Excerpt from "Microchip-Induced Tumors in Laboratory Rodents and Dogs: A Review of the Literature 1990–2006"

By Katherine Albrecht, Ed.D., CASPIAN Consumer Privacy

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Ball et al., 1991

Evaluation of a microchip implant system used for animal identification in rats. *Laboratory Animal Science*. 1991;41(2):185—186.

Author(s)	Species	# of Animals	Length of Microchip Exposure	Developed Cancer
Ball et al., 1991	rats	10	2 weeks	none observed
		10	3 months	
		10	6 months	
		10	1 year	

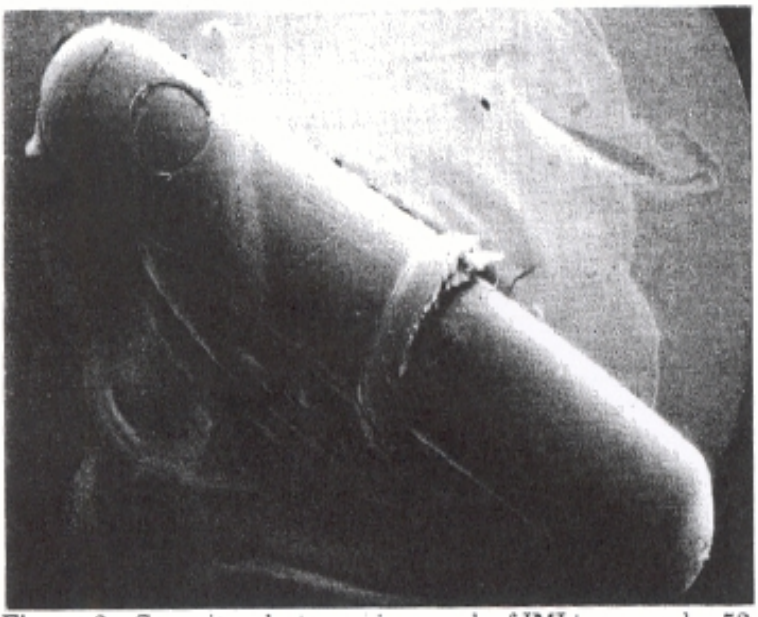

Figure 2. Scanning electron micrograph of IMI transponder 52 weeks postimplantation. The general morphology of both the glass capsule and polypropylene sheath were comparable to transponders before implantation. Higher magnifications revealed comparable results.

Summary of Study

40 rats were implanted with subcutaneous microchips and evaluated for adverse reactions. The tissue surrounding the implants was evaluated after periods ranging from two weeks to one year. No palpable masses or visible tissue reactions were observed.

Study design and key findings

This was one of the original studies undertaken to evaluate what was then referred to as "a new microchip-based animal identification system" being marketed to laboratory researchers by BioMedic Data Systems, Inc. The goal of the study was to evaluate the safety and effectiveness of implanted microchip transponders for laboratory animal identification.

For this study, 20 male and 20 female Sprague-Dawley rats were injected with microchip implants and observed for adverse reactions. At weeks 2, 12, 26, and 52, five rats of each sex were sacrificed (killed). The microchips and surrounding tissue from each rat were examined macroscopically and through histopathologic examination.

Although the researchers reported the development of "thin rims of immature fibrous connective tissue with occasional subacute inflammatory cells present in the subcutis 2 weeks after implantation" (p. 185-186) and later found that "very thin rims of mature fibrous connective tissue were seen surrounding the implant sites" (p. 186) they did not find any cancerous changes. They concluded that the implant was a "reliable, easy-to-use, nonadverse identification system." (p. 186)

Concern over the Design and Statistical Validity of the Study

Although the authors conclude that the implanted transponders "produced no adverse clinical or histopathological side effects in the rats," the findings must be evaluated in light of the short time period the rats were implanted and the small sample size used.

Of the 40 rats used in this early study, none were in contact with the implants for longer than a year. Later researchers, however, found that cancerous tumors generally occur in the second year of exposure.[1] When Elcock et al. (2001) examined a much larger sample of rats (n = 1,040), for example, they found a nearly 1% incidence of microchip-induced cancer, all of which occurred during the second year of the study. The average age of the animals at tumor onset in that study was 585 days, or approximately one year and seven months. Johnson (1996) similarly found that tumors in mice develop during the second year of exposure.

The absence of cancerous tumors in the present study—in which animals were examined after only 2 weeks, 3 months, 6 months, and 1 year of implant exposure—is in accord with the findings of other researchers. It is neither surprising nor anomalous, nor does it rule out the potential that microchip-induced tumors may develop in rats after a longer exposure period.

Another problem with the present study is the small number of animals that were evaluated. A sample size of 40 rats lacks the statistical power to detect a small effect. This was the case in the Murasugi et al. dog study discussed earlier, and the same discussion of sample size and statistical power is applicable.

When Elcock et al. (2001) conducted a subsequent study using a much larger sample of Fischer 344 rats (n = 1,040), they found a nearly 1% incidence of tumor formation. Due to the larger sample size, those results have greater statistical validity than those of the present study.

Study Details

- The study was conducted by D.J. Ball from Boehringer Ingelheim Pharmaceuticals, Inc. in Ridgeford, Connecticut, and associates.[2]

- The researchers thanked BioMedic for contributing to the study: "We would like to thank BioMedic Data Systems, Inc. of Maywood, N.J. for the implants and associated electronic equipment..."

- Animals used were Sprague-Dawley rats.

- Microchips used were from BioMedic Data Systems, Inc., Maywood, New Jersey. The chip was described as a miniature transponder hermetically sealed in an inert glass capsule with a polypropylene sheath that covered one end of the transponder.

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1 The only exception in the studies reviewed was the Blanchard et al. (1999) study in which 10.2% of mice developed cancer within six months of implantation. These findings were atypical, however, and may be attributable to the type of genetically altered mouse used in the Blanchard study.

2 Additional authors include G. Argentieri, R. Krause, M. Lipinski, and R. I. Robinson from the Sandoz Research Institute of East Hanover, New Jersey; R.E. Stoll from Cetus Corporation of Emeryville, California; and G.E. Visscher from Roche Dermatologics in Nutley, New Jersey.