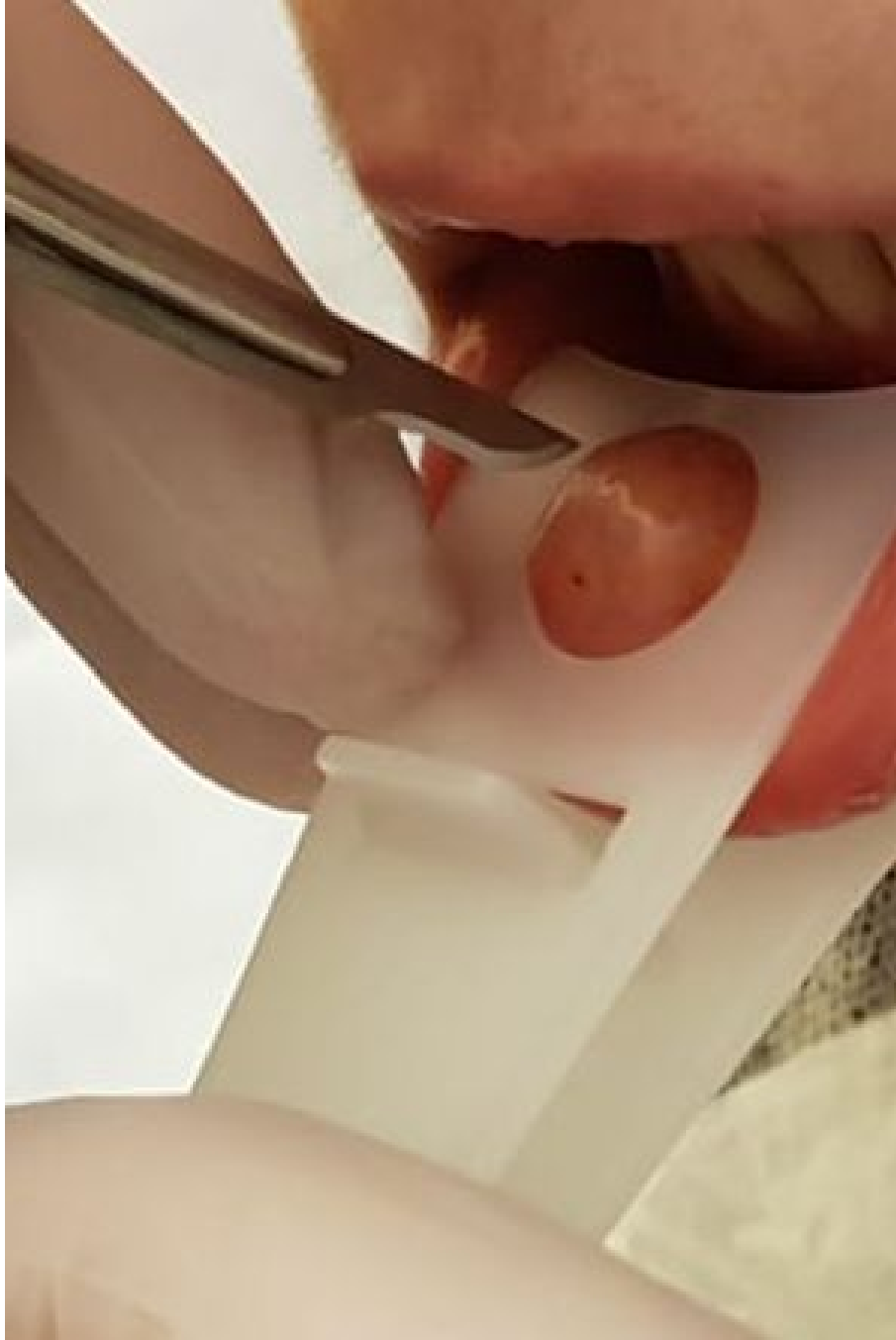
SALICLICK®

A new technique for biopsy of the minor salivary glands

Standardized, safe collection of labial salivary gland tissue for the diagnosis of Sjögren's syndrome.



Clinical Background

Why the Salivary Gland Biopsy Is Decisive

Diagnostic Value

The histopathological detection of **focal lymphocytic sialadenitis** in the labial salivary gland biopsy is one of the strongest individual factors in the EULAR/ACR classification criteria for Sjögren's syndrome.

A **Focus Score ≥1 focus/4 mm²** counts **3 out of the minimum 4** points required for classification.

The Problem with Classical Techniques

Conventional surgical extraction techniques are poorly standardized and, in a **meta-analysis of 27 studies** with 3,208 patients, are associated with a pooled complication rate of **11%**:

- Neurological complications: 3%
- High dependence on examiner experience

Valdez et al., Oral Pathol Med 2021

The Instrument: The Saliclick Lipholder

Saliclick is a **CE-certified lip holder** that fixes, exposes, and stabilizes the oral mucosa on the inner side of the lower lip. This mechanical standardization makes tissue sampling reproducible.

Fixation

Stable positioning of the lower lip for optimal exposure of the mucosa

Reduction

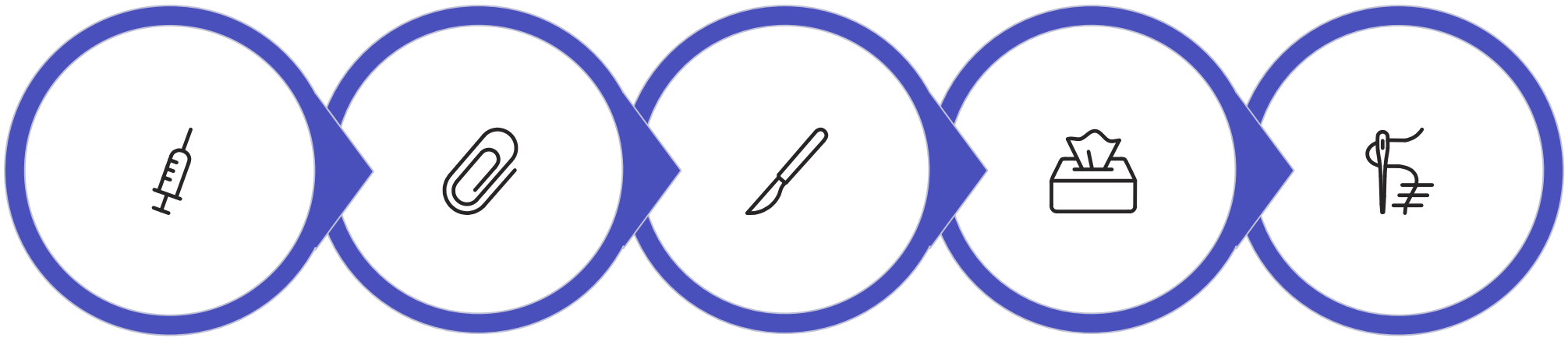
Smaller incision size through precise guidance of the instrument

Reproducibility

Standardized procedure, published in *BMJ Innovation 2021* (Dumusc et al.)

Step-by-Step

Biopsy Procedure with SALICLICK®



Local Anesthesia

Fixation

Single Incision

Gland Removal

Wound Closure

The mean procedure duration is **13.8 minutes** (median 11 min., range 4–60 min.) – from incision to dressing application. In the vast majority of cases, only a single incision is necessary, and wound closure by suture is rarely required.

08/2023–04/2026, n = 185 biopsies, 6 examiners

Clinical Experience & Safety Data

185

Biopsies

Exclusively with Saliclick, unpublished data

100%

Gland Yield

Usable glandular tissue was obtained in every procedure

71%

≥4 Glands

Optimal tissue quantity for histopathological evaluation

84%

Would Repeat

High acceptance and willingness to undergo biopsy again

Tolerability & Complication Profile

Intraprocedural Complications (13%)

All intraprocedural events were mild; no severe or permanent complications were observed in any case:

- **7%** mild discomfort / presyncope
- **4%** minor bleeding
- **2%** other mild events

96% of patients found the procedure tolerable.

Self-reported adverse effects after 1 week (response rate 78%)

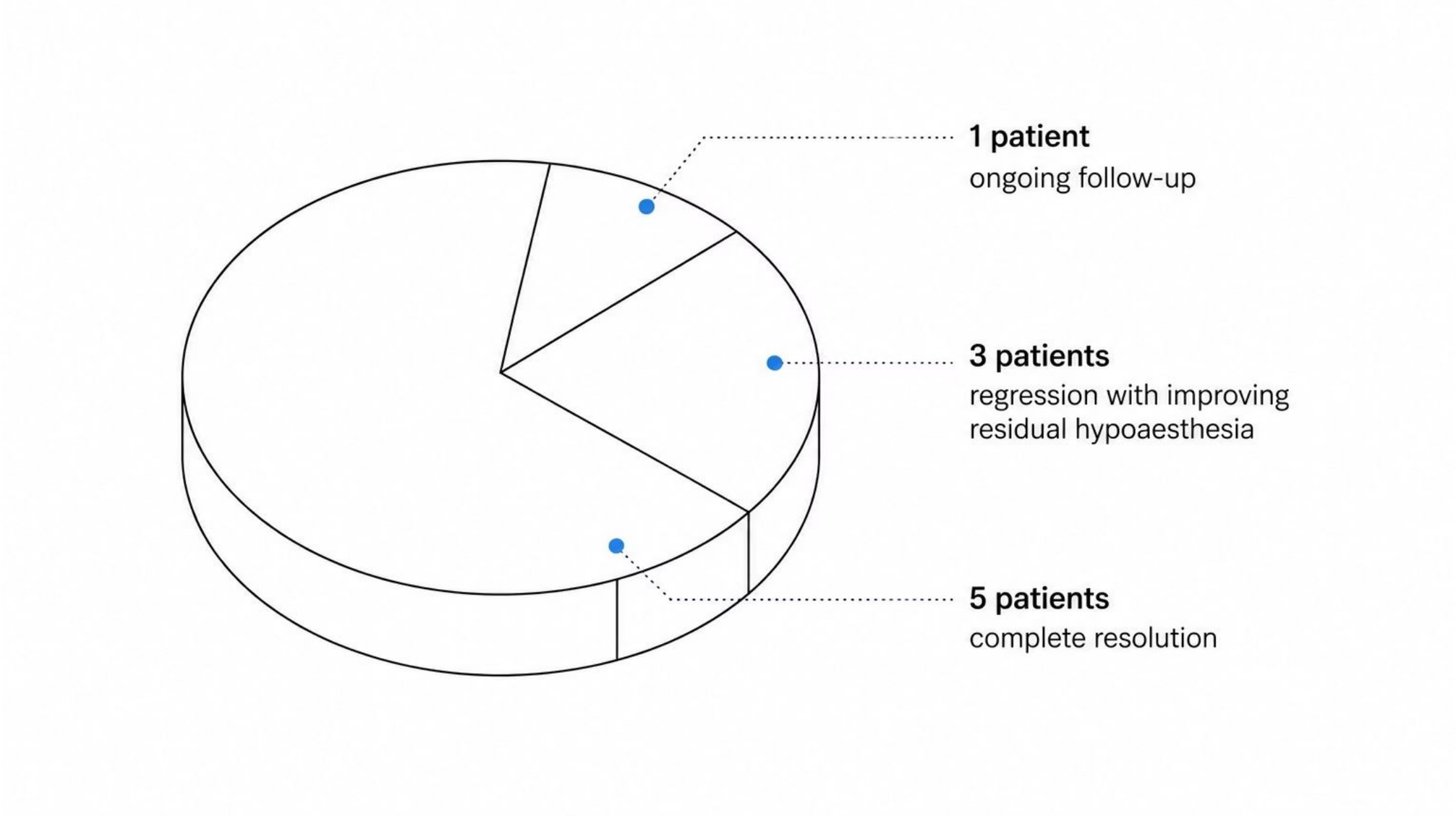
Most complaints were transient and resolved within a few days:

- **47%** pain
- **45%** tingling / paresthesia
- **38%** swelling
- **30%** hematoma

After 1 month, complaints were rarely present **(≤ 5%)**.

Course of Paraesthesias: Targeted Follow-Up

9 patients with initial paraesthesia after biopsy underwent targeted follow-up. The results show largely complete neurological recovery:



For comparison: The pooled neurological complication rate across all biopsy techniques in the literature is **3%** (95% CI; Valdez et al., Oral Pathol Med 2021) – with SALICLICK®, **no permanent neurological damage** was observed.

Comparison with the Literature

SALICLICK® in Context: Benefits at a Glance

Standardized & Reproducible

Independent of the examiner's experience; 6 examiners in the cohort

Short Procedure Duration

Median 11 minutes – performed on an outpatient basis without general anesthesia

100% Tissue Yield

Consistently sufficient glandular tissue for histopathological evaluation

CE-Certified

Regulatory approved; wound closure is required in <12% of cases

Onboarding & Training

Training Concept for Rapid Implementation

Video Tutorials

Structured **video tutorials** are available for each procedural step, clearly demonstrating the complete workflow – from anesthesia to wound closure. The tutorials are accessible online and enable flexible onboarding.

Artificial Practice Model

A specially developed **training pad** (simulated lip model) allows practice with the Lipholder and surgical instruments – completely independent of patients. This enables the technique to be learned and refined without hesitation before the first clinical application.

Further information and training materials at **www.saliclick.info** – Contact: Thomas.Hugle@chuv.ch | Dr. Alexandre Dumusc, Service de Rhumatologie, CHUV Lausanne

Summary

SALICLICK® – Standardized Diagnostics for Sjögren's Syndrome

Clinical Relevance

The salivary gland biopsy is a central diagnostic tool within the EULAR/ACR criteria. SALICLICK® makes this procedure safely, quickly, and standardizedly available.

Proven Safety

185 biopsies in the Swiss Sjögren Cohort with no serious or permanent complications. 96% tolerability, 84% willingness to repeat.

Sources & Conflict of Interest

Dumusc et al., *BMJ Innovation* 2021 · Valdez et al., *Oral Pathol Med* 2021 · Swiss Sjögren Cohort, unpublished data (08/2023–04/2026, n=185). **Note:** Prof. Thomas Hügle receives license fees (royalties) for the Saliclick Lipholder from Curmed / Caredeluxe GmbH.