

Local complications after industrial liquid silicone injection – case series

Complicações locais após a injeção de silicone líquido industrial – série de casos

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A B S T R A C T

Objective: To analyze a case series of patients who underwent injection of industrial liquid silicone in a clandestine manner and by unauthorized persons. **Methods:** We conducted a retrospective analysis of medical records of patients treated between September 2003 and December 2010. Data regarding gender, age, location and volume of silicone injected, time between application and clinical manifestations, complications, treatment and outcome were collected. Early manifestations were defined as occurring within 30 days of injection and late manifestations, the ones arising after this period. **Results:** We treated 12 patients, eight were male, seven transsexuals. The volume injected ranged from 5ml to 2000ml, being unknown in three cases. The most often used injected sites were the thighs and buttocks. Eight patients had early manifestations, with inflammation and/or infection. Surgical debridement was necessary in five cases. Three patients with a history of injection in the breast region underwent adenomastectomy. There was one death due to refractory septic shock. **Conclusion:** The use of industrial liquid silicone should be completely contraindicated as a filling material and modification of body contouring, and may have serious complications, even death.

Key words: Silicone oils. Fasciitis. Skin transplantation. Wound healing. Wound infection.

INTRODUCTION

The use of industrial liquid silicone as a material in aesthetic body contouring changing is a clandestine practice carried out for almost 60 years. Most reports come from countries in Asia and South America, and the victims are mostly women and transgenders¹⁻³.

Initially utilized in pure form, silicon had to be added to other substances like vegetable oils and minerals, in order to increase local tissue response and reduce migration related to the application of large volumes. The Sakurai formula, described in Japan, was the best known, associating liquid silicone with olive oil^{1,2}.

Currently, this practice is still carried out in our country by unauthorized and unscrupulous persons, using excessive amounts of the product in its industrial presentation, ie, non-sterile and with residues. Most injections are made subcutaneously, but there are cases of intramuscular injections. The volume is variable, with reports of the injection of up to eight liters in a single session^{4,5}.

Various complications have been described with the use of liquid silicone, ranging from localized

inflammation (abscesses, fistulas, granulomas), siliconomas formation and migration of the material, to severe systemic inflammation, associated or not with infections. The difficulty or even impossibility of removing the injected material and the adjacent fibrotic and scarring tissues hinder treatment^{4,5}.

Due to the increasing number of these complications, its medical use has become restricted. In 1994, liquid silicone was approved by the Food and Drug Administration (FDA) only for ophthalmological use in cases of retinal detachment, remained prohibited for other purposes⁴.

This paper aims to report the complications, treatment and outcome of a series of patients who underwent injection of industrial liquid silicone and were subsequently treated at the Department of Plastic Surgery, Holy House of Mercy of São Paulo – ISCMSP.

METHODS

A retrospective analysis of medical records of patients admitted for treatment of complications related to

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the injection of industrial liquid silicone in the period from September 2003 to December 2010 was held.

We evaluated the following data: gender, age, location and volume injected, time between application and clinical manifestations, complications, treatment and outcome.

The time between product application and clinical manifestations was characterized as early (<30 days) and late (> 30 days).

RESULTS

Twelve patients were treated, four females and eight males. Of these, seven were transsexuals. The mean age was 30 years, ranging from 19 to 57 (Table 1).

The injections of liquid silicone were made in the face - frontal, malar (Figures 1a and 1b) and upper lip, breasts, buttocks (Figures 2a and 2b) and thighs - lateral and posterior regions (Figures 3a and 3b).

Table 1 - Data related to the patients treated.

	Sex	Age (years)	Place	Volume (ml)	Time beginning	Symptoms manifestations	Treatment	Time of admission
1	Male (transsexual)	26	Face-frontal	5	2 days	Erythema edema, pain	ATBT, NSAIDS, CTC	7
2	Male (transsexual)	19	Face-superior lip	10	2 days	Edema, erythema, pain	ATBT, NSAIDS, CTC	7
3	Male (transsexual)	25	Face -bilateral malar region	20	2 days	Edema, erythema pain, ulcerations	ATBT, NSAIDS, CTC	7
4	Male (transsexual)	21	Right Thigh	1000	2 days	Edema, erythema, epidermolysis, necrosis	ATBT, NSAIDS, CTC, surgical debridement, partial skin graft	19
5	Female	22	Buttocks bilateral	100/100	5 days	Edema, erythema, pain, bubbles, fever	ATBT, NSAIDS, CTC, OHB	10
6	Male (transsexual)	27	Posterior thigh bilateral	1000/1000	6 days	Edema, erythema, pain, bubbles, fever necrosis, septic shock	ATBT, NSAIDS, CTC, surgical debridement	Death (5 th day of admission)
7	Male (transsexual)	27	Right Thigh	unknown	8 days	Edema, erythema, pain, bubbles, fever, necrosis, abscesses and fistulas	ATBT, NSAIDS, CTC, surgical debridement, partial skin graft	22
8	Male	29	Buttocks bilateral	300/300	4 days	Edema, erythema, pain, bubbles, fever, necrosis, abscesses	ATB, NSAIDS/CTC, surgical debridement, OHB, partial skin graft	27
9	Male (transsexual)	30	Left Thigh	unknown	10 years	Edema, erythema, pain, fever, abscess, necrosis	ATB, NSAIDS/CTC, surgical debridement, partial skin graft	20
10	Female	35	Breasts	unknown	2 years	Chronic Mastitis, abscess, fistula	ATBT, NSAIDS, CTC, bilateral adenomastectomy and bilateral reconstruction TRAM	4
11	Female	43	Breasts	10/10	Right - 15 days Left - 6 years	Abscess, chronic mastitis	ATBT, NSAIDS, CTC, Draining (initial, side Right). Bilateral Adenomastectomy and reconstruction with bilateral silicone prosthesis	3
12	Female	57	Breasts	160/140	12 years	Chronic Mastitis	ATBT, NSAIDS, CTC, bilateral partial adenomastectomy and mastopexy	3

USED ACRONYMS:

ATBT - systemic Antibiotics, NSAIDS – non-steroidal Anti-inflammatory drugs, CTC - systemic corticosteroids, OHB - hyperbaric oxygen therapy



Figure 1 - bilateral malar Injection - 20 ml (each side): (a) second and (b) seventh day after injection

All patients clearly reported the type of material injected into their bodies, performed in non-hospital facilities and by unqualified individuals. The volumes injected ranged from 5ml to 2000ml, being unknown in three cases.

In eight patients there were early complications, directly related to infectious and inflammatory

manifestations, with edema, erythema, ischemic skin changes and fasciitis.

Of the four patients who had late complications, there was one case of infection in deep tissue, requiring surgical treatment in a patient who remained asymptomatic for ten years after injection of the product. In the three remaining cases the region injected was the breast, with manifestations of chronic mastitis, two of them with abscesses and fistulas.

All patients initially received conservative medical treatment with anti-inflammatory drugs, corticosteroids and systemic antibiotics. We used oxacillin associated with gentamicin; in six cases considered severe, metronidazole was also used.

Hyperbaric oxygen therapy was used in two cases, the first as a complement to medical treatment, with no need for surgical treatment; in the second, as a complement after surgical debridement with the aim of improving the granulation of the open area for further partial skin grafting.

In four patients with early complications and in one case with late ones it was necessary to perform surgical debridement due to the presence of ischemia and/or necrosis of the skin and subcutaneous tissue or established infection (abscesses, fistulas and fasciitis). The resulting wound area was initially maintained with daily changes of dressings and small additional debridement (Figure 4) until improvement in local conditions (granulation tissue), and then submitted to partial skin autograft (Figure 5).

In three patients with a history of injection product in the breast, it was necessary to perform adenomastectomy due to chronic mastitis. One of these patients had a history of breast abscess drainage 15 days after the injection of the liquid silicone. We used different reconstruction options

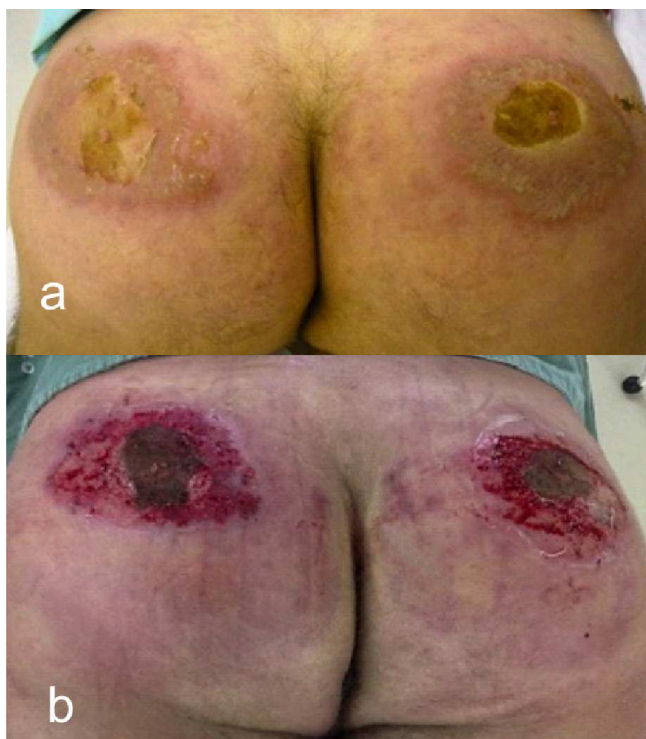


Figure 2 – Bilateral silicone injections in the gluteal region: a) admission; b) fourth day after injection.

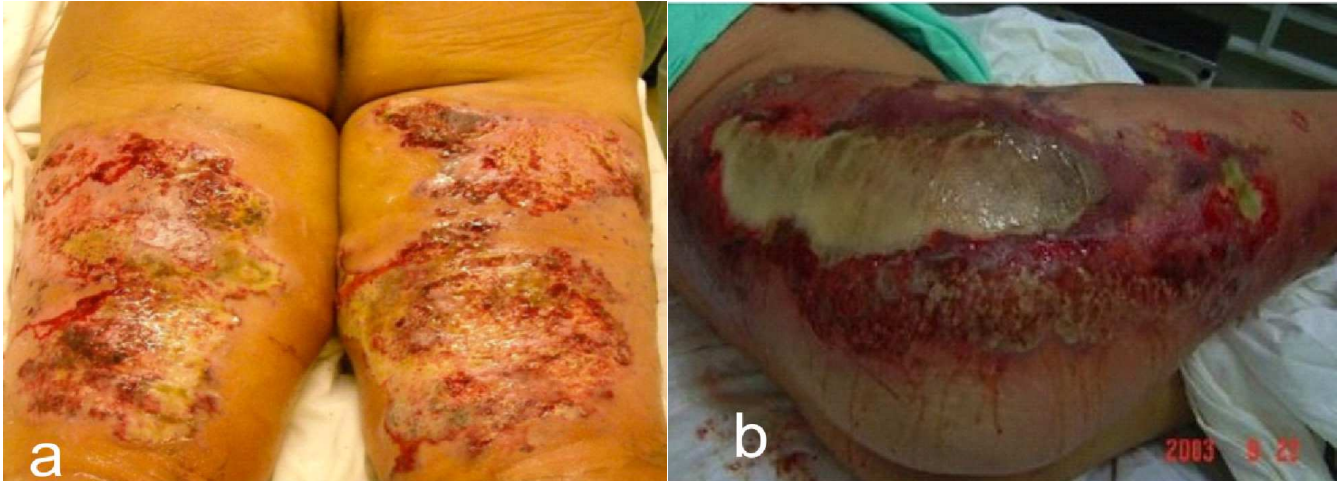


Figure 3 - a) aspect of the posterior thighs (R and L) on the sixth day after silicone injection; b) lateral aspect of the right thigh on the ninth day after injection



Figure 4 – Raw area of the lateral region of the right thigh – fifth day after debridement.

for each case, with bilateral transverse rectus abdominis myocutaneous flap (TRAM – one case), mastopexy with the residual breast tissue after partial adenomastectomy (Figure 6 – one case) and use of silicone implants in one case.

There was one death due to refractory septic shock secondary to necrotizing fasciitis. This was a patient with AIDS being treated for secondary syphilis, who had undergone injection of 1000ml (on each side) in the posterior thigh. After six days, there was development of necrosis and local abscesses; fasciitis was found in the initial debridement, performed on the second hospital day. Even with the completion of additional debridement and intensive support there was no clinical improvement, with death on the fifth day of hospitalization.

Follow-up of the eight of 11 patients was not possible after hospital discharge, and the others are in outpatient treatment with satisfactory results and no other complications reported so far.

DISCUSSION

Dimethylsiloxanes are substances derived from the polymerization of silica, oxygen, and methane. The

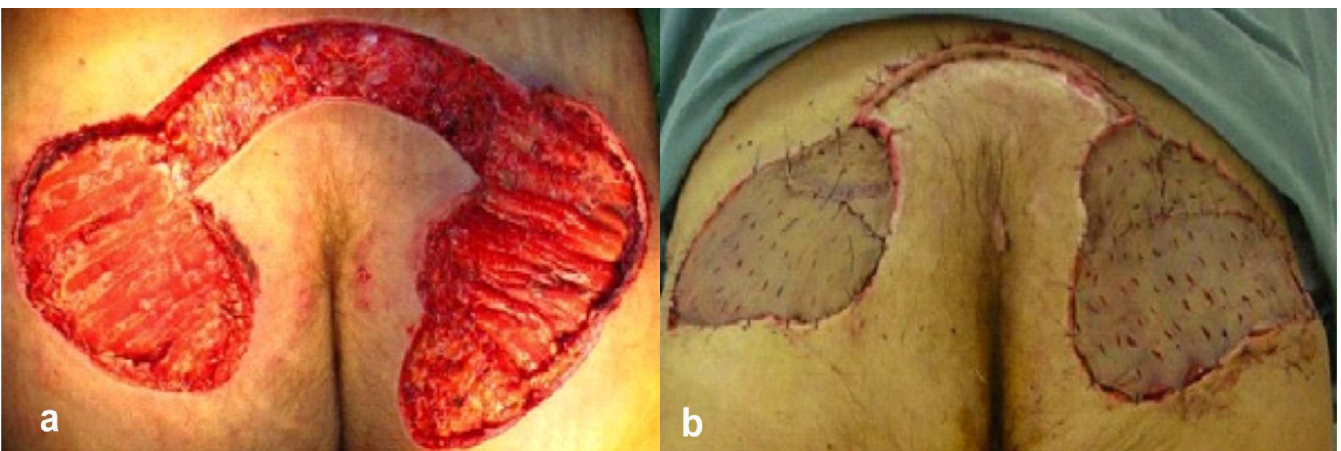


Figure 5 – a) raw area in the gluteal region after debridement; b) after skin autograft.

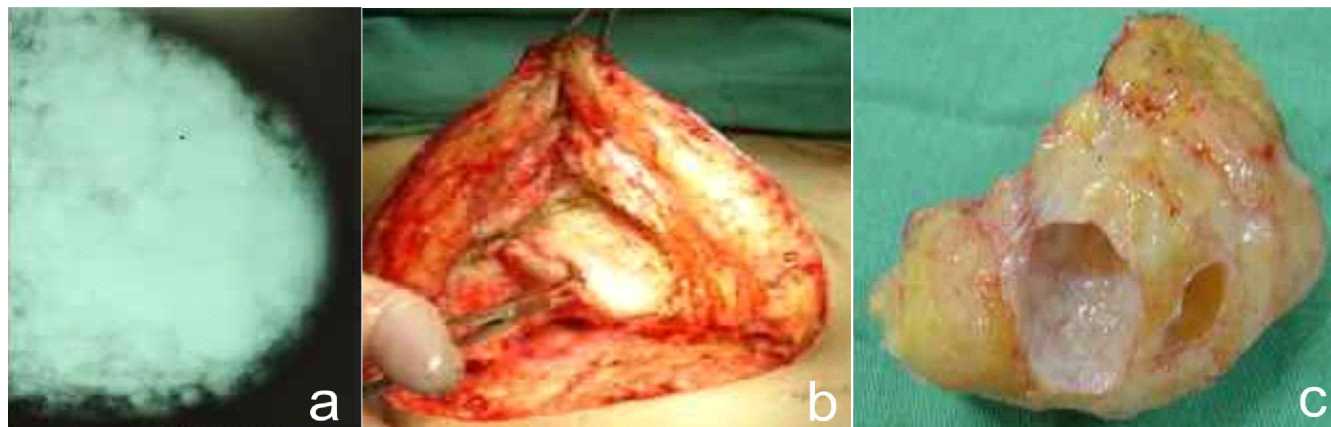


Figure 6 – a) Appearance radiological breast infiltrated with silicone; b) identification and resection of siliconoma; c) aspect of the surgical.

viscosities found are the result of different degrees of polymerization and number of crosslinks between molecules. The unit for viscosity is the centistoke (cS), using water as reference (100 cS). Products range from 20cS to 12.500cS^{4,5}.

Besides liquid silicone, other series have reported the use of substances such as paraffins, mineral oils and automotive transmission fluids. These substances promote a similar type of pathologic tissue reaction, called sclerosing lipogranulomatosis⁵⁻⁷. The term siliconoma was first used in 1965 by Sternberg and Winer to characterize the foreign body reaction similar to those reported after injection of paraffin oil and^{4,7}.

Local complications after industrial liquid silicone injections range from changes in color and consistency of the skin, with the formation of nodules and granulomas, to intense inflammation with necrosis and ulceration, fistulas and abscess formation, elimination of injected material, retractions and scarring deformities^{1-6,8}.

Due to the high potential of migration of the material, related to the use of larger volumes, tissue changes may be identified at sites distant from those in which the silicone was injected. Regional lymph node involvement and infiltration of adjacent tissues can be found in the long term. Respiratory conditions such as pneumonitis and pulmonary edema are described as systemic complications and can cause death^{2,3,5,7,9,10}.

The onset of the acute inflammation Vinfection as early manifestation, present in eight cases in this study, is not common. In the literature ranges without clinical manifestations of three to 20 years are found, with an average of six to ten years^{1,4,11}. Hage *et al.* treated 15 transsexuals and noted an interval of six months to 17 years, with an average of six years³.

The clinical treatment using anti-inflammatories, antihistamines, corticosteroids and systemic antibiotics may be given initially for all cases. These measures have proved sufficient in cases of erythema, edema and cellulitis. For cases of medical treatment alone it is recommended to

use amoxicillin and clavulanate intravenously for seven days, followed by clindamycin orally for 12 weeks³. Small areas of cutaneous ischemia and necrosis may also eventually be treated conservatively.

Several authors recommend the use of systemic and intralesional corticosteroids in the presence of granulomas, as well as topical immunomodulators such as imiquimod (Aldara®)^{1,2,3,7,8}.

We used hyperbaric oxygen therapy in two patients, with improvement in evolution. Freitas *et al.*⁵ reported the use of this method in one case of injection in the breast region, with significant clinical improvement. Although not having been used in this series, continuous aspiration dressings, as the VAC® system, must also be considered.

The use of aspiration cannulas is not a recommended technique for treatment of siliconomas, since tissue fibrosis makes removal difficult by this method and there is risk of injury to adjacent, not affected areas^{3,12}. Zandi published the first case in which the aspiration technique was successful, but he considered this method inappropriate due to failure in another 20 procedures, maintaining surgical excision as the standard treatment for siliconomas¹².

To Chui and Fong the use of CO₂ laser vaporization proved to be an effective treatment for minor facial siliconomas presenting palpable nodularities or visible deformities and may require more than one session to remove. There being injection of larger volumes, surgical excision may be required⁸.

In many cases, adenomastectomy proved to be the most appropriate treatment for the removal of breast siliconomas and treatment of chronic mastitis, with the possibility of reconstruction, either with implants or flaps^{9,11}. Although the harmful effects of the injection of liquid silicone in the breasts have been well documented, there is no evidence that its use is associated with the development of breast cancer^{3,11}. However, clinical and mammographic changes may complicate the differential diagnosis of lesions.

Surgical treatment should be indicated in the acute phase in the presence of more extensive or deep areas of ischemia/necrosis, as well as in cases of abscesses, fistulas and fasciitis. Usually, coverage of debridement areas is not carried during the first surgery, due to the potential for further debridement or the presence of residues of the product. The main option used to cover the resected areas is the performance of skin autografts. In selected cases, primary synthesis or flaps can be carried out.

Complete removal of the injected liquid silicone is difficult or even impossible, there being thus no specific treatment. Whenever possible, one should limit the resection to siliconomas and affected tissues, in view of the consequences of more extensive local resections^{3-5,7,12}.

We conclude that the use of industrial liquid silicone is a practice which must be completely contraindicated for aesthetic purposes, because the complications can be severe and difficult to treat.

R E S U M O

Objetivo: analisar uma série de casos de pacientes submetidos à injeção de silicone líquido industrial de maneira clandestina e por pessoas não habilitadas. **Métodos:** análise retrospectiva de prontuários de pacientes atendidos no período de setembro de 2003 a dezembro de 2010. Foram avaliados: sexo, idade, local e volume de silicone injetado, tempo decorrido entre a aplicação e as manifestações clínicas, complicações, tratamento e evolução. Definiu-se como precoce as manifestações ocorridas até 30 dias da injeção e manifestações tardias após este período. **Resultados:** Foram atendidos 12 pacientes, oito eram do sexo masculino, sendo sete transexuais. O volume injetado variou de 5ml a 2000ml, sendo desconhecido em três casos. Os locais mais frequentemente utilizados para injeção foram a região de coxas e glúteos. Oito casos apresentaram manifestações precoces, com quadros de inflamação e/ou infecção. Foi necessária a realização de desbridamento cirúrgico em cinco casos. Três pacientes com histórico de injeção na região mamária foram submetidas à adenomastectomia. Houve um óbito por quadro de choque séptico refratário. **Conclusão:** O uso do silicone líquido industrial deve ser totalmente contraindicado como material de preenchimento e modificação do contorno corporal, podendo apresentar graves complicações e até mesmo óbito.

Descritores: Óleos de silicone. Fasciite. Transplante de pele. Cicatrização. Infecção dos ferimentos.

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