

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

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Murasugi et al., 2003

Histological reactions to microchip implants in dogs. *The Veterinary Record*. 2003(Sept 13);328.

Author(s)	Species	# of Animals	Length of Microchip Exposure	Developed Cancer
Murasugi et al., 2003	dogs	6	≤ 1 year	none observed
		3	3–6 years	

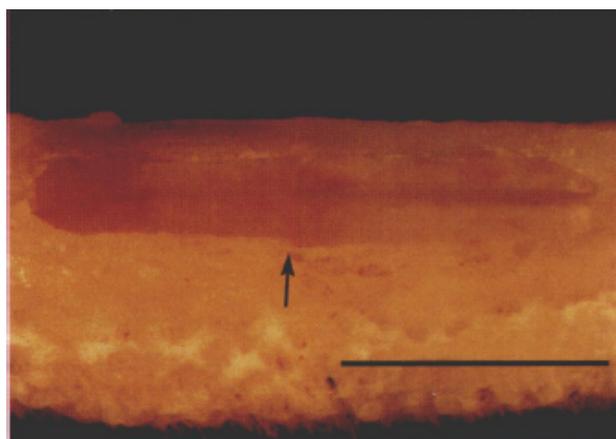


FIG 2: Cutaneous tissue section 72 months after microchip implantation showing infiltration of the tissue into the space between the cap and the body of the microchip (arrow). Bar=5 mm

"As the mean lifespan of dogs as companion animals increases, long-term evaluation of the safety and biological stability of implants is necessary." (p. 328)

Summary of Study

Nine dogs were implanted with microchips and observed for adverse outcomes over periods of three days to three years. One dog was exposed to the implant for six years. The chips and surrounding tissue were removed and examined microscopically. Inflammation and encapsulation had occurred, but no tumors or cancerous changes were found.

Study Design and Key Findings

Nine dogs (one female beagle, six female crossbreeds, and two male crossbreeds) were implanted with Destron Fearing LifeChip microchips. At selected time periods, the implants and a surrounding 2x2x2 cm cube of tissue were surgically

removed from each dog and microscopically evaluated. The evaluations took place on the following schedule:

# of Dogs Evaluated	Length of Microchip Exposure
2	3 days
2	3 months
2	1 year
2	3 years
1	6 years

After three days, a rim of inflammatory cells, blood congestion, and newly formed capillaries had developed around the implants. At three months, a capsule composed of connective tissue, elastic and collagen fibers had surrounded the implant. At twelve months, the encapsulation was complete

and no inflammation was observed. The evaluations at 36 and 72 months were similar to those made at 12 months.

The researchers summarized these findings as follows:

"a foreign body reaction to the subcutaneously implanted microchips was observed [initially] . . . followed by . . . the development of a thin capsule in close contact with the microchip. The inflammatory reactions disappeared three months after implantation, and enclosure of the microchip by a capsule consisting of fibroblasts, collagen fibres and elastic fibres was complete after 12 months. No marked difference was observed . . . 36 or 72 months after implantation, compared with those 12 months after implantation." (p. 329)

The researchers concluded that "These findings suggest that implanted microchips are likely to function safely throughout a dog's lifetime, without causing further histological [microscopic] changes."

Concern over the Statistical Validity of the Study Findings

Although the authors conclude that "implanted microchips are likely to function safely throughout a dog's lifetime," the absence of cancerous changes in a small sample of dogs exposed to microchips for a limited period is not sufficient evidence to conclude that microchip implants are safe for long-term use. Problems with this study include the small number of dogs examined and the short time of their exposure to the microchip.

A small sample size of just nine dogs lacks the statistical power to detect an effect that may be on the order of a percentage point or less. *Statistical validity* is the degree to which an observed result, such as a difference between two measurements, can be relied upon and not attributed to random error in sampling and measurement (National Women's Health Resource Center). *Sample size* is what gives a study statistical power, or accurate and valid predictive ability.

Dr. Elise Whitley and Dr. Jonathan Ball (2002), experts on medical statistics, explain the importance of sample size in medical studies designed to prove the safety of a device and rule out an adverse effect. They write:

"The ideal study for the researcher is one in which the power is high. This means that the study has a high chance of detecting a difference between groups if one exists; consequently, if the study demonstrates no difference between groups the researcher can be reasonably confident in concluding that none exists in reality. The power of a study depends on several factors, but as a general rule higher power is achieved by increasing the sample size.

It is important to be aware of this because all too often studies are reported that are simply too small to have adequate power to detect the hypothesized effect. In other words, even when a difference exists in reality it may be that too few study subjects have been recruited . . . the erroneous conclusion may [then] be drawn that there is no difference between the groups. This phenomenon is well summed up in the phrase, 'absence of evidence is not evidence of absence'. In other words, an apparently null result that shows no difference between groups may simply be due to lack of statistical power, making it extremely unlikely that a true difference will be correctly identified." [Emphasis added]

Source: Whitley & Ball, "Statistics review 4: Sample size calculations"

In this case the "difference" described is the difference between the rate of cancer formation in dogs that have and have not been microchipped. The present study assumes that the difference between these populations is zero or non-existent, but the sample size lacks the statistical power to state that conclusion.

To determine whether microchips are safe in dogs would require the statistical power of a much larger sample on the order of hundreds or even thousands of dogs.¹

In addition to the small sample size used, a further problem with this study is the short duration of time the dogs were in contact with the implants. Of the nine dogs studied, six had the implant removed within a year or less and only one dog retained the implant for six years. The researchers do not state the age of the dogs at the time they were implanted.

In mouse and rat studies, the onset of microchip-induced cancer typically did not occur until the second year after implantation. Very few tumors were seen in the first year of the study when the animals were in adolescence and early adulthood; most tumors arose during middle age and older for those animals. If dogs develop adverse microchip reactions at a comparable rate, we would not expect to see an onset of tumors in dogs until they, too, reached middle age and beyond. This would correspond to roughly six years of age, given that the average life span of a dog is just over 12 years.²

The two microchip-induced cancers reported in dogs (Vascellari et al., 2006, 2004) occurred in 9-year-old and 11-year-old dogs after exposure times of seven months and 19 months, respectively. Given the small number of reported cases, it is difficult to draw conclusions about the development of microchip-induced tumors in dogs, but it could be that older dogs are more susceptible to the possible cancer-inducing effects of implants than younger dogs. Future research could help determine the role of an animal's age and the duration of microchip exposure.

Study Details

- The study was conducted by E. Murasugi, H. Koie, M. Okano, T. Watanabe, and R. Asano, of the Department of Veterinary Medicine, College of Bioresource Sciences at Nihon University in Fujisawa, Kanagawa, Japan.
 - An acknowledgment at the end of the article states, "We would like to thank Dainippon Pharmaceutical for providing the microchips."
 - Microchip implants were described as "LifeChip injector; Destron Fearing. The microchips were approximately 2 mm in diameter and 11 mm long and contained an IC recording a unique identity number. . . [the microchips] are made of biocompatible glass and polypropylene..."
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1 In the recommendation section at the end of the present report, it is proposed that researchers could draw on the existing population of microchipped dogs in the United States to reach more statistically valid conclusions about the implant's safety and long term effects.

2 The average life span of the domestic dog is 12.8 years, with wide variation across breeds. The average bulldog lives just nine years, while the average chihuahua has a 15 year life expectancy (McCulough, 2007).