LONG TERM COMPLICATIONS CAUSED BY INJECTED SILICONE GEL AND PARAFFIN OIL

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ABSTRACT

The majority of people who have received the injections of the materials used in mammoplasty during the past thirty years have been admitted to the hospital with complaints of induration, redness, and/or pain of the injected areas.

Since 1970 the relationship between the injected materials and later complications of 103 cases have been under observation.

Induration of the injected areas has been observed in 90 of the 103 cases. Swelling, redness, and/or pain which recurred at intervals of several months to several years were observed in 100 of the one hundred-three patients, 18 lapsed into general malaise; seventeen had arthralgia and stiffness; 8 had high fever and 10 patients had lymphoadenopathy. Four cases had collagen disease like symptoms, i.e. tests for LE-cell, anti-nuclear anti-body, and anti-DNA antibody were all positive.

Extirpation performed on 42 patients disclosed that 25 had injected silicone gel; 12 had injected paraffin oil; and 5 patients had undiagnosed materials. Seventeen of the forty-two cases were analysed by an infrared spectrum analysis. Nine showed medical grade silicone gel and 8 cases showed paraffin oil. In this follow-up study of 10 years, complete cure was not encountered in patients who developed systemic symptoms. We suspect that silicone induced adjuvant disease may occur in persons with a special disposition in immunoreaction.
INTRODUCTION

Cosmetic surgery by injected materials is simple and achieves its purpose without leaving scars. It has been performed extensively during the past thirty years in Japan. In the prior years a variety of injected fluid materials, such as a mixed oil, "organogen" and paraffin oil were used. Later a medical grade silicone gel was used extensively. However, due to the growing suspicion about the stability and safety of such substances in the human body, the injection method for cosmetic purposes is nonexistent today.

Recently, a great number of patients who had received such injected materials for the purpose of augmentation are entering hospitals with complaints of induration, redness, pain of the injected area; general disorders and collagen-disease like symptoms.

Since 1970 the relationship between the injected materials and later complications on 103 patients has been observed.

SUBJECT AND METHODS

The present research consists of 103 cases at Keio University Hospital, of which 38 are patients in the Department of Plastic Surgery and 65 are patients in the Department of Internal Medicine. Patients were classified according to sex; localization of injected materials; presence or absence of extripation and types of injected substance used (Table 1). A majority of the female patients had

<table>
<thead>
<tr>
<th>Area of Injection</th>
<th>Sex</th>
<th>Extirpation</th>
<th>Type of Injected Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>F</td>
<td>M</td>
</tr>
<tr>
<td>Breast</td>
<td>59</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>Cheek</td>
<td>9</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Nose</td>
<td>20</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Eyelid</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Forehead</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mentum</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Auricle</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Leg</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Penis</td>
<td>-</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>7</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>103</td>
<td></td>
<td></td>
</tr>
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</table>
Complications by Silicone Gel and Paraffin Oil

breast augmentation. Fifty percent of the patients have cancerphobia and anxiety about the side effects of injected materials.

Methods:

Clinical findings

Local and systemic symptoms were observed in all one hundred-three (103) patients.

Laboratory test:

Hemogram, blood chemistry, urinalysis, radiogram or CT scan, also serological and immunological tests such as LE-cells, anti-DNA antibodies, and anti-nuclear antibodies were studied thoroughly. Injected materials were analysed by infrared spectrum in order to confirm the presence of contaminants and degenerative products of silicone. The histopathological testing was done by HE stain.

Treatment policy

1. No surgical treatment was done on patients with minor induration or tumor at the area of injection.
2. Extripation is performed on a case-by-case basis in patients who have no systemic symptoms but have intermittent inflammatory symptoms.
3. If ulceration is present, surgical treatment is necessary.
4. When a patient has systemic symptoms and does not respond to medical treatment, surgery is recommended.
5. In cases having autoimmune disease with local inflammation, total extripation is performed.
6. Reconstruction is performed in some instances.

RESULTS

Of the one hundred-three patients, 19 had systemic symptoms. Arthralgia was the most common complaint. Patients were grouped according to the serum test results. Patients in Group A indicated positive and patients in Group B indicated negative to systemic symptoms (Table 2).

Clinical Results

Local Symptoms:

Nearly all patients developed induration or tumor in the area of injection, most frequently from several months to two years after surgery. It was considered almost inevitable in patients whose post-operative course lasted more than five years. Mass adhesion to the adjacent tissue was usually observed, de-
Table 2

Table shows signs and symptoms of patients

<table>
<thead>
<tr>
<th>Clinical Results</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local symptoms</td>
<td></td>
</tr>
<tr>
<td>Palpable tumor</td>
<td>90</td>
</tr>
<tr>
<td>Cutaneous infiltration</td>
<td>24</td>
</tr>
<tr>
<td>Repeated inflammation</td>
<td>81</td>
</tr>
<tr>
<td>Ulcer formation</td>
<td>2</td>
</tr>
<tr>
<td>Systemic symptoms</td>
<td></td>
</tr>
<tr>
<td>General malaise</td>
<td>18</td>
</tr>
<tr>
<td>Arthralgia and stiffness</td>
<td>17</td>
</tr>
<tr>
<td>High fever</td>
<td>8</td>
</tr>
<tr>
<td>Lymphoadenopathy</td>
<td>10</td>
</tr>
<tr>
<td>Cancerphobia</td>
<td>46</td>
</tr>
</tbody>
</table>

Laboratory Results

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RA factor (+)</td>
<td>12</td>
</tr>
<tr>
<td>LE cell (+)</td>
<td>4</td>
</tr>
<tr>
<td>Hyperglobulinemia</td>
<td>7</td>
</tr>
<tr>
<td>ANA</td>
<td>5</td>
</tr>
<tr>
<td>anti-DNA</td>
<td>4</td>
</tr>
</tbody>
</table>

Pending upon the type of injected material and duration of time after surgery. Two patients complained of chronic ulceration in the injected area. Swelling, redness, and pain which recurred at intervals of several months to several years were observed on about one third of the patients. Swelling of the regional lymph nodes was occasionally noticed.

Systemic Symptoms:

Systemic disorders progress slowly, and were discovered by chance during a medical health examination. The most frequent symptom observed was general malaise. Eighteen cases of shoulder stiffness, arthralgia, and numbness; 17 cases of lymphadenopathy, pyrexia of an unknown cause and transient erythema were also noted.

Systemic symptoms, considered to be caused by the injected substances, were occurring after the onset of the local symptoms. Intermittent swelling and redness at the area of injection was evident, particularly in patients who were given a relatively massive amount of material, as in the case of breast augmentation.

Laboratory Results

RA factor was positive in 12 cases, LE phenomenon and anti-DNA antibodies
were positive in 4 cases.
Anti-nuclear antibodies, positive in 5 cases (Table 2).

Surgery

Surgery was performed on 42 patients (Table 1). In patients who were given paraffin injection, the injected material was scattered, and each mass was surrounded by granuloma. Subcutaneous or intradermal invasion of a foreign body is frequently detected. In patients who were given facial injection, complete removal of the injected materials was difficult in some cases, because such surgery inevitably leads to extensive deformity and disfunction. Therefore, paraffin oil and granuloma were removed as much as allowable.

Silicone gel was found as a colorless, transparent, viscid mass, frequently covered by a thin capsule. Its removal was not complicated. In some cases, silicone gel was scattered within the tissue, just as the paraffin oil. Scattered silicone gel was usually found in patients who were told to massage the site of

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Fig. 1 Case 1  A 35 year old, female (left) Pre-operative finding of widely scattered injected silicone gel in the breast and axilla. Laboratory finding: LE-cell (+), antinuclear antibody (+), anti-DNA antibody (+).
(right) Cut section of the specimen is colorless and mucous like or degenerated to a white wax-like substance.
injection after surgery. When scattered, it was difficult to remove the mass without the surrounding granuloma. The isolated silicone gel was usually colorless and mucus-like, or sometimes changed to a white-wax-like substance. Such an appearance indicates that the silicone itself undergoes degenerative changes (Fig. 1).

In breast surgery, occasionally the pectoralis major and minor muscles had to be resected when the foreign body invasion was as deep as the muscular layer. The cases with severe post-operative deformity were repaired by the musculocutaneous flaps or silicone bag prosthesis. However, it was often necessary to remove the prosthesis because of a marked capsule formation and reinserting a new prosthesis.

Representative Cases

Case 1. A female, 35 years old (Fig. 1)

Breast augmentation was performed in 1957. Injected material is silicone gel. Bilateral induration was noted one year later. Bilateral swelling of the proximal interphalangeal joints as well as digital arthralgia manifested six years after surgery. These symptoms were temporarily eliminated by treatment with steroidal anti-inflammatory agents. Raynaud's phenomenon was noted on cold mornings. Patient was admitted to the Department of Internal Medicine and underwent a series of tests in 1970.

Physical examination revealed hard tumors of the breast with axillary lymphadenopathy. Laboratory tests for LE-cell, anti-nuclear antibody, and anti-DNA antibody were all positive. The injected silicone gel was found widely in the breast and axilla. Total extirpation was attempted in 1970. While apparent aggregation of the symptoms ceased after operation, it was not completed and arthralgia remained.

Case 2. A female, 46 years old (Fig. 2)

Breast augmentation was performed in 1961. Injected material is paraffin oil. Bilateral mammary induration was noted 6 months later.

The induration increased gradually and pigmentation of the chest skin was also observed. The patient was not treated by a medical doctor. In the past five years she experienced attacks of cool perspiration and dizziness.

Laboratory results for RA factor, high γ-globulin, anti-nuclear antibody and anti-DNA antibody were all positive. Skin, mammary gland and adipose tissue with injected paraffin were surgically removed en masse on June 18, 1983 and primary reconstruction was performed with the bilateral rectus abdominis musculocutaneous flaps.
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Fig. 2 Case 2 A 46 year old.
(Left) Pre-operative finding. Induration and pigmentation of the bilateral breast.
(Right) Post-operative finding. After total extirpation of the breast, the defect was reconstructed by bilateral rectus abdominis musculocutaneous flaps.
(Bottom) Cross section of the specimen filled with wax-like substance.

Analysis of Materials

Of the cases analysed, medical grade silicone gel was found in 6 chest; 2 cheeks and 1 ear. Paraffin oil was found in 2 chests; 3 noses; 1 cheek and 1 penis. On infrared spectrum analysis the silicone gel used on all the patients was found
Fig. 3 Infrared spectrum analysis:
(upper) Specimen from the breast.
(lower) Medical grade silicone gel.

Fig. 4 Microscopical examination of foreign body granuloma. Numerous macrophages envelope the foreign body. (H.E. stain, 400×)
to be highly purified dimethyl polysiloxane, also known as medical grade silicone gel (Fig. 3). Histopathologically, numerous macrophages enveloping the foreign body, fibroblasts and foreign body granuloma were observed in all patients who were given paraffin oil. Also cell infiltration was observed.

In patients injected with silicone gel, a thin fibrous capsule formation is generally detected, but in patients with marked local induration, granuloma accompanied by a large foreign body cell is detected (Fig. 4).

Prognosis

In this follow-up study of 10 years, complete cure was not encountered in patients who had systemic symptoms. In such patients, however, general malaise frequently subsided, and medical control of arthralgia was feasible.

Two patients who had no systemic symptoms showed positive results on the antibody and LE-cell tests. These tests suggest the necessity of keeping a watch on human adjuvant disease after silicone gel injection.

DISCUSSION

We gave an account of 103 patients who visited our department with complaints of severe systemic disorder following foreign body injection.

The main topics were the development of induration at the site of injection; the relationship between the foreign body injection and systemic systems, such as rheumatoid arthritis, Raynaud's phenomenon and recurrent febrile attacks as well as erythematous rash.

An obvious fact is that foreign body granuloma always ensues from injection of paraffin oil and wax has an adjuvant effect. However, immunological studies with silicone gel have not been reported.

Miyoshi reported two cases of hypergammaglobulinemia and disorders developed after augmentation of mammaplasty in 1964. According to Rees, experimental data shows that medical grade silicone gel induces adjuvant tissue reaction, particularly atrophy of adipose tissue. Abe reported 11 cases of human adjuvant disease in 1972. Yoshida reported 7 cases of post-mammaplasty disorder, such as human adjuvant disease in 1973. Elleiborgen reported four patients who received silicone gel injections and as a result had the following complications: migration, hepatic disease, hypopigmentation and death in 1975. Kumagai described 4 cases of scleroderma observed among 9 cases of human adjuvant disease on 1979. Chang reported adjuvant polyarthritis on 1980. Kumagai reported a case of mixed connective tissue disease after breast augmentation using silicone gel injection in 1981. Baldwin reported a case of systemic disorder resulting from mammaplasty with silicone prostheses.
In depth of analysis revealed that the isolated silicone gel was of medical grade. Although a medical grade silicone gel was used, foreign body reaction is inevitable in 4 patients. In patients with arthritis-like disorder as the principal complaint a recurrent heat sensation and swelling occurred initially; followed by arthralgia and lymphadenitis. In patients who had recurred extirpation on the injected material, control was easy with nonsteroidal anti-inflammatory agents.

We are on the opinion that if the protective protein connected with the foreign body is incised, productive antibodies must be expedited. Therefore, the relationship between the amount of foreign body injected and the onset of general disorder cannot be disregarded. Knowing that the removal on injected material alleviated symptoms, compels us to recognize the causal relationship between foreign body injection and such symptoms.

We suspect that human adjuvant disease may occur in persons with a special disposition in immune reaction.

REFERENCES