Summary of Field Studies Evaluating the Efficacy of Bio-Bond®

A Porous Polymer Sheath, on Radio Frequency Identification (RFID) Transponders to Prevent Migration from a Known Implant Site)

Dean Park and John Wieser
Destron Fearing Corporation, South Saint Paul, MN 55075 U.S.A
Editors: Martha A. Acosta DVM, MS and Vincent Chan, Ph.D.

Abstract

This study investigates the effect of placing Bio-Bond®, a porous polymer sheath, on Radio Frequency Identification (RFID) transponder implants (Fig. 1) to reduce migration from a known implant site. Two-year studies demonstrate that implanted Bio-Bond® transponders remain at a known implant site.

Introduction

Migration of RFID transponder implants, defined as measurable movement from known and usual implant sites, is a cause of concern for regulatory and animal shelter personnel, attending veterinarians and, most importantly, pets owners. Earlier studies dealt specifically with tissue reaction to various foreign bodies placed in, on, or through the skin of laboratory animals.[1,2,3,4,5] One of these studies specifically addresses the tissue reaction to Bio-Bond® in laboratory mice. The scope of this study is restricted to evaluate the efficacy of Bio-Bond® in limiting the movement of RFID transponder implants in research facility beagles.

Methods

The Destron Fearing TXI400L transponder implant is a miniature, battery-free, passive device enclosed in a biocompatible glass receptacle. Bio-Bond®, a porous polypropylene polymer sheath is placed on these transponder implants (Fig.1). Observations were made and documented that the Bio-Bond®, sheath fit snugly on the RFID device. These transponder implants were then placed in single use, disposable surgical cannula assemblies and sealed in Ty-Vek pouches and subjected to a FDA validated gas sterilization process. Beagle colony licensed veterinarians performed implantation with instructions for specific implant placement.

The RFID implants were specifically positioned subcutaneous, interscapular, mid dorsal on all test subjects. Spent packaging and cannula assemblies were discarded in an approved and acceptable manner. Periodic reading of all test subjects was done along the following protocol:

Testing Protocol

1. Read all transponders 5 days post implantation.

2. Read all transponders 90 days post implantation.
3. Read randomly selected dogs 365 days, ~1 year, post implantation.
4. Read randomly selected dogs 550 days, ~18 months, post implantation.[6]
5. Read randomly selected dogs 730 days, ~2 years, post implantation.
6. Read randomly selected dogs periodically to maintain familiarity of kennel staff with reading equipment.
7. Sample sizes of subjects in No's 3 through 6 immediately above of sufficient size to eliminate sampling error.
8. When the number of subjects remaining from original population falls below 50 animals, all remaining subjects would be evaluated and results reported.
9. When number of subjects remaining from the original population falls below 30 animals, the study will be terminated because of statistical unreliability of the results due to number of subjects available from original pool.
10. Test subjects would be periodically sacrificed and histological evaluations done on tissue surrounding the RFID implant performed as results reported in rat and mice (Fig. 2 and Fig. 3).

This was done to evaluate retention, functionality, and evaluate incidence of migration for those implants that might be found within measurable distances from prescribed implant sites.

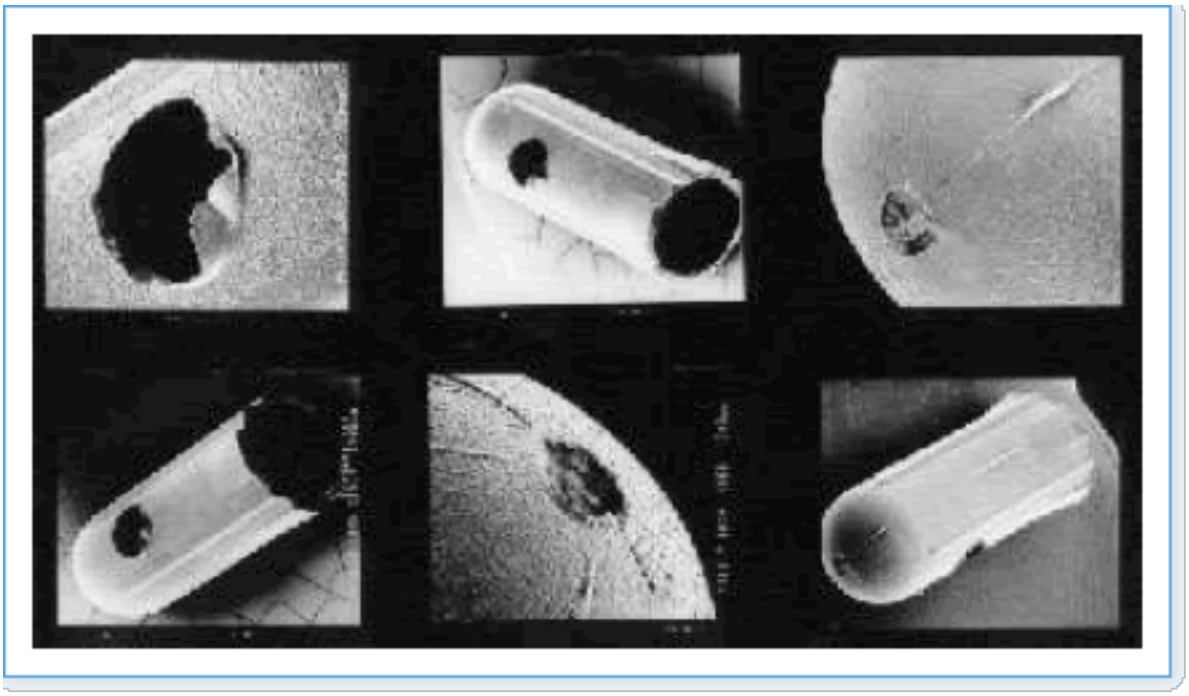

FIGURE 1: ELECTRON MICROGRAPH OF BIO-BOND

In December 1994, Destron Fearing TX1400L RFID implants fitted with Bio-Bond® were implanted in 148 beagles. Animals were fed and otherwise managed as normal residents of this research facility. This facility euthanizes a fixed number of animals annually to rotate their genetic program, which accounts for the reduction in test animals from 148 to the current 37. To fulfill the requirements laid out in testing protocol #5, in February 1997, transponder implants in 37 beagles were evaluated (read) and all were found to be fully functional in that they responded immediately to Destron Fearing RFID equipment. This represents all of the animals remaining from the original group and conforms to the Testing Protocol # 8 listed above. Various readers were used to ascertain the specific location of the transponder implant. All were found to be in the interscapular site where these individuals were fitted with the transponder implant. Results are reported in Table A.

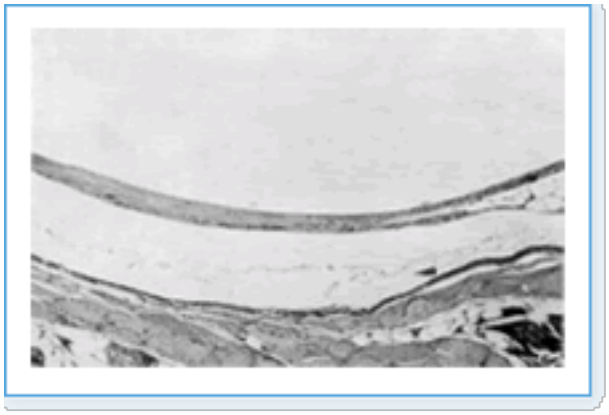

FIGURE: 2

This photomicrograph of space in the subcutis of a research rat shows where microcapsule was removed after two years of implantation. Only a very thin rim of mature fibrous connective tissue was present surrounding the implant. No inflammatory reaction was present. The reaction is considered to be completely non-adverse The panniculus muscle is seen at the top of the photograph.

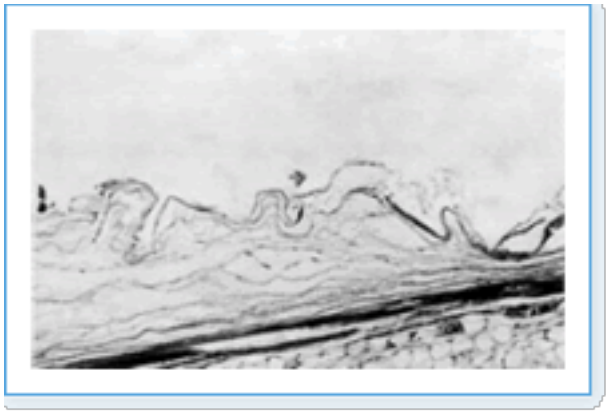

FIGURE: 3

This photomicrograph of space in the subcutis of a research mouse shows where microcapsule was removed after 95 weeks of implantation. One or two connective cell layers surrounded the implant: collagen was absent from most areas. No inflammatory reaction was present. The reaction is considered to be completely non-adverse. The panniculus muscle is seen at the top of the photograph.

Number of subjects	Transponders found in interscapular region	Percent of Transponders evaluated in interscapular region
37	37	100

Table A
Summary of functional implanted identification transponder twenty-four (24) months after implantation.
Note: All RFID transponders were found to be fully functional (responded to appropriate reading equipment) and were located precisely in the interscapular region.

Discussion

Research has demonstrated that none of the transponder implants migrated from the implantation site. Knowing that the RFID transponder fitted with Bio-Bond®, did not migrate is important for developing and refining scanning techniques used in animal control and recovery agencies. Animal identification programs continue to gain sophistication and are becoming mandatory in progressive countries, states and cities. This is being done in the interest of disease control and eradication and to promote human safety. Knowledge that RFID transponders, particularly those fitted with Bio-Bond® will remain in usual implant sites is critical to development of reading equipment and procedures for people who routinely come into contact with unknown, potentially diseased dogs and cats.

Field tests conducted by the Animal Humane Association (AHA) and reported in early 1997, evaluated microchips implanted in dogs and cats in the United States. The published report concluded that reliable scanning equipment is available to read the various U.S. manufacturers implanted microchips. The unreliability of equipment has long been recognized as a significant hindrance to the development of fullscale, mandatory animal identification programs centered around RFID transponder implants. Now animal control personnel will

have reliable equipment at their disposal that will identify all major types of RFID implants. Further, has been demonstrated that there are proven methods to assure that the RFID implant will remain at the sight of implantation. This equipment and these assurances will provide the impetus for programs designed to educate the pet-owning public that electronic animal identification is now at a dependable level of sophistication that, until recently, has not been possible.

Acknowledgement

We acknowledge the cooperation and assistance of the management and staff at the beagle colony research center who facilitated this valuable and ongoing research work. In appreciation of the continued support of the veterinary medical and other animal health professionals, the Research and Development Department of Destron Fearing Corporation publishes these results as part of our commitment to the veterinary and scientific community.

References

1. Brand KG (1982). Cancer associated with asbestosis schistosomiasis, foreign bodies or scars. In: Cancer a ComprehensiveTreatise. Etiology: Chemical and Physical Carcinogenesis, FF Becker (ed.). Plenum Press New York. p.p. 671-682.
2. Brand KG, Johnson KH, and Buoen LC (1976). Foreign body tumorigenesis. CRC Crit. Rev. Toxicol. 4: 353-394.
3. Haseman JK, Huff JE, Rao GN, Arnold JE, Boorman GA, and McConnell EE (1985). Neoplasms observed in untreated and corn oil gavage control groups of F344/N rats and (C57BL/6N x C3H/HeN)F1 (B6C3F1) mice. J. Nah. Cancer Inst. 75:975-984.
4. Waalkes MP, Rehm S, Kasprzak KS, and Issaq HJ (1987). Inflammatory, proliferative and neoplastic lesions at the site of metallic identification ear tags in Wistar [Crl: (W1) BR] rats. Cancer res. 47: 2445-2540.
5. Rao GN and Edmondson J (1990). Connective tissue encapsulation of polypropylene implant. Tissue Reaction to an Implantable Identification Device in Mice. Toxicological Pathology ISSN: 0192-6233. 18: 412-416. 1. Park D, Wieser J, Chan V. (1996). Nonmigration of Destron Fearing Implantable Microchips.
6. Olson PN, Fisher R, Petersdorf M. (1997) Results from the Field Test of Universal Microchip Scanners. AHA Shoptalk V5: 1-5,10.2