

## Management of silicone granuloma: A systematic review



*To the Editor:* In 2017, the US Food and Drug Administration issued warnings against injectable silicone for cosmetic enhancement.<sup>1</sup> Despite well-established associations between silicone injection and granuloma formation, current evidence-based management guidelines are limited.<sup>2,3</sup> The current guidelines by the American Society of Dermatologic

**Table I.** Study-level data and participant demographics

Study-level data	N
Total studies	93
Study design, n (%)	
Case report or series	89 (96)
Cross-sectional study	3 (3)
Cohort study	1 (1)
Participant-level data, n (%)	
Total number of participants	227
Mean number of participants (SD)	2.4 (24)
Study-described sex or gender, n (%)	
Number of females or cisgender females	139 (61)
Number of males or cisgender males	69 (30)
Transgender	10 (4)
Male-to-female transgender	6 (3)
Other transgender*	4 (2)
Not reported	9 (4)
Study-described race, n (%)	
White	12 (5)
Latin American or LatinX	11 (5)
Other <sup>†</sup>	20 (9)
Not listed	184 (81)
Study-described ethnicity, n (%)	
Hispanic	18 (8)
Non-Hispanic	6 (3)
Not Listed	203 (89)
Granuloma location, n (%) <sup>‡</sup>	
Face	87 (38.7)
Breasts	62 (27.6)
Penis	58 (25.8)
Buttocks	25 (11.1)
Lip	24 (10.7)
Other	38 (16.9)
Biopsy-confirmed granuloma, n (%)	
Yes	129 (57)
No	46 (20)
Unknown	52 (23)

Continued

**Table I.** Cont'd

Study-level data	N
Patients with prior treatment, n (%)	
Yes	57 (25)
No	118 (52)
Unknown	52 (23)
Treatment outcomes (n = 225), n (%) <sup>§</sup>	
Complete response	94 (42)
Partial response	116 (52)
Stable disease	12 (5)
Disease worsening	1 (0)
Other <sup>  </sup>	2 (1)

\*Other transgender includes "F (male trans-sexual)," "transsexual" with the article using the pronoun "he," "transsexual" with the article using pronouns "she/her" and "woman," and "man with transgender identity disorder" with the article using the pronoun "he."

<sup>†</sup>Other races or ethnicities include Chinese, Italian, Mexican, Asian, Black, Brazilian, Latin American, Ecuadorian, Indonesian, Malay, Middle Eastern, and Thai.

<sup>‡</sup>These percentages do not add up to 100% because >1 area might be reported.

<sup>§</sup>Patients did not undergo treatment; however, their demographic data cannot be separated from those of other included patients. So, their demographic data are included above.

<sup>||</sup>Death due to underlying disease occurred in 2 patients.

Surgery recommend "intralesional injections of 5-FU (5-fluorouracil) mixed with triamcinolone at monthly intervals" for the treatment of silicone granulomas, with low certainty of evidence.<sup>3</sup> We aimed to characterize treatments and associated outcomes for silicone granulomas following silicone injection.

This systematic review was registered on the International prospective register of systematic reviews (PROSPERO) (CRD42021260380) and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (Supplementary Material 1, available via Mendeley at <https://data.mendeley.com/datasets/nvmxbjdnb/2>). PubMed or MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, Scopus, and Web of Science were searched on April 13, 2022, for studies that reported treatment outcomes for silicone granulomas secondary to silicone injections (Supplementary Table I, available via Mendeley at <https://data.mendeley.com/datasets/nvmxbjdnb/2>). The outcome of interest was silicone granuloma response following treatment with the described intervention. The classification of outcomes (complete response, partial response, stable disease, or disease worsening) was determined by the authors based on the manuscripts' results.

The search identified 901 studies, of which 231 were subjected to full-text evaluation; 93 studies met

the inclusion criteria and were included for data analysis (Supplementary Fig 1, available via Mendeley at <https://data.mendeley.com/datasets/nvmxbjdnb/2>). The study follow-up time ranged from 0.2 to 132 months (Table 1). The most frequently reported treatments were surgical excision alone (66.2%) and systemic monotherapy (10.2%), of which minocycline was the most common (Supplementary Table II, available via Mendeley at <https://data.mendeley.com/datasets/nvmxbjdnb/2>). Of patients who underwent surgical excision, 48% and 50% attained complete and partial responses, respectively. Of patients treated with minocycline, 20% achieved complete response and 60% had partial response. Overall, 41.8% and 51.6% of the patients achieved complete and partial responses, respectively.

Silicone injections and their associated complications persist despite health warnings. Paucity of data contributes to the undertreatment of their adverse reactions. Evidence is limited to case series and a single cohort study.<sup>3</sup> In this systematic review, surgical excision was the most common treatment. Although most surgical patients achieved complete or partial response, many were not candidates for surgery because of contraindications and/or barriers to access. Systemic medical management of silicone granulomas parallels the treatment of granulomatous diseases and often achieves partial responses, although it is understudied.<sup>4</sup> Many cases trialed combinations of both single and multiple treatment modalities, particularly in refractory cases.<sup>2</sup>

The transgender community is particularly at the risk of silicone granulomas because of a high prevalence of silicone injections. In a survey of transgender women in the United States, 3% were found to have had silicone injections and 10% were found to desire them someday.<sup>5</sup> Reporting of sex and gender has not historically been separated in dermatologic research. Improved reporting of sex assigned at birth and gender identity data are needed to understand the epidemiology of silicone granulomas in sexual- and gender-minority populations.

This systematic review is limited by the exclusion of studies that were not written in English and the reporting quality of extracted studies with nonuniform outcome definitions, missing data, or limited follow-up times. No study examined patient-reported outcomes. Future studies should compare treatment efficacies through randomized controlled trials, and outcomes should be characterized through long-term cohort studies.

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#### Conflicts of interest

None disclosed.

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