork products is a serious

These research results were submitted in fulfillment of checkoff funded research projects. This report is published directly as submitted by the project's principal investigator. This report has not been peer reviewed

For more information contact:

National Pork Board, P.O. Box 9114, Des Moines, Iowa USA

800-456-7675, Fax: 515-223-2646, E-Mail: porkboard@porkboard.org, Web: <http://www.porkboard.org/>

concern and a zero tolerance for needle fragments in pork carcasses is the only acceptable alternative.

A viable alternative is a needle-free, transdermal injection, which does not use hypodermic needles. A device recently developed by Felton Medical Inc., Lenexa, KS, delivers vaccines through the skin using compressed air. However, the immunological response and the degree of injection site damage that occurs in pigs from the transdermal injection system had not been determined.

This project was designed to evaluate the effectiveness of needle-free, transdermal injections for delivery of vaccines in pigs and to compare injection site damage between the needle-free and conventional hypodermic needle injections.

Objectives

The main objectives of this study are:

- a. Evaluate the delivery effectiveness of a needle-free, transdermal injection system for swine using a common viral (pseudorabies) vaccine and a common bacterial (*Mycoplasma hyopneumonia*) vaccine.
- b. Assess and compare muscle and tissue damage resulting from conventional hypodermic needle injections and needle-free, transdermal injections.

Procedures

A total of 130 pigs were selected from the Iowa State University Bilsland Memorial Swine Breeding Farm at Madrid, IA. Two weaning groups were selected for two separate trials (replications). Pigs were bled, tagged, tattooed and randomly assigned to treatment groups at 4-5 weeks of age. Tattoos were placed on the left neck to provide a marker for the injection sites. The three injections for each pig were given 1 inch from the tattoo in a different direction each time to form a triangle (anterior, posterior, and ventral) of injection sites. Treatment groups for the pigs included controls (no injection), hypodermic needle injection and needle-free transdermal injection. For hypodermic needle injections, an 18 gauge x 5/8inch (first vaccination) or 1inch (second and third vaccinations) needle was used for intra-muscular deposition of the vaccines. Needles were changed frequently, at least every 6 pigs.

For the needle-free injections, an air-powered device currently under development for commercial applications by Felton Medical Inc. (Lenexa, KS) was used. Company personnel performed injections. Operating air pressure was adjusted according to pig size to achieve appropriate injection of the vaccine.

The pigs were vaccinated with two doses of *M.hyo.* vaccine (Respire, Pfizer Animal Health) at 5-6 weeks of age and again two weeks later, and with pseudorabies vaccine (PrVac+, Pfizer Animal Health) at 9-10 weeks of age. Blood samples were collected before vaccination, at 11-13 days after the second mycoplasma vaccination and 23-25 days after the PRV vaccination.

Immune response was evaluated by Tween 20 ELISA for the *M. hyo.* antibodies and recorded as optical density COPI values. For PRV, a commercial ELISA (IDEXX, Portland, ME) was used by the Iowa State Veterinary Diagnostic Laboratory to determine serological response and results were recorded as S/P ratios.

Injection sites were observed and palpated following the injections and at each time of blood collection. Injection sites were removed from carcasses at slaughter and dissected to assess and compare tissue damage.

All data were subjected to statistical analysis to determine statistical significance and validate treatment differences.

Results

The results from antibody analyses showed that all the pigs were negative for both *M.hyo.* and PRV before vaccination. The results of the vaccinations with the two methods are shown in Table 1. Both injection methods resulted in significantly increased serological response compared to controls. In addition, there was no significant difference between the two injection methods. Therefore, the needle-free injection system is equally effective to the conventional hypodermic needle injection for vaccinations of *M.hyo.* and PRV.

Table 1. Immune Response to Injections

Trial	Injection type	<i>M.hyo.</i> -O.D. values		PRV-S/P ratios
		Test 1	Test 2	
1	Control	0.038	0.073	0.016
	Needle	0.515	0.426	1.124
	Needle-free	0.559	0.407	1.259
2	Control	0.075	0.047	0.037
	Needle	0.377	0.259	2.116
	Needle-free	0.449	0.241	1.874

Evaluation of injection sites on live pigs showed about 15% of the transdermal sites to have a transient skin thickening shortly following injections. Less than 1% of the needle injected sites showed similar thickening. This was observed only at 2 days after injection. Evaluation of injection sites after slaughter showed 3 lesions in 117 sites for the needle-free injections and 3 in 114 sites for the needle injections. The small, mild lesions observed were of no consequence for meat quality. No abscesses or granuloma were observed in any pigs.

Conclusion

The results of this study demonstrate that the needle-free injection system is effective for delivery of *M.hyo.* and PRV vaccines. Further, no tissue damage was observed for the conventional hypodermic needle injections, but these were not expected under the controlled conditions of this experiment. These defects are well documented for commercial pork carcasses.

It is clear that the needle-free injection system will eliminate all residual needles and needle fragments from pork carcasses and it seems likely to reduce injection site lesions resulting from contaminated needles, as well.

To fully evaluate the needle-free injection system, additional studies with more and different vaccines delivered transdermally should be conducted. The needle-free,

transdermal injection system for delivery of vaccines in swine has excellent potential for use in swine production systems.