Evaluation of an Air-Powered Vaccine Delivery System

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Introduction

The lesions produced in muscle tissue from needle contamination, or from pressure necrosis due to irritating material being injected, cause considerable losses to the beef industry. These losses are due to the wasting of trimmed material and also from loss in performance in the animals' suffering from such abscesses or tissue reactions. There is also the probability that animals with injection abscesses did not respond to the vaccine or medication that was given, since the product was not properly absorbed or distributed by the tissue.

The BallistiVet® delivery system has been patented as a unique system for the non-lethal ballistic implantation of biologics and pharmaceuticals in animals. The bio-bullet is a 25-caliber bullet made from hydroxypropylcellulose. The bullets have a hollow space where the product, such as the freeze-dried vaccine, is placed for delivery. According to the company, *"The biobullets penetrate quickly, lodging 1 to 3 centimeters in the animal's muscle, and begin to be reconstituted with the animals body fluids almost immediately. The biobullet will dissolve within 10 hours, leaving no lasting tissue damage."*

In a demonstration of the system, it was observed that as the cattle were shot in a feedlot alley, there were many animals that had blood seeping from the bullet site, and also many of the bullets were seen to bounce off the animals. No information was available on a number of questions, such as: What tissue damage is done to the animal from the bullet? Is there a difference in the depth of penetration if the muscle in the limb is tense due to its bearing weight versus relaxed state? Is there a difference in the penetration and in the tissue damage when the bullet is fired at the animal from different distances and different angles? This trial was designed in an attempt to address these questions.

Objectives

1. To evaluate the extent of tissue damage in calves that have been injected with the system's biodegradable bullets.

2. To evaluate the BallistiVet®[1] system as a means of delivering intramuscular injections into calves when the gun is fired from different distances, different angles and whether the leg is weight bearing or non-weight bearing.

Figure 1. *Clipped area on rear leg showing the hole in the skin from the bullet.*

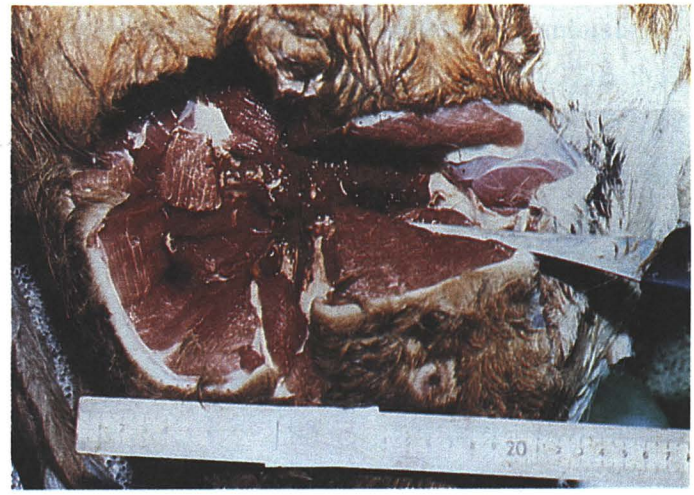

Figure 2. *An extensive area of hemorrhage deep in the muscle of the hind leg.*

[1]*BallistiVet Inc., 8990 Spring Brook Dr. Suite 250, Minneapolis, MN 55433*

Experimental Design

1. Three sedated, 400 lb beef calves were restrained so that accurate distance and angles could be maintained.
2. Firing distances were 15 feet, 20 feet and 25 feet.
3. Firing was done at 45° and 90° angles.
4. Firing into leg was done while the limb was weight bearing and non-weight bearing.
5. Animals were necropsied at 2½ hours post-injection to evaluate bullet penetration.

Methods

A total of 32 BallistiVet® hydroxypropylcellulose bullets were fired into three sedated, 400-lb calves. They were fired into the neck and leg at different angles (45° and 90°) and different distances (15, 20 and 25 feet) as noted in BallistiVet® Table 1.

All calves were euthanized and necropsied at 2½ hours post-injection. The bullet holes were identified and the area around the hole clipped and photographed. The tissue was excised, the bullet tract examined, described and photographed and then placed in 10% formalin for histopath evaluation. The intramuscular injections were considered successful if the bullet was located in the muscle (See Table 1).

Results

When the animals were shot, there was a jerking reflex as the bullet entered. Some of the bullets that were fired at 45° were seen to bounce off the skin without penetrating. It was also observed that some of the bullet holes had blood oozing from them and there was a slight swelling that seemed to develop around the hole in the skin. When these particular bullets were excised, it was noted that there was an accumulation of blood under the skin and the bullet had not penetrated into the muscle.

The neck proved to be a very poor area for the injection, with only one bullet recovered from muscle tissue of the 13 shots fired at the neck. This area also showed severe tissue destruction and hemorrhage when the bullets did penetrate. The majority of the 13 bullets

BallistiVet® Table 1. Summary of three calves shot at 15, 20 and 25 feet and at 45° and 90° angle.

LOCATION: NECK								
Angle	No. Shots Fired	Distance in Feet	Number Bullets Found	% Found	Number in Muscle	% in Muscle	Number Satis-factory	% Satis-factory
45°	3	15	1	33	1	33	1	33
	2	20	1	50	0	0	0	0
	2	25	2	100	0	0	0	0
TOTAL	7		4	57	1	14	1	14
90°	2	15	1	50	0	0	0	0
	2	20	1	50	0	0	0	0
	2	25	1	50	0	0	0	0
TOTAL	6		3	50	0	0	0	0
NECK TOTALS	13	--	7	54	1	8	1	8

LOCATION: LEG								
Angle	No. Shots Fired	Distance in Feet	Number Bullets	% Found	Number in Muscle	% in Muscle	Number Satis-factory	% Satis-factory
45°	2	15	2	100	2	100	2	--
	2	20	2	100	1	50	1	--
	2	25	1	50	1	50	1	--
TOTAL	6		5	83	5	67	4	67
90°	4	15	4	100	2	50	2	--
	5	20	3	60	2	40	2	--
	4	25	2	50	1	25	1	--
TOTAL	13		9	70	5	38	5	38
LEG TOTALS	19	--	14	58	9	47	9	47
TOTAL	32	--	2	66	10	31%	10%	31%

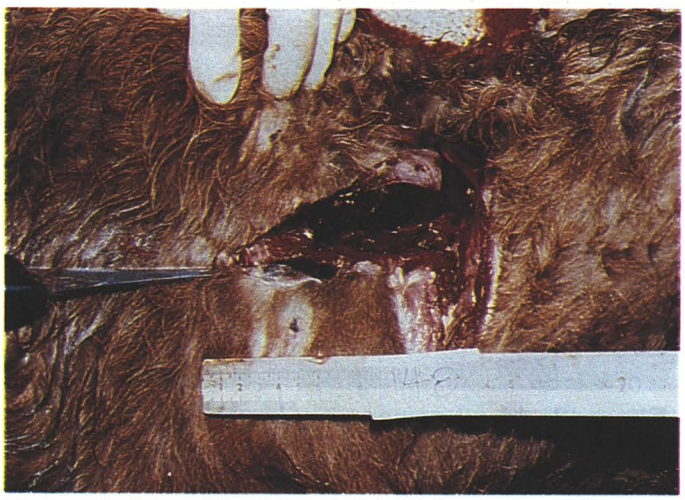

Figure 3. *Large blood clot visible both sub-Q and deeper in this cervical area where bullet was fired from 90° angle.*

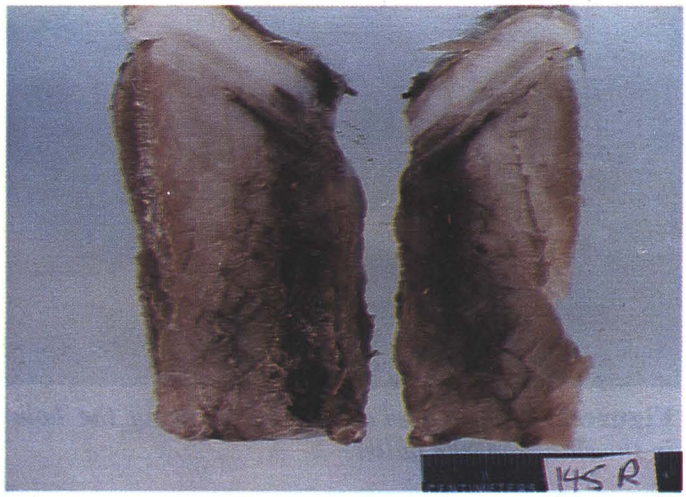

Figure 4. *Formalin fixed tissue showing the muscle drainage.*

fired at the neck bounced off or were found lodged either intradermally or just under the skin.

The most severe wound was identified as the one produced by a shot fired at the neck at 90° and from a range of 25 feet. It penetrated to a depth of 7 cm and lodged just lateral to a cervical vertebrae. There was severe hemorrhage into the fascial planes. The greater distance seemed to cause more tissue destruction. The only bullet recovered from muscle tissue in the neck was shot from a distance of 15 feet.

There were 19 bullets fired at the muscles of the hind legs. A total of 9 bullets were found in the muscle tissue. Considerable variation was found in the damage to the tissue. Bullets that followed fascial planes between muscles penetrated deeper into the leg. One hemorrhagic mass, measuring 8 cm X 6 cm X 2 cm thick, was identified next to the sciatic nerve. Another bullet was found 9 cm deep and lodged in connective tissue. One bullet was also found deep and adjacent to the hip joint surrounded by a fibrinous clot. The bullets that did not penetrate the muscle but remained subcutaneous also produced areas of hemorrhage.

After the tissue had been fixed in formalin, the tracts produced by the bullet as it passed through the muscle was quite distinct. Some of these tracts took a cylindrical shape and were up to 6 cm deep and 1 cm wide. The histopathologic examinations revealed some very severe lesions that included: tissue destruction and fragmentation, hair particles in tissue, necrosis, hemorrhage, rounded bullet tracts filled with blood clots and fibrin, and massive hemorrhage adjacent to a nerve.

Summary

Many products that are designed to be beneficial to animals can also be quite destructive. Contaminated needles that are used to inject vaccines, can introduce an infectious agent and produce severe abscesses. A large amount of some antibiotics can produce massive tissue destruction at the site of injection.

The lesions caused by shooting cattle with hydroxypropylcellulose bullets appear to be too destructive to be considered of any value as a delivery system for biological or pharmaceutical products. The lesions seen in this trial which was conducted under ideal conditions for placing the bullets, ranged from mild hemorrhages to severe tissue fragmentation and massive hemorrhages.

Bullets fired from distances greater than 15 feet cause more tissue damage. The rear limbs that were bearing weight when shot had the highest success rate with 8 out of 10 bullets being recovered from muscle tissue. Bullets that bounced off the skin, or went subcutaneous, caused considerable trauma to the tissue evidenced by fluid accumulation and hemorrhage. Where large vessels were penetrated by the bullet, there were massive hemorrhages present.

The three sedated calves in this trial were shot a total of 32 times. Only 10 bullets were recovered from muscle tissue for a 31% success rate. Of the 13 bullets fired at the neck area, only 1 was recovered from the muscle.

Regular processing procedures are intended to produce positive results by utilizing careful methods in administering vaccines to all of the animals. For a drug delivery system to be effective, it must be consistent in delivering the product to the animal tissue and also do it with a minimal amount of trauma to the animal. The air powered delivery system tested in this trial proved to be very unsatisfactory. Humane care of animals has not been mentioned, but it is the authors' opinion that indeed this .25-caliber gun is not a humane method for administering intramuscular injections into beef animals.

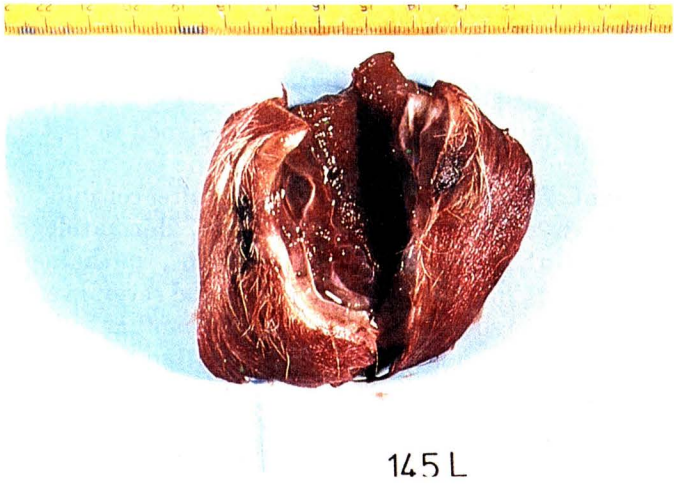

Figure 5. *Fresh sample showing where bullet entered and the subcutaneous fluid.*

Figure 6. *Formalin fixed tissue showing hole in skin and subcutaneous tissue reaction, as well as muscle damage.*