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# Minor Salivary Gland Biopsy in Sjögren Disease: From Diagnostic Criterion to Clinical Decision Tool

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## Abstract

Minor salivary gland biopsy (MSGB) remains an important tool in the evaluation of patients with suspected Sjögren disease (SjD), particularly when the clinical presentation and serologic findings are inconclusive. Although traditionally used to identify focal lymphocytic sialadenitis and determine a focus score, the potential clinical value of MSGB extends beyond a binary positive or negative result. Histopathologic findings may provide additional information about glandular inflammation, lymphoid organization, epithelial injury, fibrosis, and disease phenotype. MSGB may be particularly useful in anti-Sjögren syndrome-related antigen A/Ro (anti-SSA/Ro)-negative disease and may have a role in childhood-onset disease and the assessment of features associated with systemic disease and lymphoma risk. The procedure can generally be performed in an outpatient setting, although sensory complications should be discussed before biopsy. Salivary gland ultrasonography (SGUS) provides a complementary, noninvasive assessment of glandular structure and may help identify patients who require further tissue evaluation. This narrative review discusses the practical indications for MSGB, biopsy technique and safety, histopathologic interpretation, its role in anti-SSA/Ro-negative and childhood-onset disease, prognostic implications, relationship to SGUS, and emerging applications in tissue-based phenotyping and precision medicine.

**Categories:** Rheumatology, Oral Medicine
**Keywords:** anti-ssa/ro antibodies, focus score, histopathology, labial salivary gland biopsy, lymphoma, minor salivary gland biopsy, precision medicine, seronegative sjögren disease, sjögren disease

## Introduction And Background

Sjögren disease (SjD) is a systemic autoimmune disease characterized by immune-mediated inflammation and dysfunction of the salivary and lacrimal glands, with manifestations ranging from sicca symptoms to systemic organ involvement. Diagnosis can be challenging because no single clinical, serologic, or histopathologic test is diagnostic in every patient. Anti-Sjögren syndrome-related antigen A/Ro (anti-SSA/Ro) antibodies are an important marker of disease, but a proportion of patients with a clinically convincing phenotype remain seronegative. Objective assessment of glandular dysfunction and, in selected patients, tissue examination are therefore important components of the diagnostic evaluation.

Minor salivary gland biopsy (MSGB), usually obtained from the lower lip, provides direct histopathologic evidence of salivary gland inflammation. Its traditional role has centered on identifying focal lymphocytic sialadenitis and calculating the focus score. Accumulating evidence suggests that the biopsy may also provide information beyond classification, including inflammatory cell composition, lymphoid organization, fibrosis, and features associated with systemic disease and lymphoma. At the same time, improvements in technique and growing experience among rheumatologists have made the procedure more accessible.

The 2016 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria assign three points to a labial salivary gland focus score of ⩾1 focus per 4 $mm^2$, making MSGB particularly important for patients who do not have anti-SSA/Ro antibodies [1]. These are classification criteria rather than diagnostic criteria and should not replace clinical judgment [1]. Recent literature has expanded the potential role of MSGB from a classification component toward a tissue-based clinical tool [2]. Although previous reviews have examined the diagnostic and prognostic roles of MSGB in SjD, its practical application in clinical decision-making remains an important consideration. In particular, clinicians must determine when biopsy is likely to provide meaningful diagnostic information, how histopathologic findings should be interpreted in the context of clinical and serological features, and how biopsy findings should be integrated with emerging noninvasive approaches such as salivary gland ultrasonography (SGUS). This review synthesizes the current evidence to address these questions, with particular emphasis on anti-SSA/Ro-negative patients, histopathologic interpretation, diagnostic limitations, and the evolving role of biopsy in individualized clinical assessment.

### Literature search methodology

A focused literature search was conducted using PubMed/MEDLINE and Google Scholar through September

2026. Relevant publications were identified using combinations of terms related to SjD, MSGB, focus score, anti-SSA/Ro-negative disease, histopathology, lymphoma, and SGUS. Priority was given to original clinical studies, diagnostic and prognostic investigations, histopathologic studies, classification criteria, guidelines, and relevant reviews. Publications unrelated to the clinical or histopathologic utility of MSGB were excluded. Relevant findings were synthesized narratively, with emphasis on diagnostic utility, interpretation of biopsy findings, prognostic implications, limitations, and integration with other clinical assessments. No formal risk-of-bias assessment was performed because this was a narrative review.

# Review

## Why MSGB still matters

MSGB provides direct evidence of autoimmune inflammation in a target organ. Unlike serologic testing, which reflects systemic autoimmunity, biopsy demonstrates the local tissue response. The principal finding is focal lymphocytic sialadenitis. The focus score is the number of dense aggregates of at least 50 lymphocytes per 4 $mm^2$ of glandular tissue, and a focus score ⩾1 is considered positive in the 2016 ACR/EULAR system [1].

MSGB is particularly useful when clinical suspicion remains substantial but serologic or other objective findings do not provide sufficient diagnostic confidence. The histopathologic result must be interpreted within the broader clinical phenotype because focal lymphocytic inflammation is not entirely specific to SjD, and biopsy interpretation can be affected by sampling and observer variability [2]. The procedure also carries a small but clinically relevant risk of sensory complications.

## Which patients should be considered for MSGB?

MSGB is most useful when the result is likely to change the diagnostic assessment or clinical management. Patients who may particularly benefit include those with convincing sicca symptoms and objective glandular dysfunction but negative anti-SSA/Ro antibodies; discordant clinical, serologic, and ocular or salivary findings; suspected SjD without another clear autoimmune diagnosis; systemic manifestations suggestive of SjD when the diagnosis remains uncertain; or an atypical presentation in which tissue would help distinguish SjD from another inflammatory or infiltrative disorder.

The role of biopsy is less compelling when the diagnosis is already clinically secure. In a retrospective study of 313 patients with clinically suspected SjD, biopsy positivity was similar in anti-Ro-positive (27.8%) and anti-Ro-negative (24.2%) patients, biopsy allowed 22.3% of seronegative patients to fulfill the 2016 criteria, and the authors concluded that its additional contribution in seropositive patients was limited [3]. The decision to perform MSGB should therefore be individualized rather than based solely on whether a patient meets classification criteria [1,3].

## Performing the biopsy: technique and safety

MSGB is usually performed by removing several minor salivary glands from the lower lip through a small mucosal incision. Techniques vary, and less invasive approaches continue to be described [4]. Current recommendations, as summarized in a recent review, advise sampling four to six glands with a minimum glandular surface area of 8 $mm^2$ [2].

Recent series report high tissue adequacy. In a 2022 single-center study of 110 patients who underwent incisional MSGB in office and operating room settings, 98% of samples were adequate, 31% were positive, and no permanent complications were reported [5]. In a 2026 retrospective study of 202 patients, all biopsies were performed by rheumatologists in a nonsurgical outpatient setting using a 1-cm vertical mucosal incision and collection of up to five glands. Four biopsies (2%) were insufficient. One serious adverse event (0.5%; persistent local paresthesia) and two moderate events (1.0%) were recorded, mild adverse events occurred in 8.9%, and local discomfort in 15.8% [6].

These favorable figures should be balanced against patient-reported outcomes. In a questionnaire-based study of 630 patients from two Swedish centers, 45% reported impaired lower-lip sensation at some point after biopsy and 21% reported persistent impairment at a median follow-up of four years. Persistent impairment was associated with younger age and absence of anti-SSA antibodies, although its reported impact on everyday life was generally low. Complications were less frequent when biopsies were performed by dentists or oral and maxillofacial surgeons under optimal conditions [7]. Differences in ascertainment, technique, and follow-up likely contribute to the discrepancy between these series. Patients should therefore be counseled about the possibility of persistent sensory change before the procedure, particularly younger and seronegative patients [7].

MSGB can be incorporated into rheumatology practice when training, patient selection, and pathology support are available [6,7]. Standardization of the procedure remains important because tissue adequacy directly affects the reliability of histopathologic interpretation.

## What should the pathologist report?

A useful pathology report provides more than a statement of "positive" or "negative." At a minimum, it should address specimen adequacy and the amount of evaluable glandular tissue, the presence and distribution of lymphocytic inflammation, the focus score, lymphoepithelial lesions, ectopic germinal center formation when present, fibrosis or acinar atrophy, and other findings that may suggest an alternative diagnosis.

The focus score remains the principal standardized measure, but interpretation varies. In a multicenter study, interobserver agreement was good for the focus score ($\kappa = 0.71$) but poor for fibrosis ($\kappa = 0.16$); local pathologists often did not follow the recommended focus-score protocol, and the focus score was frequently overestimated. Germinal center-like structures showed good reliability but were inconsistently reported [8]. Discrepancies in interpretation between pathologists have also been described in other series [9], and an expert workshop concluded that tissue acquisition and histologic interpretation are variable and need standardization [10].

More recent evidence suggests that incorporating several histopathologic features may improve the specificity of tissue assessment. In a diagnostic sicca cohort, van Ginkel et al. evaluated focus score, prelymphoepithelial and lymphoepithelial lesions, IgG plasma-cell shift, and germinal centers. Although a focus score ⩾1 had the highest sensitivity, the presence of two or more histopathologic features increased specificity compared with focus score alone [11]. These findings support a more comprehensive pathology report while also emphasizing that the additional features are not yet established replacements for the standardized focus score.

For rheumatologists, the practical implication is that the report should provide the focus score, the glandular area assessed, and relevant qualitative findings rather than a general statement that the biopsy is "compatible with" SjD.

## Interpreting a positive or negative biopsy

MSGB should be interpreted as one component of a multidimensional clinical assessment. A positive result can provide substantial objective evidence of glandular involvement when the overall phenotype is compatible with SjD, particularly in patients without anti-SSA/Ro antibodies. Because focal lymphocytic inflammation can occur in other conditions, alternative diagnoses should remain in the differential; the 2016 ACR/EULAR criteria specifically identify conditions such as sarcoidosis, amyloidosis, graft-versus-host disease, and IgG4-related disease as exclusion conditions [1].

A negative result lowers the probability of SjD but must be considered alongside tissue adequacy, sampling variability, disease heterogeneity, prior treatment, and the quality of histopathologic interpretation. When clinical suspicion remains substantial, pathology review and reassessment of the overall phenotype are preferable to treating the biopsy result as definitive in isolation. Repeat biopsy should generally be reserved for a specific new diagnostic question or an inadequate initial specimen.

Examining multiple cutting levels may increase the specificity and accuracy of biopsy interpretation, particularly when the focus score is between 1.0 and 1.9 [2]. The practical value of MSGB therefore lies not simply in assigning a positive or negative label but in providing objective tissue information that can be integrated with the remainder of the diagnostic evaluation.

## What does the biopsy tell us beyond diagnosis?

The salivary gland is an immunologically active target organ, and its histology may reflect different aspects of disease biology. In addition to the focus score, studies have examined ectopic germinal centers, lymphoepithelial lesions, B-cell predominance, plasma-cell composition, fibrosis and glandular damage, and molecular evidence of B-cell clonality [2]. Lymphoepithelial lesions are characteristic ductal lesions, and ectopic germinal centers can form within the gland [12]. Early lesions are dominated by activated T cells, whereas B cells prevail in more severe lesions, where strong B-cell infiltration is associated with ectopic germinal centers [13].

Such features may identify biologically distinct tissue phenotypes, and molecular signatures could eventually help identify patients at risk of systemic complications or lymphoma [2]. At present, however, these features should be regarded as complementary rather than routine biomarkers. The focus score remains the most established histopathologic measure in routine practice.

## Prognostic information and lymphoma risk

Whether salivary gland histology can provide prognostic information is one of the most interesting developments in MSGB research. Early work associated higher focus scores with lymphoma risk in primary Sjögren syndrome [14]. In a multicenter cohort of 794 patients, the focus score was associated with several clinical and serologic features; hypocomplementemia and the focus score were the only variables associated

with lymphoma on univariate analysis, and the focus score remained associated with lymphoma independently of complement levels. By contrast, no significant differences were seen when patients were grouped by Chisholm and Mason grade [15].

In a retrospective analysis of 618 patients, including 58 with lymphoma, the focus score, cryoglobulinemia, and salivary gland enlargement were independent lymphoma-associated risk factors. Lymphoma patients with a focus score ⩾4 developed lymphoma earlier after SjD diagnosis than those with a lower score (four versus nine years) [16].

These findings are clinically interesting but do not mean that a high focus score alone predicts lymphoma in an individual patient. Lymphoma risk is multifactorial, with systemic extraepithelial manifestations, low C4, mixed type II cryoglobulinemia, and persistent salivary gland enlargement contributing to the overall risk phenotype [13,16]. Histopathology may therefore contribute to risk stratification, but it should not be used as a stand-alone indication for lymphoma surveillance or treatment.

## Special role in anti-SSA/Ro-negative disease

MSGB is particularly important in patients with suspected SjD who are negative for anti-SSA/Ro antibodies. In a retrospective study of 47 anti-SSA-negative patients, 14 (29.8%) had a positive biopsy and 15 (31.9%) received a final diagnosis of Sjögren syndrome; the authors reported a biopsy sensitivity of 93.3% and specificity of 100% [17]. The sample was small and selected, and because the final diagnosis was made by treating clinicians who likely had access to the biopsy result, these accuracy estimates should be interpreted cautiously.

In the larger study of 313 patients described above, the biopsy was positive in 24.6% overall, with no significant difference between anti-Ro-positive and anti-Ro-negative patients, and MSGB allowed 22.3% of seronegative patients to fulfill the 2016 classification criteria [3]. These findings support a practical role for MSGB when clinical suspicion remains substantial despite negative anti-SSA/Ro testing, particularly when objective tissue evidence would change the diagnostic assessment.

## Childhood-onset SjD

MSGB may have particular value in childhood-onset SjD, where no consensus classification criteria exist and only about 36% of patients fulfill the 2016 ACR/EULAR criteria. As summarized by Chatzis and Tzioufas, the biopsy shows a specificity of approximately 80% in this setting but a relatively low negative predictive value (57%) when considered in isolation, and positive biopsies appear to be rare in pediatric control populations [2].

A recent single-center study compared MSGB specimens from 18 children and 55 adults with SjD. Pediatric biopsies had a higher median focus score (3.4 versus 1.0) and more frequent germinal centers (44.4% versus 5.5%), lymphoepithelial lesions (61.1% versus 5.5%), and fibrotic changes (66.7% versus 27.3%), with a B-cell-enriched infiltrate [18]. The sample was small, and differences in disease duration, referral patterns, and biopsy indications should be considered. Larger prospective studies are needed before these histologic characteristics can be incorporated into routine pediatric risk assessment.

## Relationship between MSGB and SGUS

SGUS provides a noninvasive assessment of the major salivary glands and evaluates structural abnormalities that are not directly captured by minor salivary gland histology. Because SGUS and MSGB examine different anatomic sites and provide different types of information, they should currently be considered complementary rather than interchangeable investigations.

A systematic review and meta-analysis of studies comparing SGUS with MSGB found that SGUS had good diagnostic performance, although MSGB demonstrated somewhat higher pooled sensitivity and specificity across the included studies [19]. The findings support SGUS as a useful noninvasive diagnostic tool but do not establish that it can universally replace tissue examination.

More recent evidence directly comparing SGUS and MSGB further supports this complementary approach. In a retrospective study of 128 patients undergoing both investigations, overall concordance was only 67.2% ($\kappa = 0.334$). MSGB with a focus score ⩾1 demonstrated the highest diagnostic accuracy, while SGUS contributed additional information in patients with negative biopsies [20]. These findings are clinically relevant because discordance between imaging and tissue assessment is expected when the tests evaluate different manifestations of glandular disease.

SGUS may therefore be particularly useful as an initial or complementary investigation in patients with suspected SjD, whereas MSGB remains valuable when tissue confirmation is needed, particularly in anti-SSA/Ro-negative disease or when the clinical findings remain discordant. The optimal sequencing of SGUS and MSGB will likely depend on pretest probability, local expertise, availability, and the specific clinical question.

## Should MSGB be repeated?

Routine repeat MSGB is not established clinical practice. A repeat biopsy may occasionally be considered when the initial specimen was inadequate, when the clinical picture changes substantially, or when a specific new diagnostic question arises; for example, persistent glandular enlargement or other features concerning for lymphoproliferative disease may prompt further tissue evaluation. One study proposed a follow-up strategy based on the focus score and salivary gland enlargement to facilitate early lymphoma diagnosis [16], but this is hypothesis-generating and does not establish a role for serial biopsy. Repeating an invasive procedure solely to monitor the focus score is unlikely to be justified in most patients.

## From diagnostic test to precision medicine

The most important conceptual change is the transition from a binary diagnostic test toward a multidimensional tissue phenotype. A biopsy may describe the intensity and organization of glandular inflammation, the relative contribution of B and T cells, germinal-center formation, epithelial injury, fibrosis, and potentially molecular abnormalities, raising the possibility that tissue characteristics could eventually define clinically meaningful subgroups.

The study by van Ginkel et al. demonstrates how combining several histopathologic characteristics can improve diagnostic specificity compared with reliance on the focus score alone [11]. Similarly, contemporary studies combining MSGB with SGUS illustrate how tissue and imaging data may eventually be integrated into more individualized diagnostic models [19,20]. Digital pathology, molecular profiling, and artificial intelligence may further improve reproducibility and allow more detailed tissue phenotyping [2]. These approaches remain investigational, and their value will depend on validation in independent cohorts and on evidence that tissue-based information improves clinically relevant outcomes.

## A practical approach for the rheumatologist

The most useful approach begins with the clinical probability of SjD rather than with the biopsy itself. Patients with persistent sicca symptoms should undergo appropriate clinical evaluation and objective assessment of ocular and salivary gland function, and serologic results, particularly anti-SSA/Ro, should be interpreted in the context of the overall phenotype. MSGB should then be considered when the diagnosis remains uncertain, and the result is likely to change the assessment, especially in anti-SSA/Ro-negative patients and in those with discordant findings.

When a biopsy is performed, obtaining adequate tissue is essential; patients should be counseled about sensory complications, and the pathology report should include the focus score and, when appropriate, additional features such as lymphoepithelial lesions, ectopic germinal centers, fibrosis, and inflammatory-cell composition. The biopsy should then be integrated with clinical, serologic, ocular, salivary, and imaging findings. Key points are summarized in Table *1*.

| Clinical question | Practical consideration | Evidence/reference |
|---|---|---|
| Who benefits most from MSGB? | Most useful when SjD is suspected but anti-SSA/Ro is negative or findings are discordant; added value is limited when the diagnosis is already secure. | [1,3,17] |
| What defines a positive biopsy? | Focal lymphocytic sialadenitis with a focus score ≥1 focus/4 mm² is the histologic item used in the 2016 ACR/EULAR classification criteria. | [1] |
| Is the focus score sufficient? | It remains the principal standardized measure, although additional histopathologic features may improve specificity and provide phenotypic information. | [2,8,10,11] |
| What should pathology report? | Tissue adequacy, glandular area, focus score, lymphoepithelial lesions, germinal centers, fibrosis, and other relevant findings should be considered. | [2,8,10,11] |
| How important is standardization? | Important because interpretation varies between observers and inadequate tissue limits reliability. | [8-10] |
| Can rheumatologists perform MSGB? | Recent outpatient data are encouraging, but sensory complications are reported in other series; training, counseling, and pathology support remain important. | [6,7] |
| How safe is the procedure? | High tissue adequacy and few serious complications have been reported, although persistent sensory change occurs in a minority of patients. | [5-7] |
| What is the main role in anti-SSA/Ro-negative disease? | Provides objective tissue evidence when clinical suspicion remains substantial despite negative serology. | [3,17] |
| Does a high focus score indicate lymphoma? | Higher focus scores are associated with lymphoma at the group level, but the focus score alone is not an individual predictor. | [14-16] |
| Should MSGB be repeated routinely? | No. Repeat biopsy should generally be reserved for an inadequate initial specimen or a specific new clinical or diagnostic question. | [16] |
| What additional tissue features may matter? | Germinal centers, lymphoepithelial lesions, plasma-cell shift, B-cell enrichment, fibrosis, and other histologic features may provide additional phenotypic information. | [2,11-13] |
| Can MSGB help identify mimics? | Yes. Sarcoidosis, amyloidosis, graft-versus-host disease, and IgG4-related disease are among the exclusion conditions relevant to interpretation. | [1] |
| What is the relationship with SGUS? | SGUS and MSGB provide complementary information and should not currently be considered interchangeable tests. | [19,20] |
| What is the future direction? | Digital pathology, molecular profiling, and computational approaches may allow more reproducible tissue phenotyping and precision medicine. | [2,11,20] |

**TABLE 1: High-yield practical considerations for MSGB in SjD.**

ACR/EULAR, American College of Rheumatology/European League Against Rheumatism; anti-SSA/Ro, anti-Sjögren's syndrome-related antigen A/Ro antibody; MSGB, minor salivary gland biopsy; SjD, Sjögren disease

### Limitations

This is a narrative review, and study selection may not capture all available evidence. In addition, much of the available literature consists of retrospective, single-center, or relatively small studies, particularly in anti-SSA/Ro-negative disease, childhood-onset disease, and lymphoma risk assessment. Evidence supporting additional histopathologic features, integration of MSGB with SGUS, and tissue-based precision medicine remains heterogeneous and requires prospective validation.

## Conclusions

MSGB remains an important component of the evaluation of selected patients with SjD. Its value is particularly evident in anti-SSA/Ro-negative patients and in those with discordant or uncertain clinical findings, whereas its added value is limited when the diagnosis is already secure. Contemporary evidence also suggests that MSGB may provide information about disease phenotype and prognosis beyond the traditional focus score, although many of these applications remain investigational.

The biopsy should be integrated with clinical, serologic, ocular, salivary, and imaging findings rather than viewed as an isolated test. Adequate tissue sampling, standardized histopathologic reporting, and pre-procedure counseling about sensory complications are essential. SGUS provides complementary noninvasive

information, while emerging approaches such as digital pathology and molecular characterization may eventually allow salivary gland tissue to contribute to individualized disease phenotyping. For now, the greatest clinical value lies in using MSGB selectively and interpreting its findings within the broader clinical context.

# Additional Information

## Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Thanda Aung

**Acquisition, analysis, or interpretation of data:** Thanda Aung

**Drafting of the manuscript:** Thanda Aung

**Critical review of the manuscript for important intellectual content:** Thanda Aung

## Disclosures

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