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CHANGES IN THE LUNG FOLLOWING INJECTIONS OF SILICONE GEL

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SILICONES for reconstructive surgery may be in solid, liquid or gel form. The inertness of solid silicone in so far as it is unchanged by contact with the tissues is well established. On the other hand Silicone Fluid[1] of 350 centistokes viscosity is phagocytosed by a variety of cells after injection and can find its way into various organs. (For a full review of solid and liquid silicones see Blocksma and Braley, 1973.)

Although silicone gel makes up most of the bulk of many breast prostheses, it is not in contact with the tissues. Indeed silicone gel on its own has been little used in Britain and North America; although Spira and Hardy (1971) and Freeman (1974) have implanted Silastic gel obtained by opening a breast prosthesis they were unable to obtain the material in any other way.

By contrast, Elicon[2] silicone gel injections have been widely used in the Orient, Europe and South America mainly for breast augmentation (Uchida, 1956, 1961; Yoon, 1964; Mutou, 1965; Pigossi, 1972). The complications are also well known (Boo Chai, 1969; Mutou, 1970). Spira and Hardy implanted Silastic[1] gel from breast prostheses into rats and mice and claimed that there was "no spread or dissemination of the gel to either lymph nodes or major organs". It seemed to us strange that we could find no trace of a similar experimental study of the much more widely used Elicon gel and the following investigation was undertaken.

MATERIAL AND METHOD

Thirty-eight adult McCallum male rats weighing 250-310 g were injected with Elicon silicone gel with a viscosity of about 300,000 centistokes with the aid of a special pressure syringe, available from the silicone manufacturer.

The animals were divided into 5 groups:

Group A (7 rats)—intraperitoneal injection of 1 ml.
Group B (7 rats)—injection of 1 ml deeply into the subcutaneous tissue of the thigh.
Group C (8 rats)—intraperitoneal injection of 5 ml.
Group D (8 rats)—deep injections of 5 ml into the subcutaneous tissue of the thigh.
Group E (8 rats)—controls, not injected.

The animals were sacrificed periodically according to the following schedule:

Group A and B—after 10, 20, 30, 75, 150, 270 and 360 days.
Group C, D and E—after 15, 30, 60, 90, 120, 180 and 270 days.

A piece of the peritoneal lining (Groups A, C and E), tissue from the site of the thigh injections (Groups B and D) and the heart, lungs, liver, spleen, kidneys and adrenals of all the animals were removed for histological examination.

[1] Dow Corning.
[2] Koken Kogyo.

Results and Discussion

Many workers with silicone fluid found cysts scattered throughout the injected tissue and intracellular vacuoles which did not stain with the usual dyes. Although there was no absolute proof they assumed that silicone fluid had been present in the vacuoles and cysts and it had been lost during preparation (Ben Hur and Neuman, 1965; Ben Hut *et al.*, 1967; Rees *et al.*, 1967). By analogy, the unstained cysts and vacuoles found in the present study were assumed to have held the silicone gel.

The local findings in the peritoneum and subcutaneous tissue were similar to those which have been observed by those using silicone fluid: vacuoles surrounded by histio-

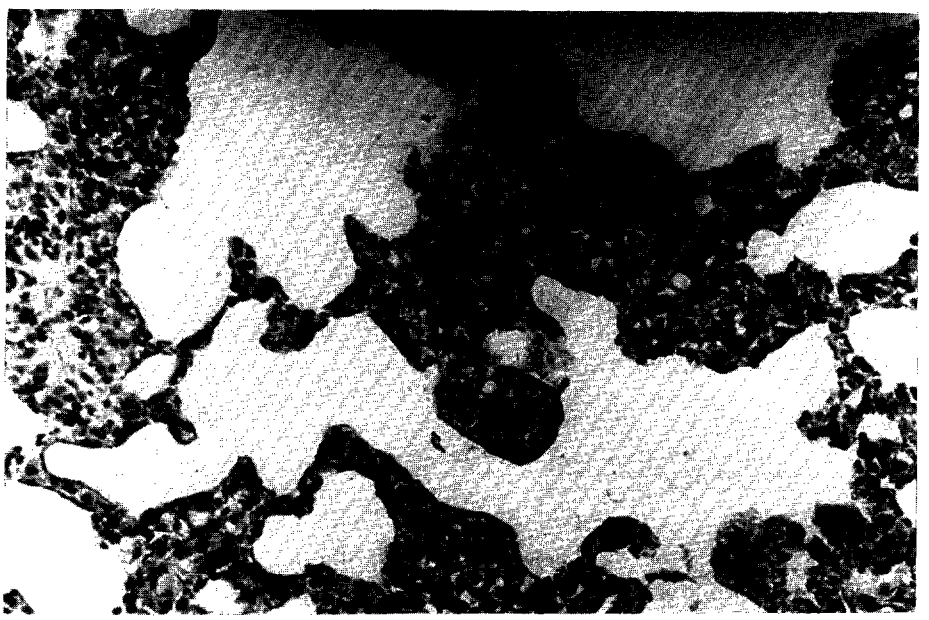

FIG. 1. Five ml subcutaneous injection, 60 days. Thickening of the septa of lungs. HE. × 250.

cytes, giant cells and lymphocytes and in the subcutaneous vacuoles a thickening layer of collagen. Intracellular vacuoles were also observed.

The only organ in which changes occurred was the lung and they appeared after 30 days in Groups A and C and after 60 days in Group D.

There was focal thickening of the alveolar septa (Fig. 1) caused by an accumulation of lymphocytes, plasmocytes, giant cells and histiocytes filled with microvacuoles (Fig. 2) which did not stain with the usual dyes.

The silicone gel in the lungs would most likely be the result of phagocytosis of the silicone by macrophages at the injection sites, which would be carried to the lungs in the bloodstream or perhaps via lymphatics; clearly this is one more proof that the membranous capsule which surrounds the silicone after subcutaneous injections is not an absolute barrier avoiding the absorption of the foreign material by phagocytes. In the subcutaneously injected groups the amount injected seemed to decrease progressively.

Similar findings have not been reported in experimental studies of silicone fluid. Accumulations of the silicone fluid were found in liver, spleen, pancreas, ovary (Rees *et al.*) and adrenals (Ben Hur, 1967) which in our study showed no abnormalities. The difference in viscosity may account for the disparity in the results.

We are uncertain about the possible risks in clinical use of Elicon gel so far as our results go. However, dispersion of the material in several multisized vesicles, progressive decrease of the injected amount, local phagocytosis and a chronic inflammatory process are proof that the silicone gel behaves like silicone fluid and is not so inert as solid silicone, as was previously supposed.

The functional importance of the changes in the lungs remains unknown. The abnormalities appeared only after increased amounts of injected gel but may have occurred also after the smaller injections, although undetected.

It follows that Elicon silicon gel is contraindicated for use in breast augmentation and other conditions in which great amounts are necessary and more experience must be available before the material is used clinically.

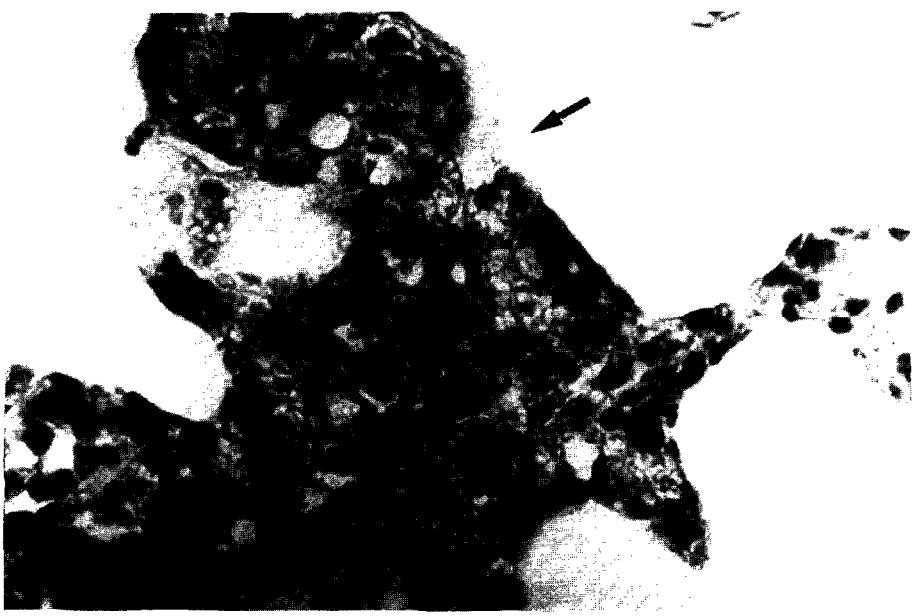

FIG. 2. Five ml subcutaneous injection, 60 days, thickened alveolar septum; in the centre histiocytes with multivacuolised cytoplasm. HE. × 400.

REFERENCES

BEN HUR, N. and NEUMAN, Z. (1965). Siliconoma—another cutaneous response to dimethylpolysiloxane. Experimental study in mice. *Plastic and Reconstructive Surgery*, **36**, 629.

BEN HUR, N., BALLANTYNE, D. L. Jr., REES, T. D. and SEIDMANN, I. (1967). Local and systemic effects of dimethylpolysiloxane fluid in mice. *Plastic and Reconstructive Surgery*, **39**, 423.

BLOCKSMA, R. and BRALEY, S. Jr. (1973). "Implantation Materials in Plastic Surgery", edited by Grabb, W. C. and Smith, J. W. Boston: Little, Brown and Company.

BOO-CHIAI, K. (1969). The complications of augmentation mammaplasty by silicone injections. *British Journal of Plastic Surgery*, **22**, 281.

FREEMAN, B. S. (1974). Reconstruction of the breast form by Silastic gel from breast prostheses. *British Journal of Plastic Surgery*, **27**, 284.

MUTOU, Y. (1965). Clinical use of DMPS in augmentation mammaplasty. *Japanese Journal of Clinical Surgery*, **26**, 1.

PIGOSSI, N. (1972). Personal communication, XII Latin American Congress of Plastic Surgery, Sao Paulo.

REES, T. D., BALLANTYNE, D. L. Jr., SEIDMANN, I. and HAWTHORNE, G. A. (1967). Visceral response to subcutaneous and intraperitoneal injections of silicone in mice. *Plastic and Reconstructive Surgery*, **39**, 402.

SPIRA, M. and HARDY, S. B. (1971). Soft tissue augmentation with silicone gel. A preliminary report. "Transactions of the Fifth International Congress of Plastic and Reconstructive Surgery". Butterworth, Australia.

UCHIDA, J. (1956). Clinical use of cross linked DMPS in esthetic surgery of breasts. *Geka no Ryoiki*, **4**, 824.

UCHIDA, J. (1961). Clinical application of cross-linked DMPS; restoration of breasts, cheeks, atrophy of infantile paralysis, funnel shaped chest, etc. *Japanese Journal of Plastic and Reconstructive Surgery*, **4**, 303.

YOON, H. S. (1964). Injective method of artificial fat (DMPS) for undeveloped breasts. *Japanese Journal of Plastic and Reconstructive Surgery*, **7**, 217.