Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)

Anthony A. Malizia, Jr, MD; Herbert M. Reiman, MD; Robert P. Myers, MD; Jonathan R. Sande; Steven S. Barham, PhD; Ralph C. Benson, Jr, MD; Mrinal K. Dewanjee, PhD; William J. Utz

• **Although patients with urinary incontinence have been treated successfully by periurethral injection of polytef paste, this study in continent animals demonstrates migration of polytef particles from the injection site. We injected polytef paste periurethrally into female dogs and male monkeys. Particles were found at 50 to 70 days in pelvic nodes in six of seven animals and lungs in four of seven (the kidneys and brain were not studied); and at 10½ months in pelvic nodes, lungs, and brain in seven of seven; kidneys in four of seven; and spleen in two of seven. X-ray microanalysis confirmed that the particles were polytef. At 10½ months, polytef granulomas were found at all injection sites and some sites of distant migration. Since these granulomas signify chronic foreign-body reaction, we believe that until the long-term effects in humans are known, polytef paste should not be used in children or young adults with normal life expectancy.**

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MANY urologists inject polytef paste periurethrally into adults and children as treatment for urinary incontinence; more than 1,000 patients in the United States and several thousand in other countries have received such injections.[1-4] Recently, the use of polytef paste in children has been extended to include periureteral injection for vesicoureteral reflux.[5] Although articles in urologic literature have stated that the polytef implant retains its shape and position at the injection site,[3,4] we found no reports of histological studies, animal or human, confirming this statement.

Laryngologists, since 1964, have injected polytef into the vocal-cord region as treatment for dysphonia; and histological studies have been made of the local effects of that use.[6-23] These demonstrated foreign-body granuloma formation at the injection site and also local migration—which was believed to involve only particles less than 50 μm in diameter. The possibility of distant migration, however, was still not addressed.

The purposes of our study were (1) to analyze the currently marketed polytef paste for particle size; (2) to determine—in animals—whether the polytef particles remain at the periurethral site of injection; and (3) to observe any tissue reaction to the injected polytef. This article presents our short-term and long-term findings (50 to 70 days and 10½ months after injection).

MATERIALS AND METHODS

Polytef Paste

Polytef paste is a sterile mixture of polytetrafluoroethylene, glycerin, and polysorbate. It was supplied with an expiration date of February 1984 and was used in the study in July 1982.

The size of the polytef particles in the paste was analyzed by scanning electron microscopy. A 0.4-mL sample of paste was placed in a clean, 3-mL glass centrifuge tube. Distilled water was added, and the sample was spun for ten minutes in a tabletop centrifuge. This washing was repeated five times, after which a suspension of the particles was placed on an aluminum stub and allowed to air dry. The stub was then sputter-coated with a 60:40 mixture of gold-palladium metal in a vacuum evaporator and examined with a scanning electron microscope.

Experiment

The design of our experiment was to inject polytef paste periurethrally into dogs (female) and monkeys (male) as it would be injected into human patients, to wait for short-term and long-term developments, and then to search for the injected polytef particles, identify them unequivocally, and observe any tissue reaction associated with their presence.

(To guide the search for polytef particles after distant migration, if that should occur, we added a radionuclide marker to the paste injected into several animals. Since polytef is so inert that direct labeling is not practical, we used microspheres of radioactive strontium with diameters similar to those of the smaller particles of polytef in the paste. Our reasoning was that the microspheres and polytef particles of similar size, administered in the same injection, would behave alike in regard to migration, and that sites where radioactivity was detected would be potential sites of polytef. Of course identification of the polytef itself was the crux of the experiment.)

Animals.—The experimental animals were 14 female mongrel dogs weighing 20 to 30 kg and four male monkeys (two

From the Departments of Urology (Drs Malizia, Myers, and Benson, and Mr Utz) and Cell Biology (Mr Sande and Dr Barham) and the Sections of Surgical Pathology (Dr Reiman) and Diagnostic Nuclear Medicine (Dr Dewanjee), Mayo Clinic and Mayo Foundation, Rochester, Minn.

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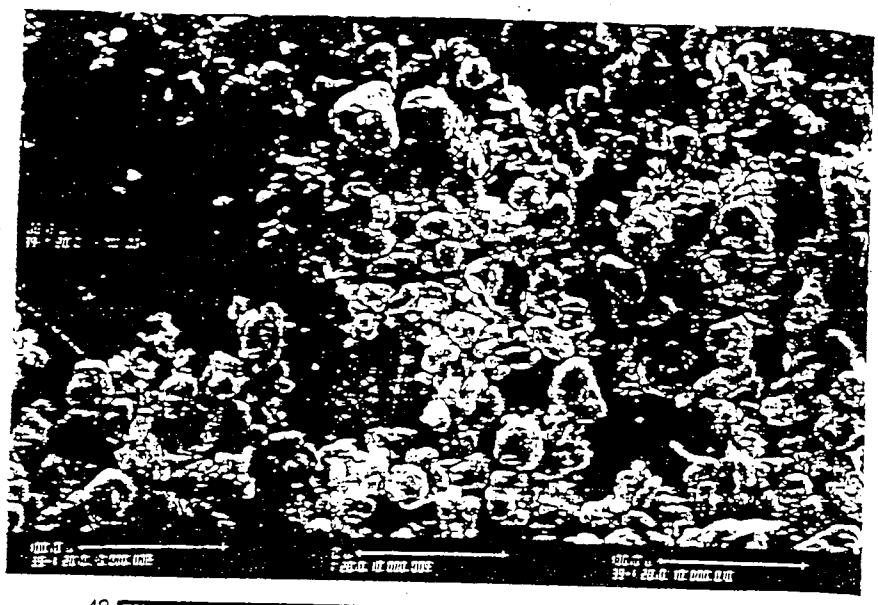
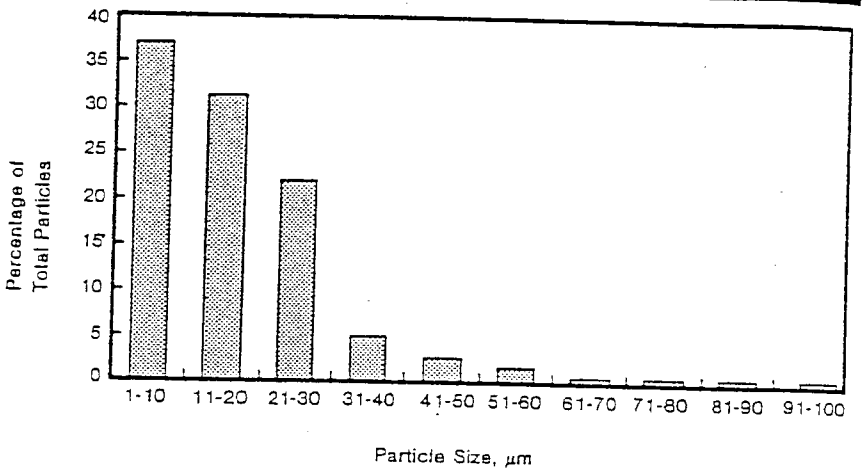
Reprint requests to Section of Publications, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (Dr Malizia).

Fig 1.—Composition of polytef paste. Top, Scanning electron micrograph of particles (X390). Bottom, Size distribution of polytef paste particles as measured from scanning electron micrograph.



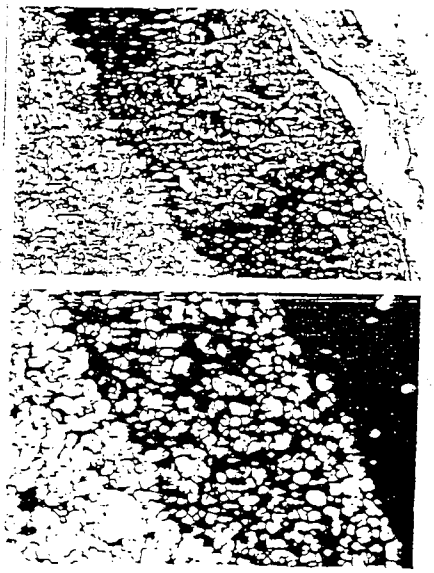


Macaca mulatta, one *Macaca nemestrina*, and one *Macaca arctoides*) weighing 12 to 20 kg. Since the study was not concerned with the cure of incontinence, we used continent animals.

Injections.—The injections were performed by the method of Politano,[3] with an 18-gauge, 9-cm needle and a syringe loaded with polytef paste (either with or without the radionuclide marker). Each animal was anesthetized and placed in the lithotomy position.

In the female dogs the needle (with syringe attached) was inserted 0.5 cm lateral to the urethral meatus and advanced, parallel to the urethra, 3 cm toward the bladder. After retraction of the plunger to check for intravascular placement, the paste was injected along the entire length of the urethra as the needle was withdrawn. Repetition of this procedure on the opposite side of the urethra left 1 mL of paste at the 3-o'clock position and 1 mL at the 9-o'clock position. After each injection, the urethra was inspected with a panendoscope to be certain that the needle had not perforated the bladder or urethra and that some bleb formation had occurred.[3]

In preparation of the male monkeys, the external genitalia and perineum were



2.—Periurethral injection site. Angular polytef particles (top) are brightly refringent under polarized light (bottom). Aggregated polytef particles are surrounded by marked foreign-body giant-cell reaction with minimal fibrosis. Scattered black microspheres are radionuclide markers (X100).

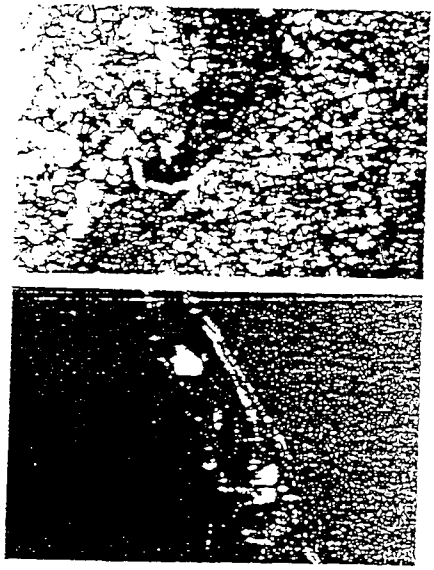


Fig 3.—At distant sites (polarized light, X100). Top, In pelvic node, polytef particles and black microspheres within foreign-body reaction. Bottom, In brain stem, several polytef particles trapped within subarachnoid space.

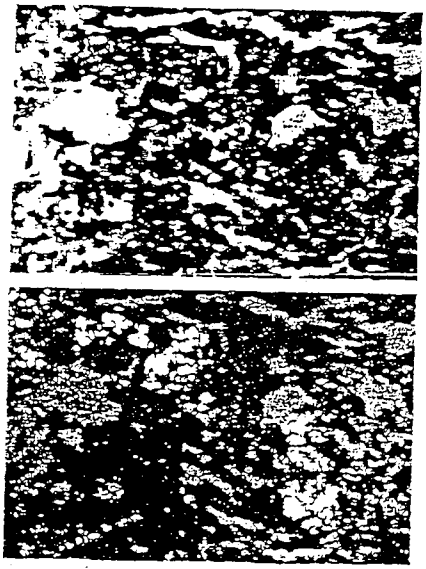


Fig 4.—In pulmonary interstitium (X400), histiocytic aggregates containing numerous particles under ordinary light (top) and polarized light (bottom).

cleansed. The urethra and bladder were inspected by means of a pediatric panendoscope, which was left in the urethra. The injection needle was inserted into the perineum and advanced, beside the urethra, into the apex of the prostate. Location of the needle was verified by gently moving it back and forth and observing, via panendoscope, the movement of tissue adjacent to the needle tip. Once the needle was in place, the loaded syringe was attached and the paste was injected. Repetition on the opposite side of the urethra left 1 mL of paste at the 3-o'clock position and 1 mL at the 9-o'clock position. Each injection made a bleb clearly visible via the panendoscope.[43]

Procedures Related to Radionuclide Marker.—The marker selected was a microsphere[24] of radioactive strontium (^{85}Sr) measuring 8.7 μm in diameter (SD, 1.3) and having a half-life of 65.2 days. For each occasion of use, a quantum of 160 μCi, mixed in 0.1 mL of 10% dextrose and 4 drops of glycerin, was added to 2 mL of polytef paste in a sterile polyethylene cup. The contents were stirred with a glass rod and transferred to the barrel of a 5-mL syringe (Luer-Lok). The plunger was inserted into the barrel and pushed gently until all air bubbles were removed, and the final volume was adjusted to 2 mL. The radioactivity in the syringe before and after periurethral implantation was measured in an ionization chamber.

Paste containing radionuclide marker was administered to eight dogs and one monkey. Four of the dogs were killed (by the protocol method) at ten days after injection; and the injection site, pelvic lymph nodes, kidneys, lungs, liver, spleen, and brain were studied for radioactivity by use of an ionization chamber and gamma counter. These four dogs were not studied histologically because the radioactivity was too intense. The remaining five animals given paste containing radionuclide marker were killed at 10½ months, and their organs were studied with the gamma counter before histological examination.

Histological Evaluation.—Exclusion of the four dogs killed at ten days left 14 animals (five with radionuclide marker, nine without) for histological study. Seven were killed at scheduled times from 50 to 70 days after injection (short term) and seven at 10½ months (long term). This was accomplished by injection: for dogs, 10 mL of 26% pentobarbital sodium intravenously; for monkeys, the same or 1.2 mL of ketamine hydrochloride intramuscularly.

Just after death in every case, the pelvic organs were removed en bloc and fixed in a 40% solution of formaldehyde, and the entire nodal specimens and representative samples of lung, liver, and spleen were taken and placed in separate containers of 40% formaldehyde.

After fixation, the pelvic block was dissected, the polytef injection site was identified, and representative sections of tissue from that site and of other tissues were taken for histological study. Also, from long-term animals, sections of the brain and kidneys were taken for detailed study. The sections were embedded in paraffin and stained with hematoxylin-eosin by routine methods and then examined by microscopy under ordinary light and polarized light.

Identification of Polytef Particles.—From tissue in which light microscopy showed particles thought to be polytef, samples were selected for definite identification of the substance by x-ray microanalysis, directed by transmission electron microscopy.

In this procedure, visualization by means of the transmission electron microscope allows precise selection of target areas for bombardment by its incident electron beam. The excitation of atoms within the area causes them to emit x-rays with energies that are unique to each element. Capture of these emissions and measurement of their energies provide the basis for identifying the elements present.

This analysis demonstrates polytef by identifying fluorine, which is a prominent component of polytef (a carbon fluorine polymer consisting of very long chains of linked C_2F_4 units) but does not occur in detectable amounts within normal body tissue. At the low levels of x-ray energy emitted by fluorine (0.677 keV), less than 10% of its emissions are detected"; but the high concentration of fluorine in polytef overcomes this insensitivity.

Tissue samples from all three short-term monkeys, two short-term dogs, and three long-term dogs were prepared by routine methods and embedded in resin blocks.[44,47] Sections cut 1 μm thick and stained with toluidine blue O allowed localization of particles in the resin blocks by polarized light microscopy. For transmission electron microscopy of the areas thus located, new sections were cut 50 to 60 nm thick, mounted on copper grids, and poststained with 2% uranyl acetate and 0.3% aqueous lead citrate. These showed the smaller particles and surrounding tissue, but larger particles tended to be dislodged and lost in the cutting. For the x-ray microanalysis, sections from blocks not postfixed with osmium tetroxide were cut 130 nm thick and mounted on titanium grids without poststaining. In these, the tissue detail was less distinct but all particles were retained.

All sections were analyzed for fluorine with an energy-dispersive x-ray spectrometer interfaced with a transmission electron microscope. The product of each analysis was a graphed spectrum of the x-ray energies emitted from the bombarded area. After each spectrum from a particle was acquired, two control spectra were obtained: one from a cellular region adjacent to the particle, another from an area containing only embedding medium. All spectra were acquired for a minimum of 180 s with use of an accelerating voltage of 60 kV, an electron-beam spot size 500 nm in diameter, a specimen tilt of 25° from the horizontal toward the x-ray detector, and a magnification of ×19,500.

RESULTS

Particles in Polytef Paste

In currently marketed polytef paste, scanning electron microscopy showed that the polytef particles ranged from 4 to 100 μm in greatest dimension and more than 90% of them were between 4 and 40 μm. The shapes were angular and irregular (Fig 1).

Distribution of Injected Polytef Particles

Search and Recognition.—Radioactivity was detected at the injection site and in the pelvic nodes, liver, spleen, lungs, and brain of all nine animals that received polytef paste containing the radionuclide marker. The radioactivity indicated not only which organs should be searched for polytef, but sometimes which part of an organ should be examined.

On light microscopy, the microspheres and polytef particles often were seen close together (as in Figs 2 and 3). The polytef particles were nonstaining and refractile. Under polarized light they were brightly birefringent (Fig 2), which is characteristic of polytef.

At Injection Site (Fig 2).—Polytef particles were seen at the injection site in all 14 animals studied histologically (short term or long term). The particles tended to be situated in aggregates, as injected, which ranged from 0.1 to 1.0 cm in greatest dimension.

At Distant Sites (Figs 3 and 4).—Polytef particles were demonstrated at distant sites in all of the animals studied (Table). The histological features in dogs and monkeys were similar, and the migrant particles appeared identical to those seen at the injection site. Their greatest dimension ranged from 4 to 80 μm.

Among the seven short-term animals, the pelvic nodes of six contained particles, and so did the lungs of four

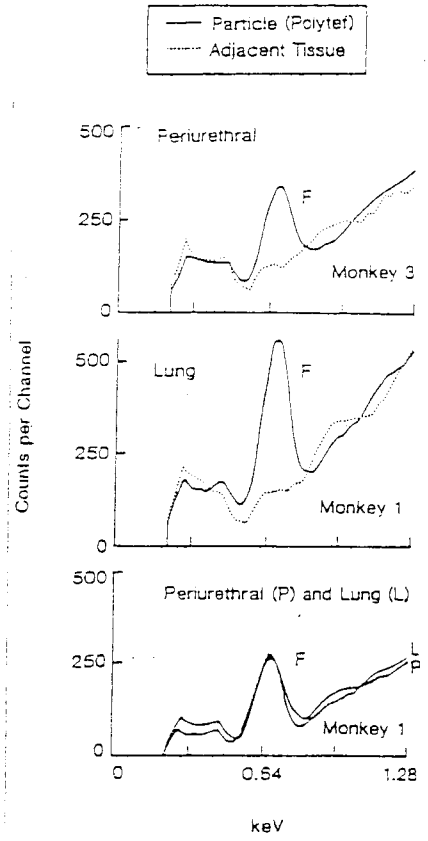


Fig 5.—Graphed spectra of x-ray energies emitted from particles and adjacent tissues of monkeys 50 to 70 days after periurethral injection of polytef paste. Peak F (at 0.677 keV) represents x-ray emission from fluorine. At top, Spectra from aggregate of particles in prostate and from adjacent cellular area (monkey 3). At center, Spectra from particles in lung and from adjacent cellular area (monkey 1). At bottom, Spectra from aggregate of particles in prostate and from aggregate of particles in lung (monkey 1).

Anatomic Distribution of Periurethrally Injected Polytef

Interval After Injection	No. of Animals Studied	No. With Polytef Particles in						
		Injection Site	Pelvic Nodes	Lungs	Spleen	Liver	Kidney	Brain
50 to 70 days								
Dogs	4	4	3	2	0	0	...	...
Monkeys	3	3	3	2	0	0	...	...
Total	7	7	6	4	0	0	...	...
10½ mo								
Dogs	6	6	6	6	1	0	3	6
Monkeys	1	1	1	1	1	0	1	1
Total	7	7	7	7	2	0	4	7

animals—three of which had particles within the pulmonary interstitium (inside of histiocytes). No particles were found in the spleen or liver of short-term animals; the kidneys and brain were not studied.

Among the seven long-term animals, particles were found in the pelvic nodes, lungs, and brain of all and in the kidneys of four and spleen of two, but still not in the liver. In the lungs, some particles were free within alveoli, blood vessels, or bronchi; but others were subpleural and many were in the interstitium.

Tissue Reaction to Polytef Particles

Injection Site.—Among the seven short-term animals (50 to 70 days) reaction to the polytef particles at the site of injection was minimal. A thin fibrous capsule had formed around aggregates (but individual particles still could be found apart from the aggregates).

Among the seven long-term (10½-month) animals, however, each polytef-particle aggregate at the injection site was surrounded by a pronounced chronic inflammatory reaction: histiocytes had phagocytized the outer particles and coalesced to form giant cells (polytef granuloma, Fig 2).

Distant Sites.—In short-term animals, the lymph nodes exhibited minimal tissue reaction, most particles being free within the sinusoids. However, there was a foreign-body giant-cell reaction in the lung of one animal (among those having particles inside histiocytes in the pulmonary interstitium).

In two of the long-term animals, particles within the pelvic nodes had elicited marked foreign-body reaction (Fig 3); but in the other five, the particles were in the sinusoids and the reaction was minimal. Again, as in the short-term group, three of seven long-term animals had particles (4 to 20 μm) inside localized histiocytic aggregates (polytef granulomas) within the pulmonary interstitium (Fig 4). The kidneys containing particles (in four animals) showed some loss of glomeruli. Although birefringent particles were freely dispersed in the subarachnoid space of the brain stem and cerebral hemispheres of all seven long-term animals, no tissue reaction was seen in the brains (Fig 3, at bottom).

Elemental Identification of Injected Polytef Particles

The x-ray spectra from particles at the injection site of all short-term monkeys confirmed the presence of polytef, as explained before (Fig 5, at top and bottom); and so did spectra from particles in the lung of one monkey (Fig 5, at center) and in lymph nodes (data not shown) of the other two. The spectra from particles at different sites (injection site or lung) in the same animal were alike (Fig 5), and so were the spectra from the corresponding injection sites in different monkeys (not shown).

X-ray spectra acquired from particles in tissue of one long-term dog showed fluorine in the injection site and kidney; and those from particles in tissue of another long-term dog showed fluorine in the pelvic nodes and lung.

Simultaneous transmission electron microscopy verified that the sources of the spectra were indeed the particles selected for analysis.

COMMENT

This study demonstrated that periurethral injection of polytef paste is followed by distant migration of component polytef particles with diameters of 4 to 80 μm—and by granulomatous reactions in host animals.

Polytef particles at both local and distant sites were identified by standard and polarized light microscopy; and x-ray microanalysis coupled with electron microscopy confirmed, on an elemental basis, that these particles were indeed polytef.

The polytef paste administered to our animals was only one eighth of the usual initial dose for humans—or, in proportion to body weight, one half the human dose.

Previous Experience and Present Concerns

Particle Size and Migration.—Our analysis of the currently marketed

polytef paste brings to attention certain publications of past decades. A laryngologic study, reported in 1967, determined that a diameter of 50 μm was necessary to inhibit migration of polytef particles injected into the vocal-cord region.[11,12] In 1970 it was reported that the company manufacturing polytef paste at that time had agreed to adopt the specification of 50 μm for minimum diameter of particles in the paste.[21] As recently as 1982, the paste was described as composed of particles about 50 to 100 μm in diameter.[4]

Nevertheless, our analysis of the currently marketed polytef paste revealed 90% of the particles to be between 4 and 40 μm. Laryngologists and urologists are now using a paste containing particles that were proved long ago to migrate locally. Moreover, our study demonstrated that—after periurethral administration to animals—particles with diameters up to 80 μm migrate to distant locations.

Potential Harm?—There remains the question of potential harm. Although we know of no untoward side effects from the urologic use of polytef to date, both orthopedic and laryngologic experiences have demonstrated foreign-body granuloma formation. Particles abraded from polytef used in more than 300 total hip replacements (1958 to 1962) caused "voluminous masses of caseous material adjacent to the joint,"[28-30] necessitating replacement of the majority of the prostheses.[30,31] Laryngologists, after intracordal injection of polytef paste, found local migration with granuloma formation and advancing tissue fibrosis.[21]

The finding of polytef granulomas in all of our long-term dogs and monkeys raises concern about use of polytef paste in humans. Such granulomas signify a chronic foreign-body reaction, which after a longer period may result in fibrosis. Although carcinogenesis by polytef has not been demonstrated in humans, polytef—like asbestos (another inert substance)—has been shown to be carcinogenic in rats.[32] Leukemia, myeloma, and malignant mesothelioma have developed in humans long after exposure to asbestos,[33] and it has been suggested that polytef exposure may lead to tumor formation in humans, given a long enough lag period.[32,34,35]

Conclusion

We believe that physicians currently using polytef paste should be aware of its distant migration and of the tissue reaction to local and migrant particles. Our opinion is that this substance should not be given to children or young adults with normal life expectancy until its long-term effects in humans are known.

Addendum

Since the submission of this article, a report has confirmed its findings in a human. Polytef granulomas were found in the lungs of a patient who had received two periurethral injections of polytef paste, two years and one year before his death by suicide.[36]

William L. Furlow, MD, Frank J. Leary, MD, and David M. Barrett, MD, suggested the need for this animal study; Paul E. Zollman, DVM, helped in care and anesthetizing of animals; Frank J. Leary, MD, and David C. Utz, MD, assisted in and supervised the injections; Cheryl R. Kramer typed the manuscript; and Guy Whitehead, PhD, provided editorial assistance.

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