

1.0 PURPOSE

The purpose of this study is to compare the surface of two groups of nitinol sleeves (Used and Unused Smileloc by Rodo Medical) using Scanning Electron Microscope (SEM) analysis.

2.0 SCOPE

The Rodo Smileloc is a nitinol component used to retain a dental crown onto a dental abutment. Each Smileloc contains 8 flaps: 4 flaps that engage the implant abutment and 4 flaps that engage the crown coping. The end of each flap, which is in direct contact with either the abutment or coping undercut, was inspected for any significant change in surface condition such as wear, fracture, chipping, using SEM analysis.

3.0 REFERENCE DOCUMENTS

N/A

4.0 TEST DEVICES AND MATERIALS

All Smilelocs were provided and labeled by Rodo Medical. The following devices were tested:

- N=2 Unused Smilelocs in finished condition (Ref. No. 1.001, Lot No. L14-0025; Ref. No. 1.012, Lot No. L15-0178)
- N=10 Used Smilelocs (labeled as 01-005, 01-006, 01-009, 02-002, 02-003, 02-004, 02-009, 02-010, 02-012, 02-005)

The following testing equipment was used:

- FEI Nova™ SEM 230 Scanning Electron Microscope with Field Emission gun and variable pressure capabilities, equipped with X-ray Energy Dispersive Spectrometer and Raman Detector
- This equipment is maintained by a core facility operated by the Department of Materials Science and Engineering at the UCLA Henry Samueli School of Engineering and Applied Science.

5.0 TEST PROCEDURE

- 5.1 Identify 4 inner and 4 outer flaps on each Smileloc (see Figure 1).
- 5.2 Take SEM images of the end of each flap (total 8 images per Smileloc) at 200X magnification.

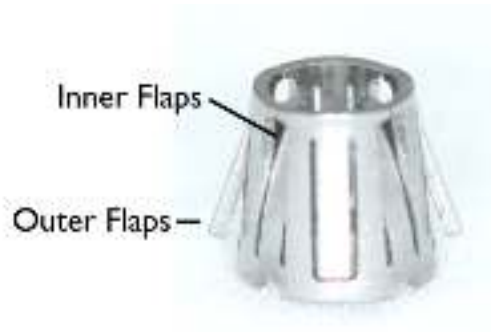


Figure 1: Smileloc inner and outer flaps

6.0 RESULTS

SEM images of all 12 Smilelocs are shown in Appendix A.

7.0 CONCLUSIONS

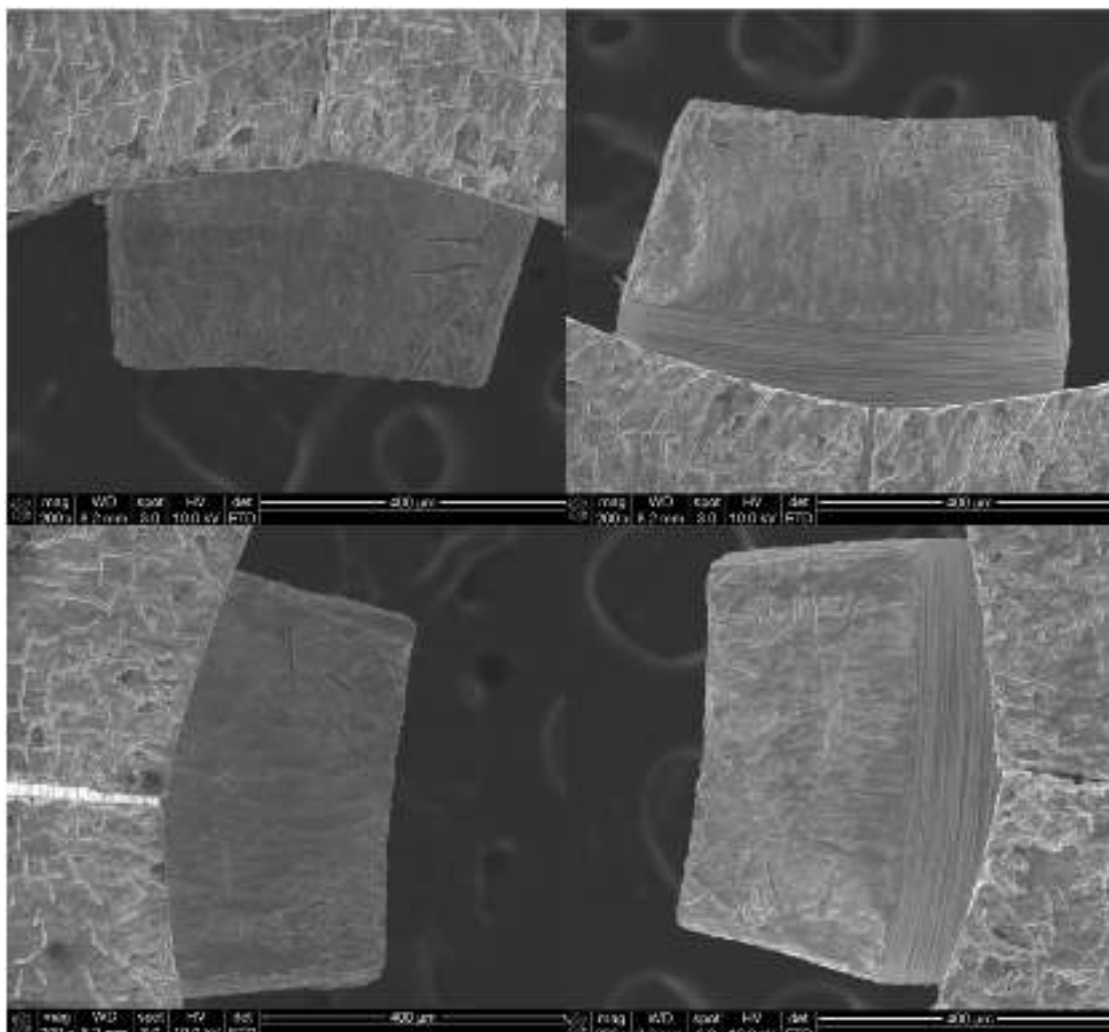
There are no observable differences between the ends of the flaps, which lock the Smileloc to the abutment and crown coping undercuts. The surfaces appear to be identical with no evidence of wear, fracture, chipping, on any flap end.

Appendix A

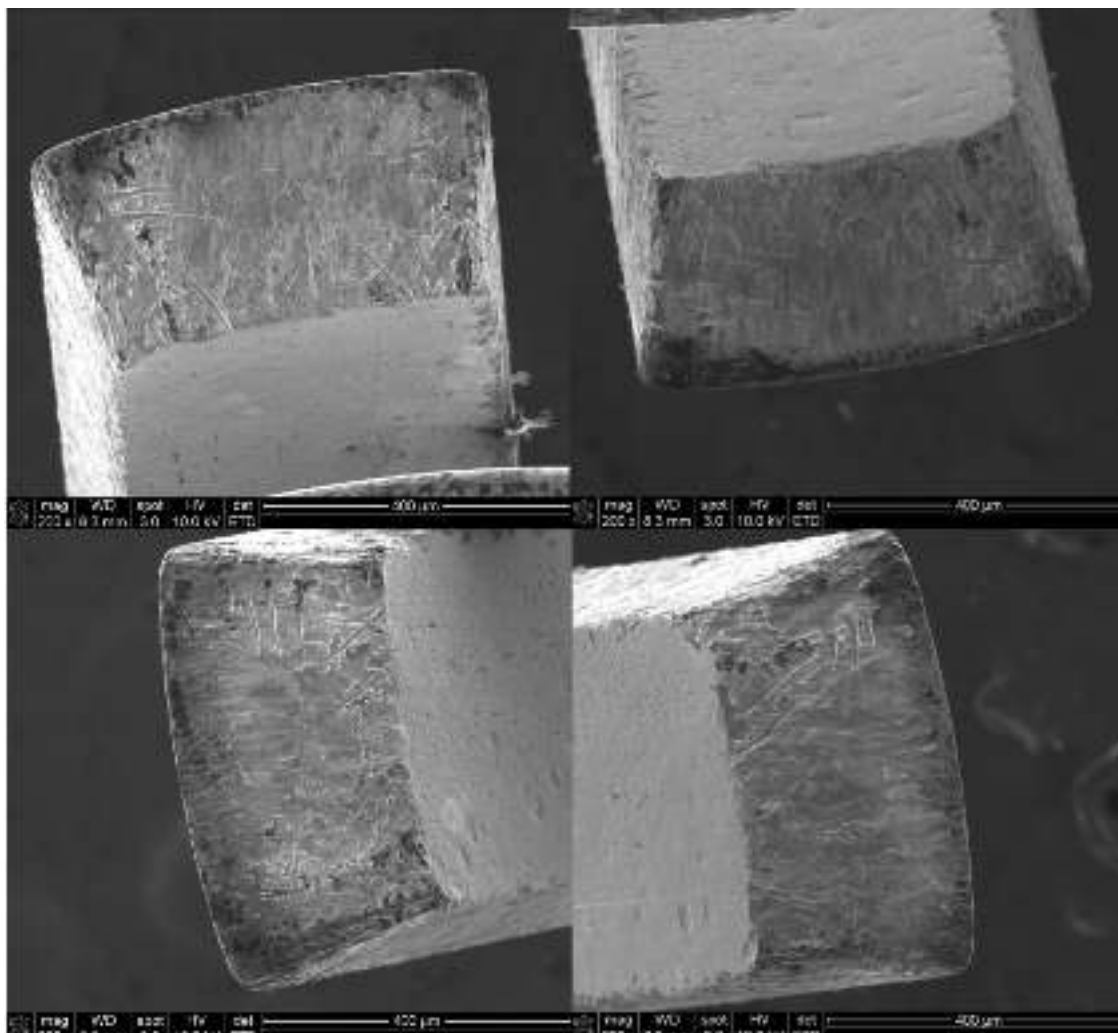
SEM Images of Unused Smilelocs

Unused Smileloc #1 Ref. No. 1.001, Lot No. L14-0025

Inner Flaps

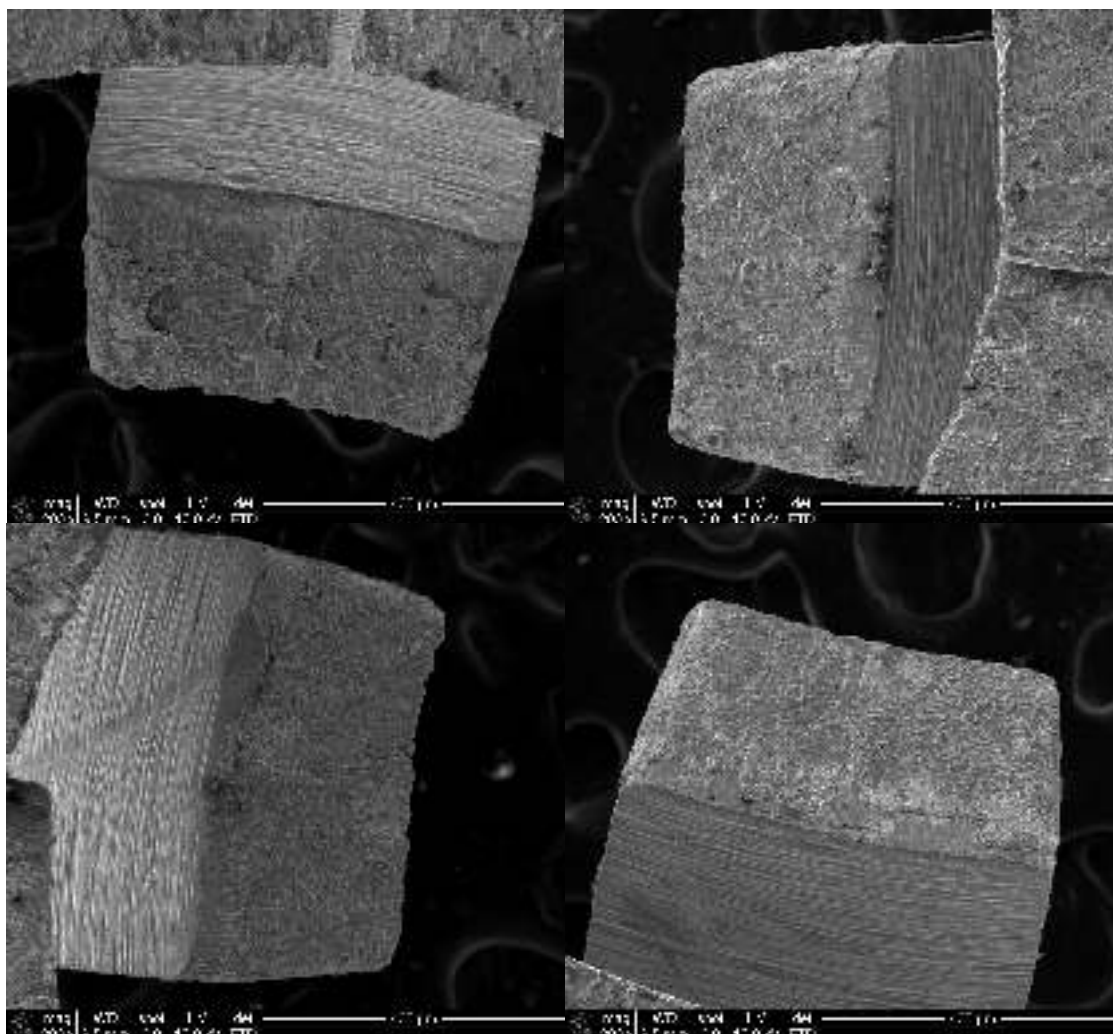


Outer Flaps

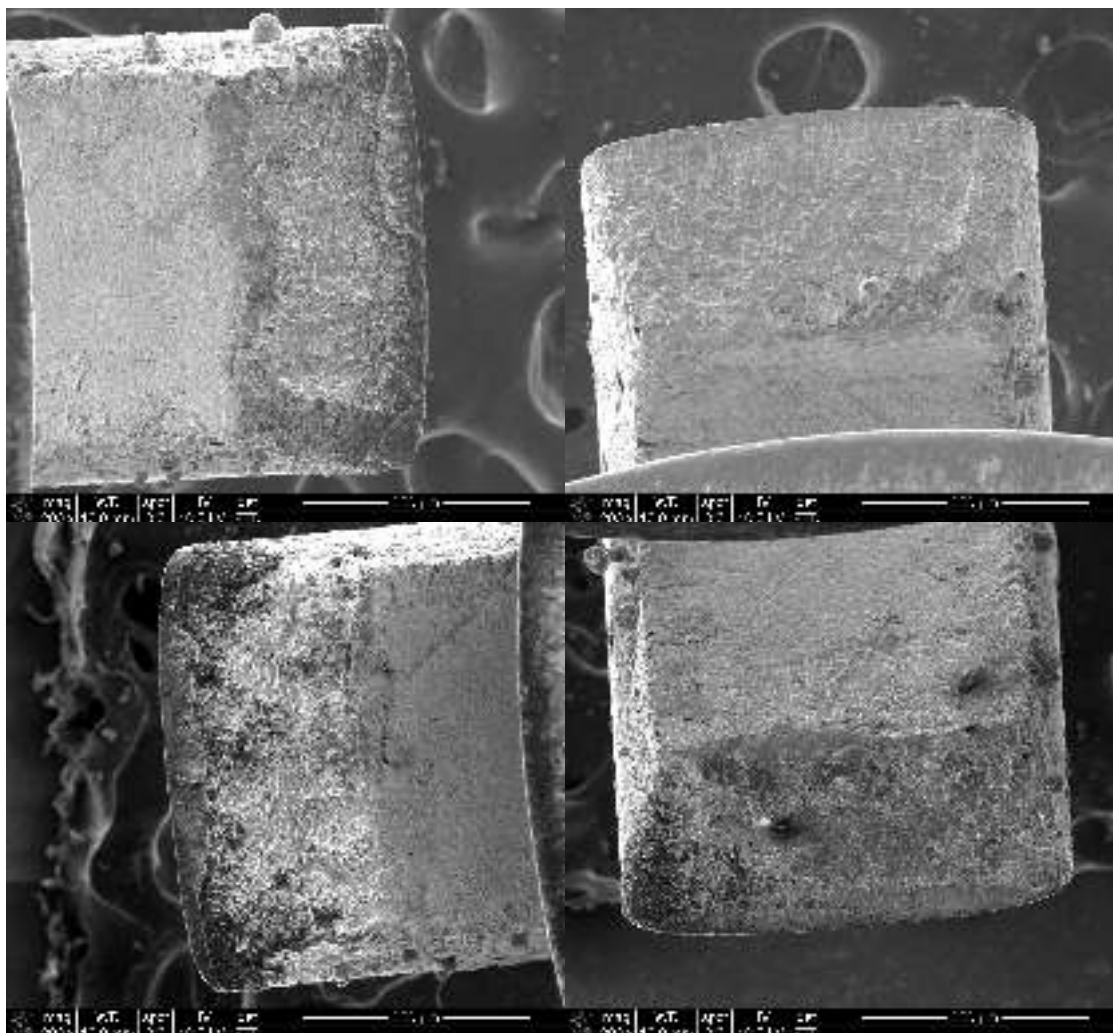


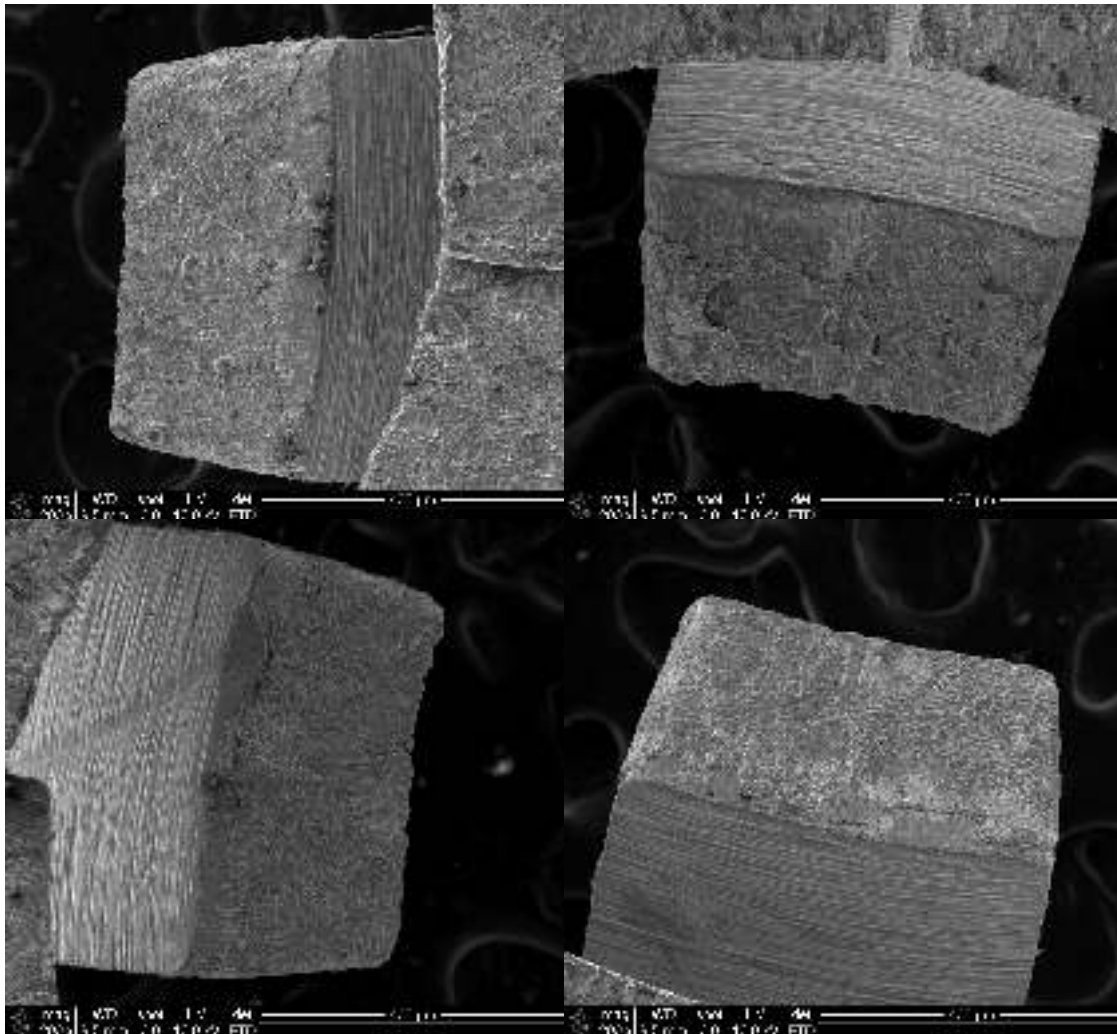
Unused Smileloc #2 Ref. No. 1.012, Lot No. L15-0178

Inner Flaps

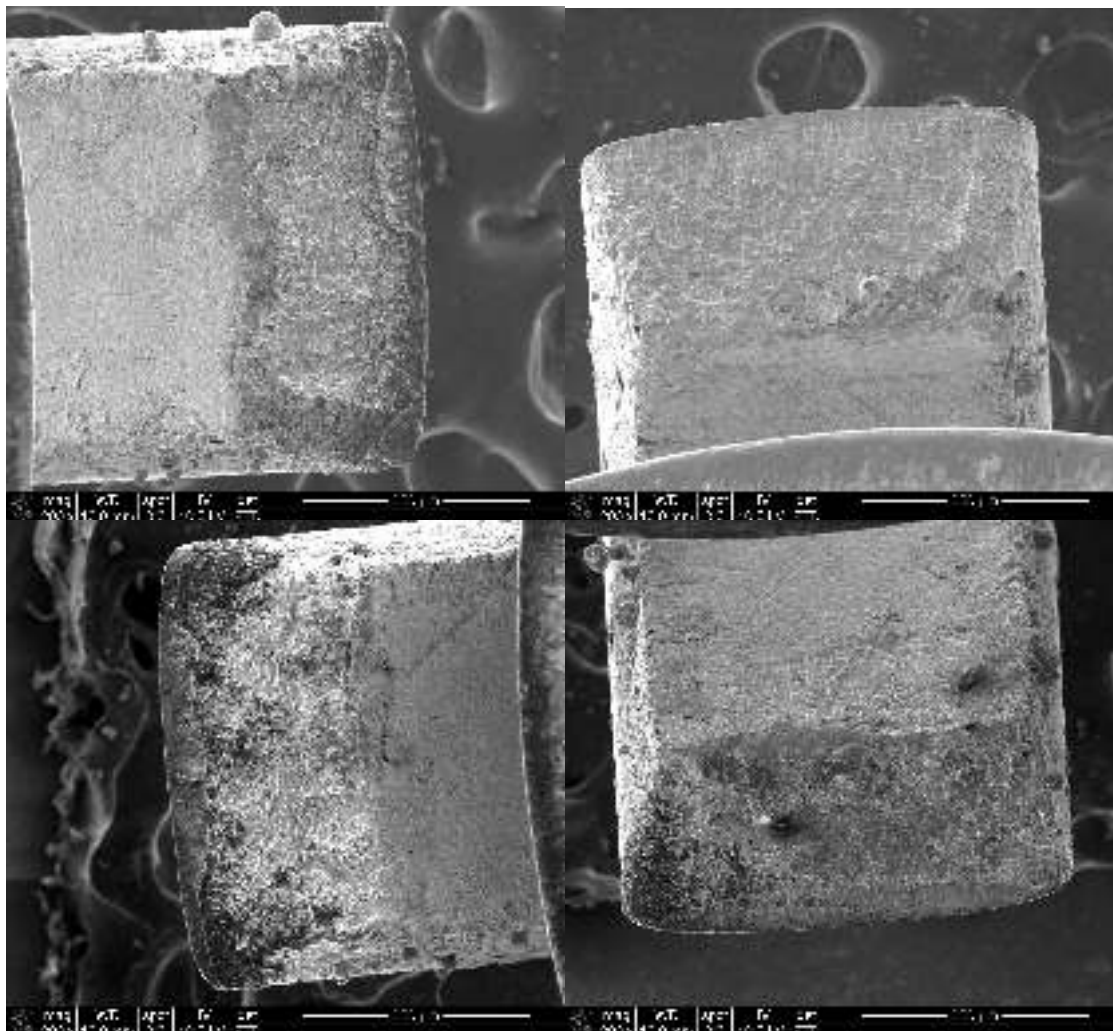


Outer Flaps



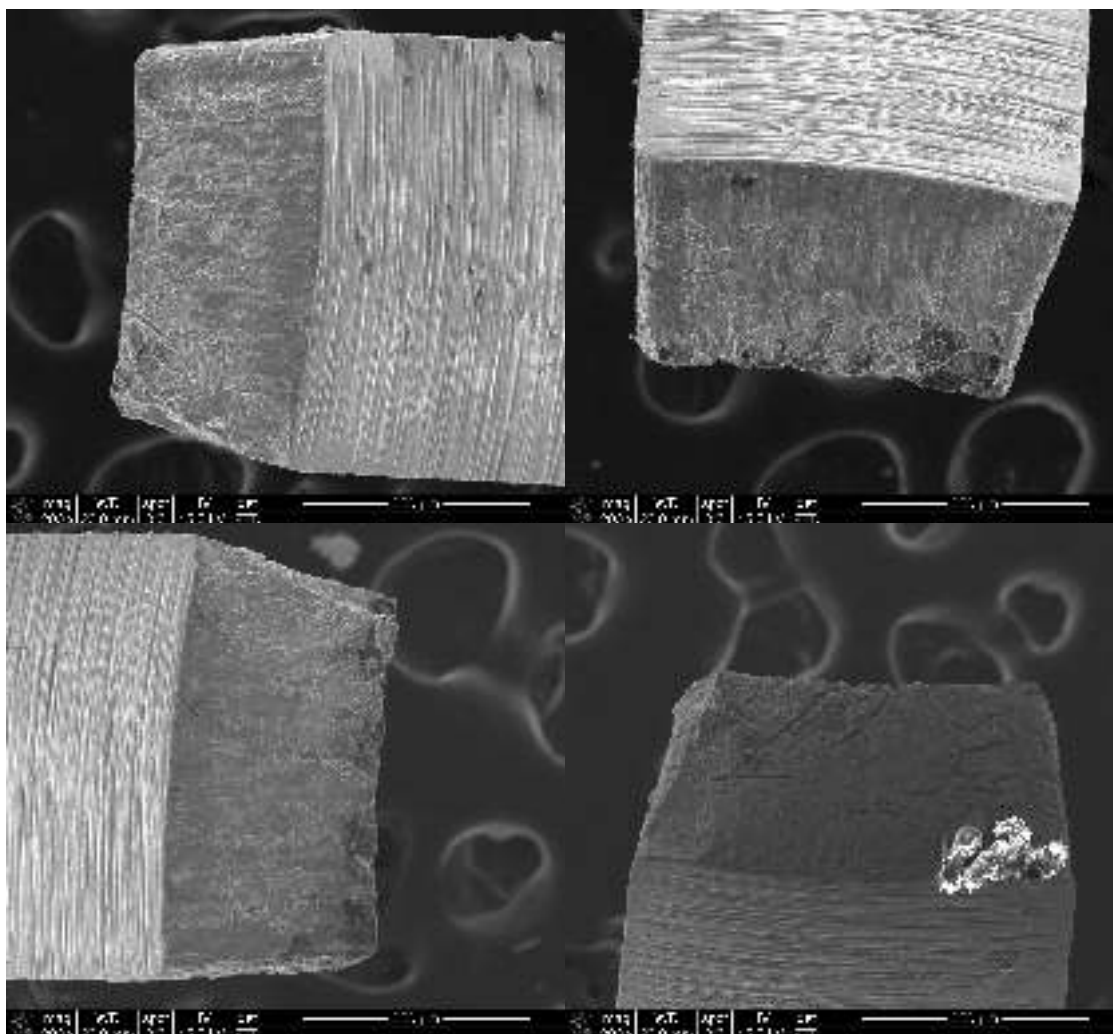


Outer Flaps

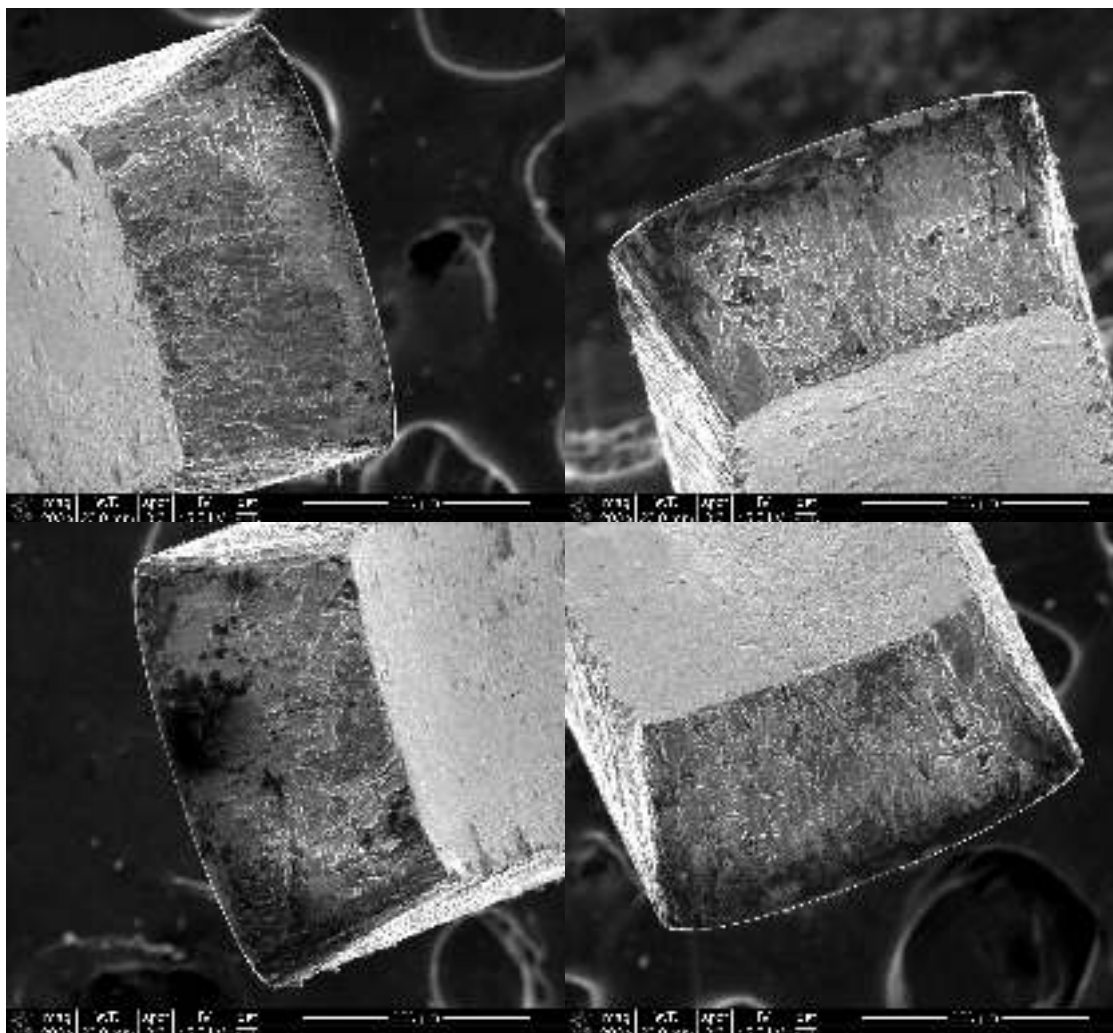


Used Smileloc #2 (01-006)

Inner Flaps

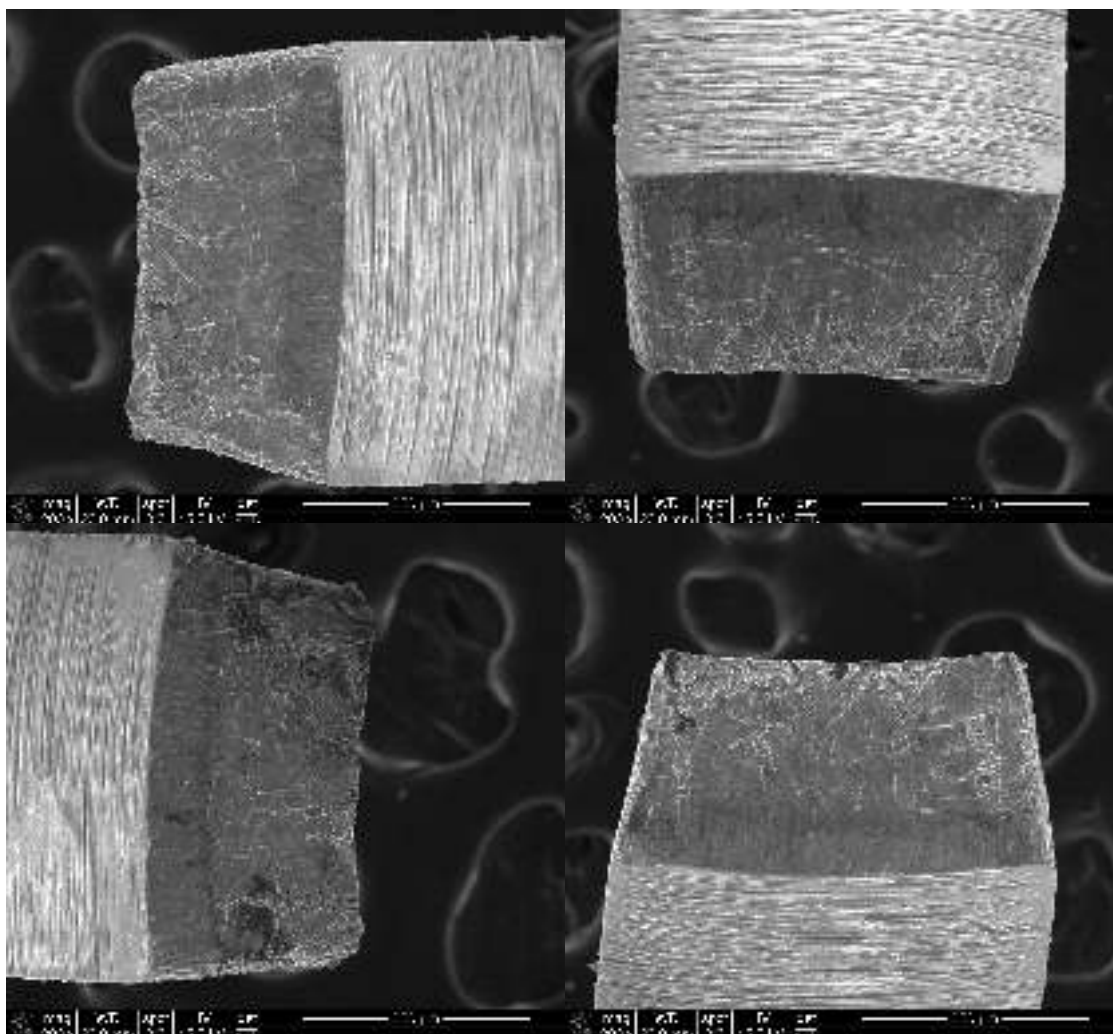


Outer Flaps

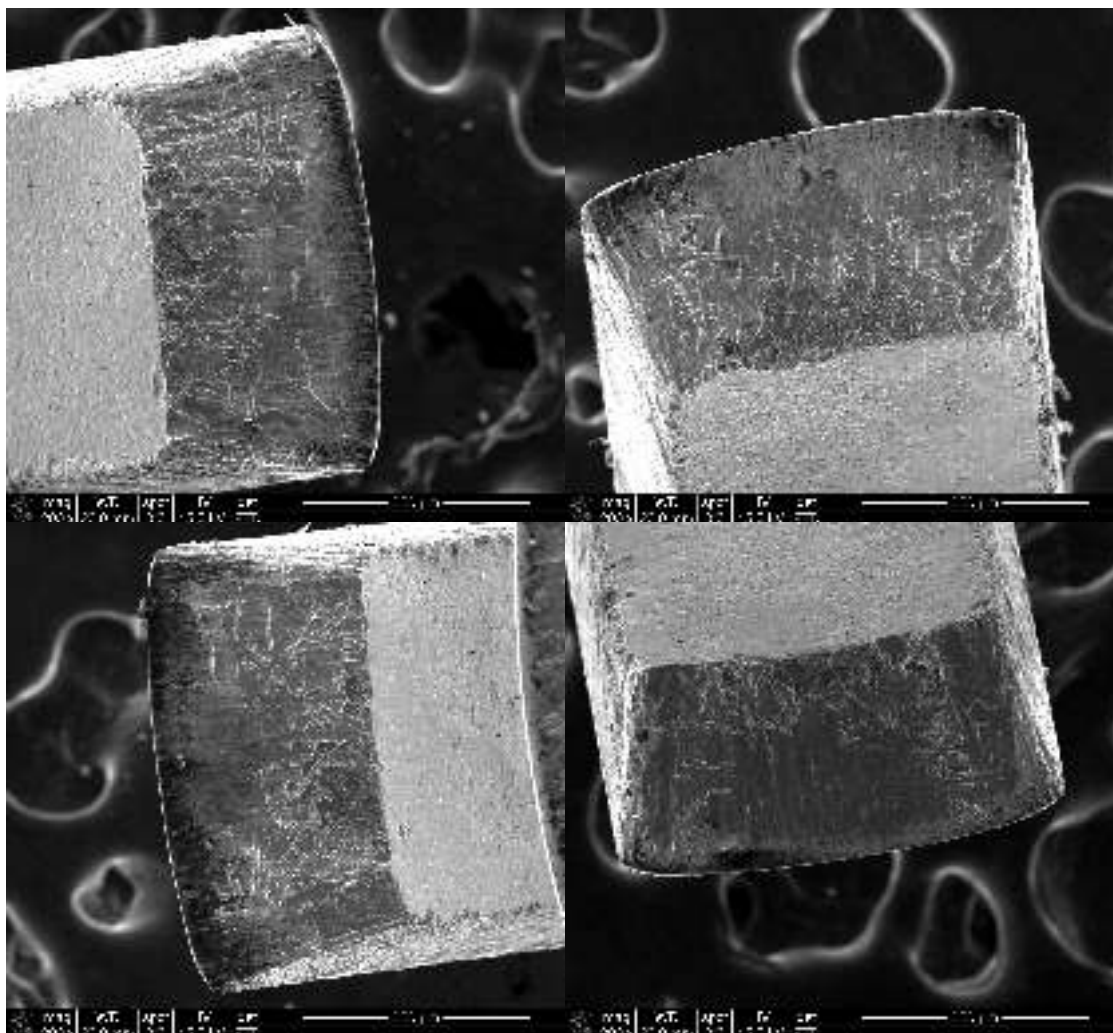


Used Smileloc #3 (01-009)

Inner Flaps

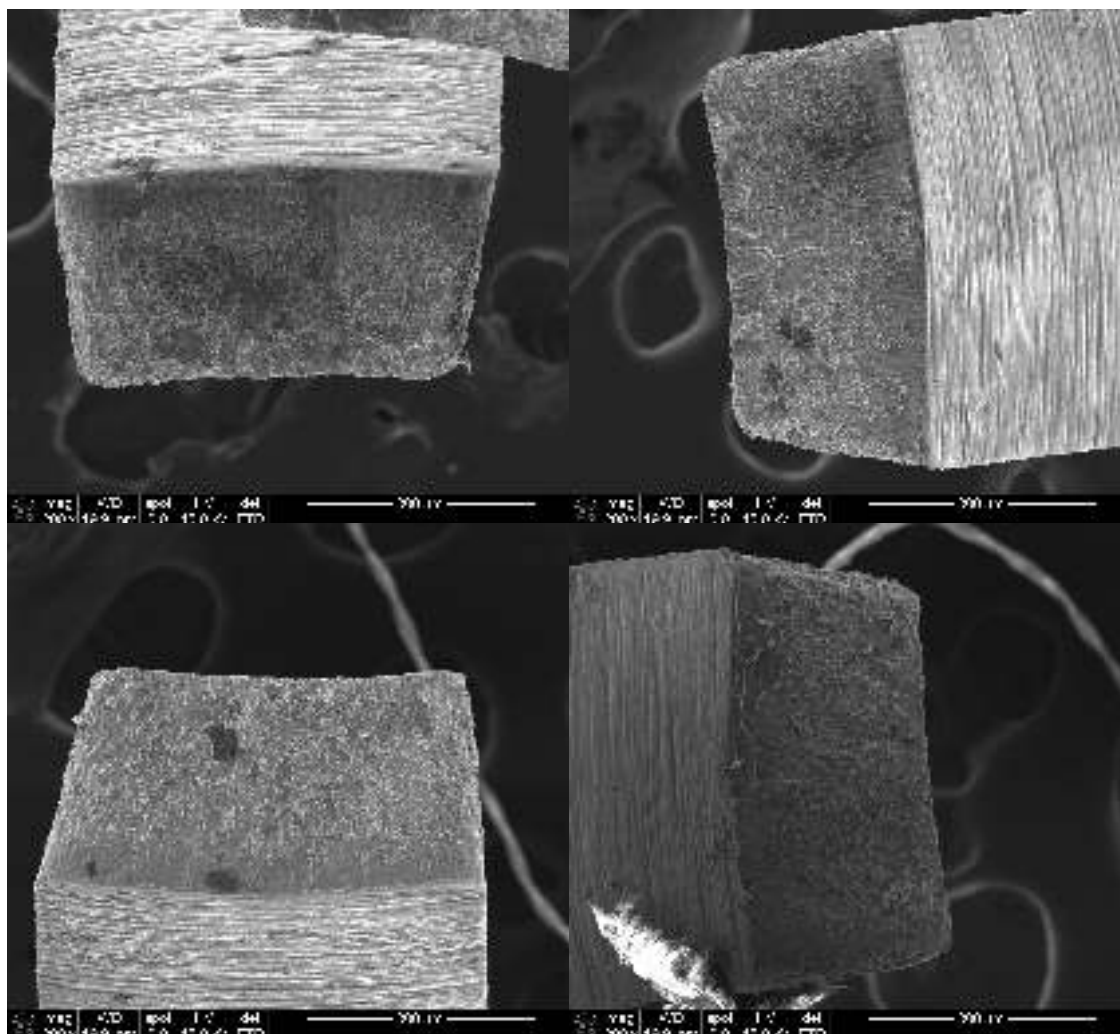


Outer Flaps

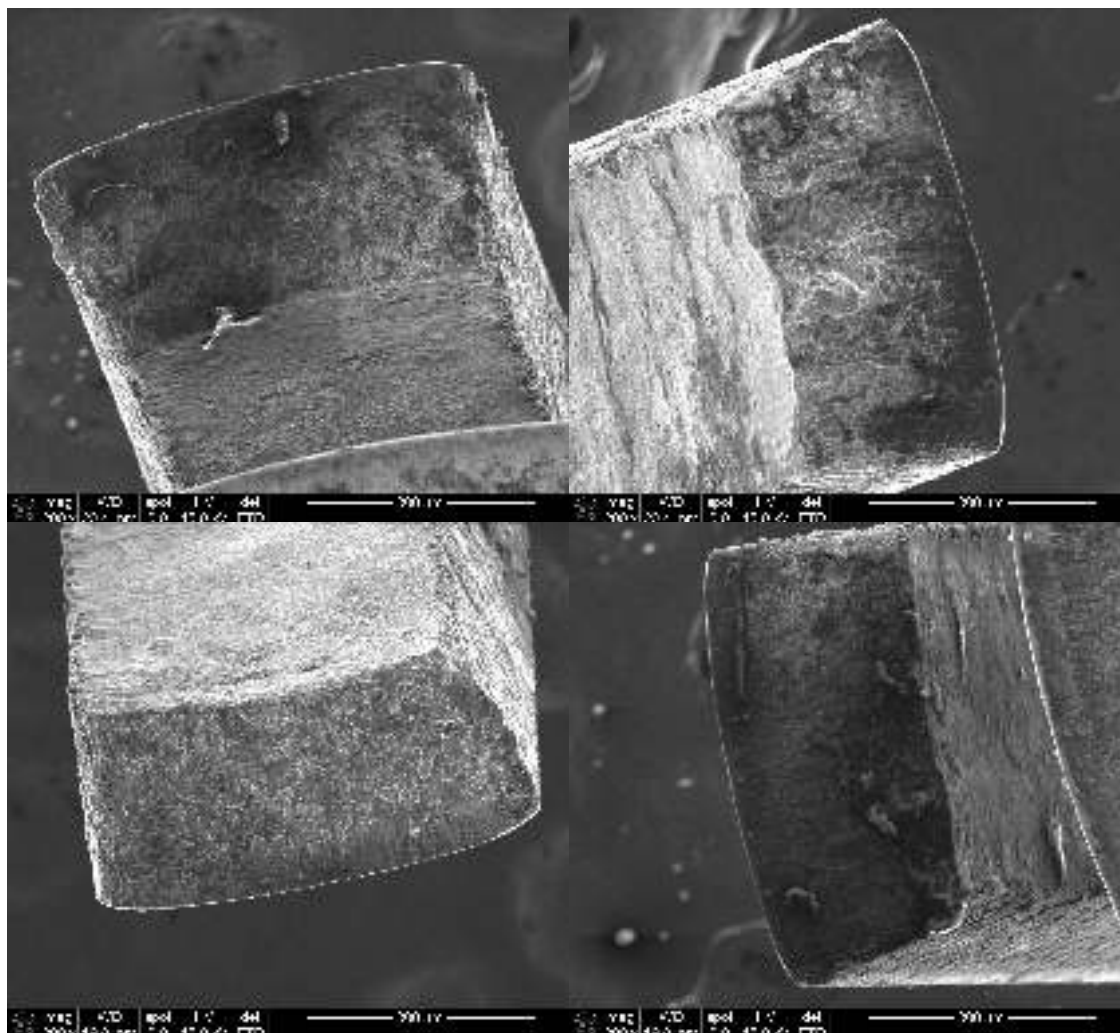


Used Smileloc #4 (02-002)

Inner Flaps

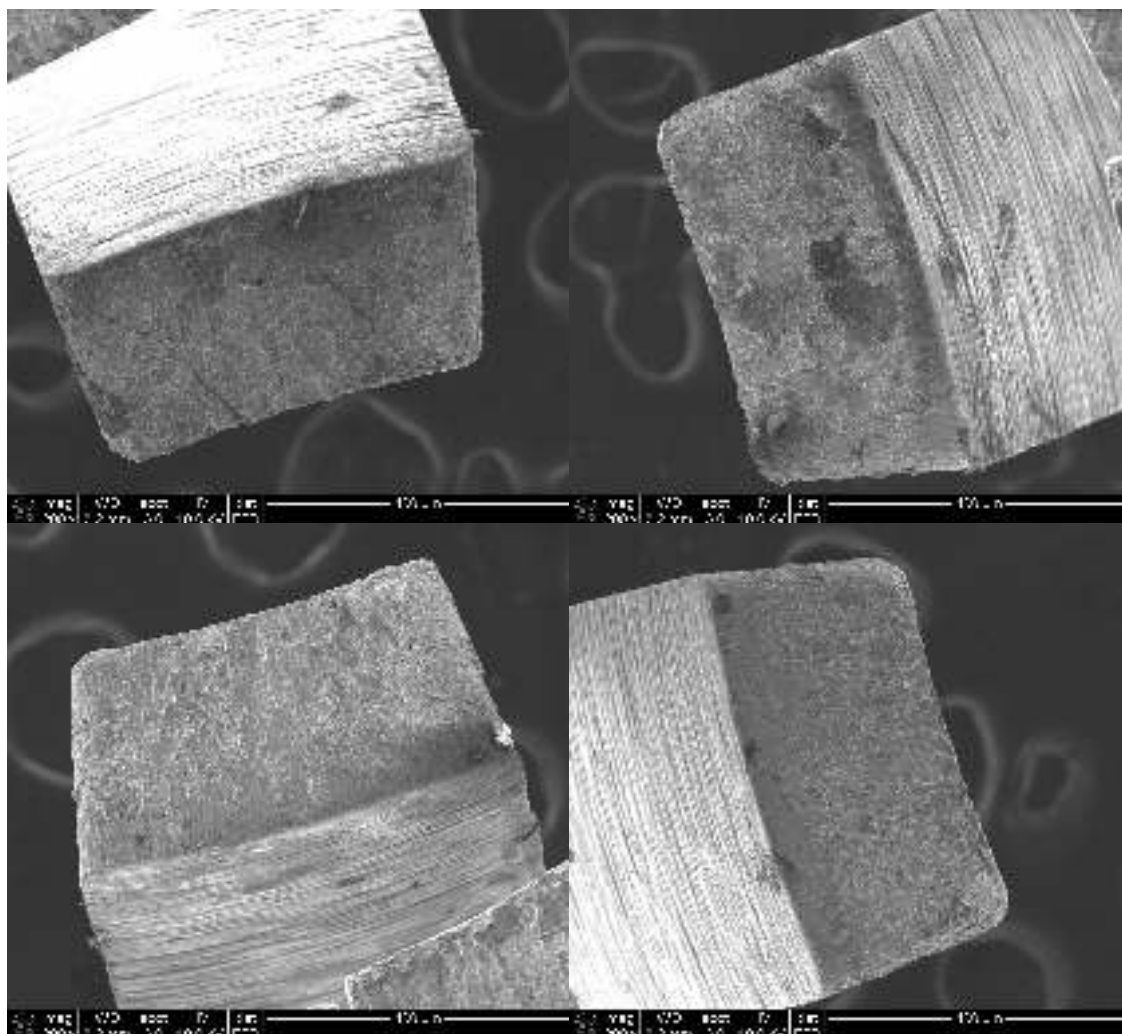


Outer Flaps

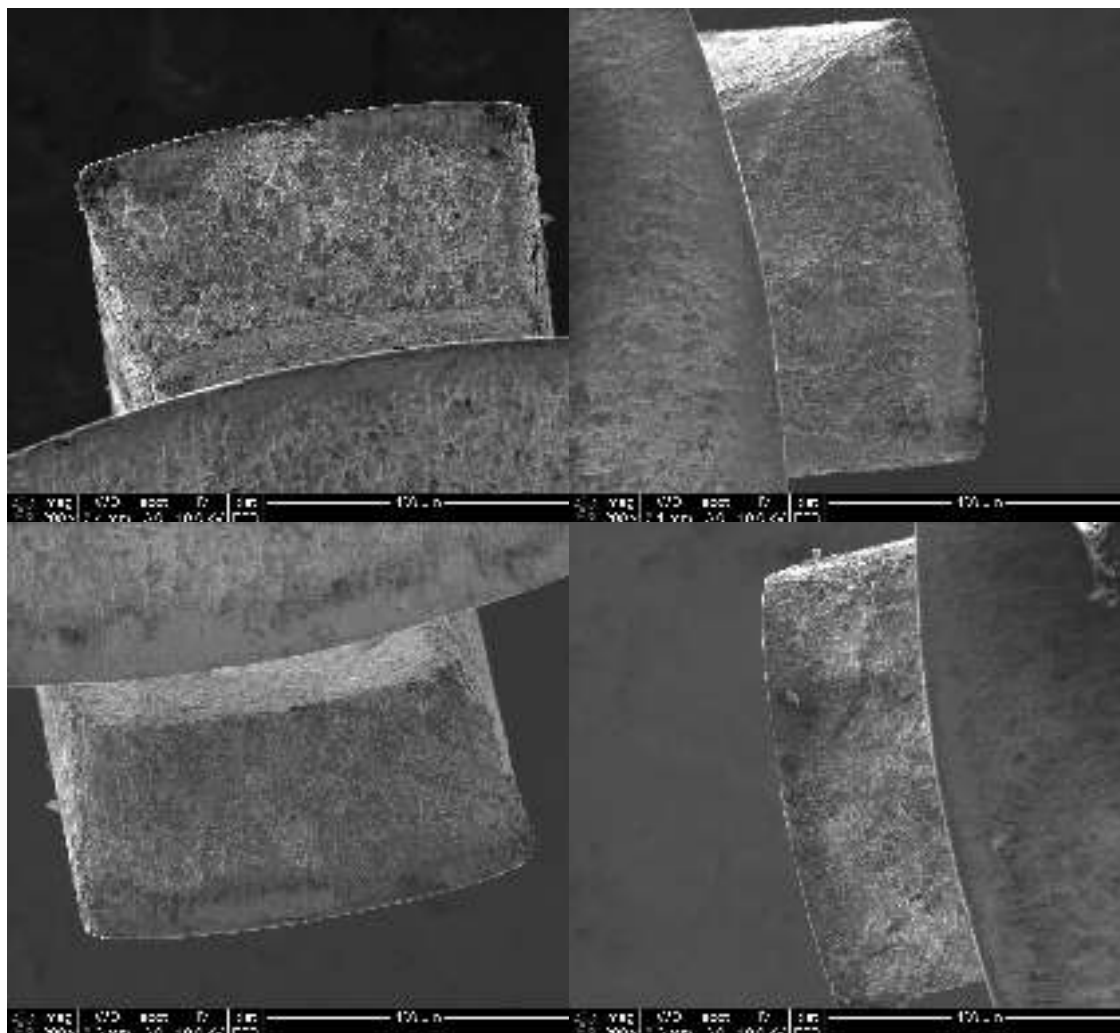


Used Smileloc #5 (02-003)

Inner Flaps

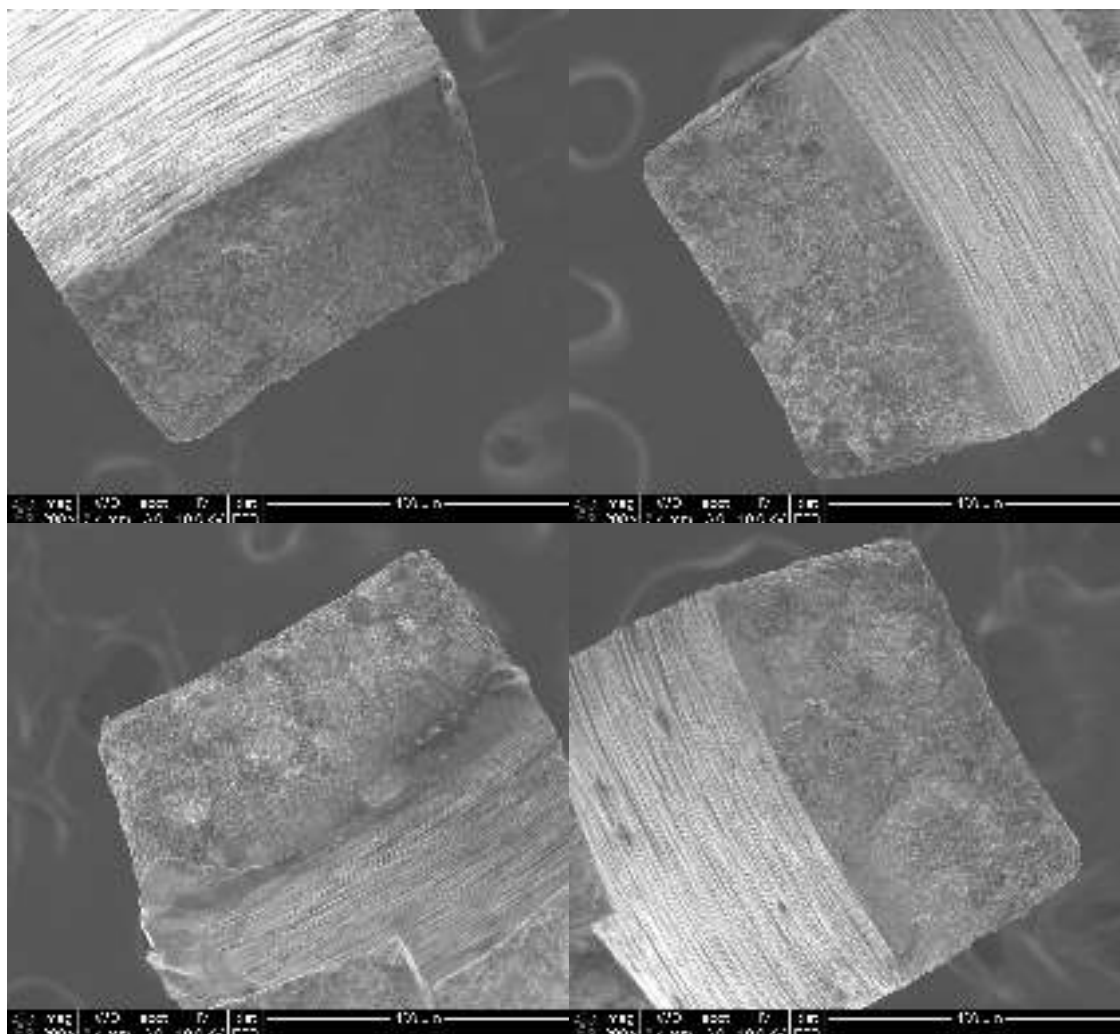


Outer Flaps

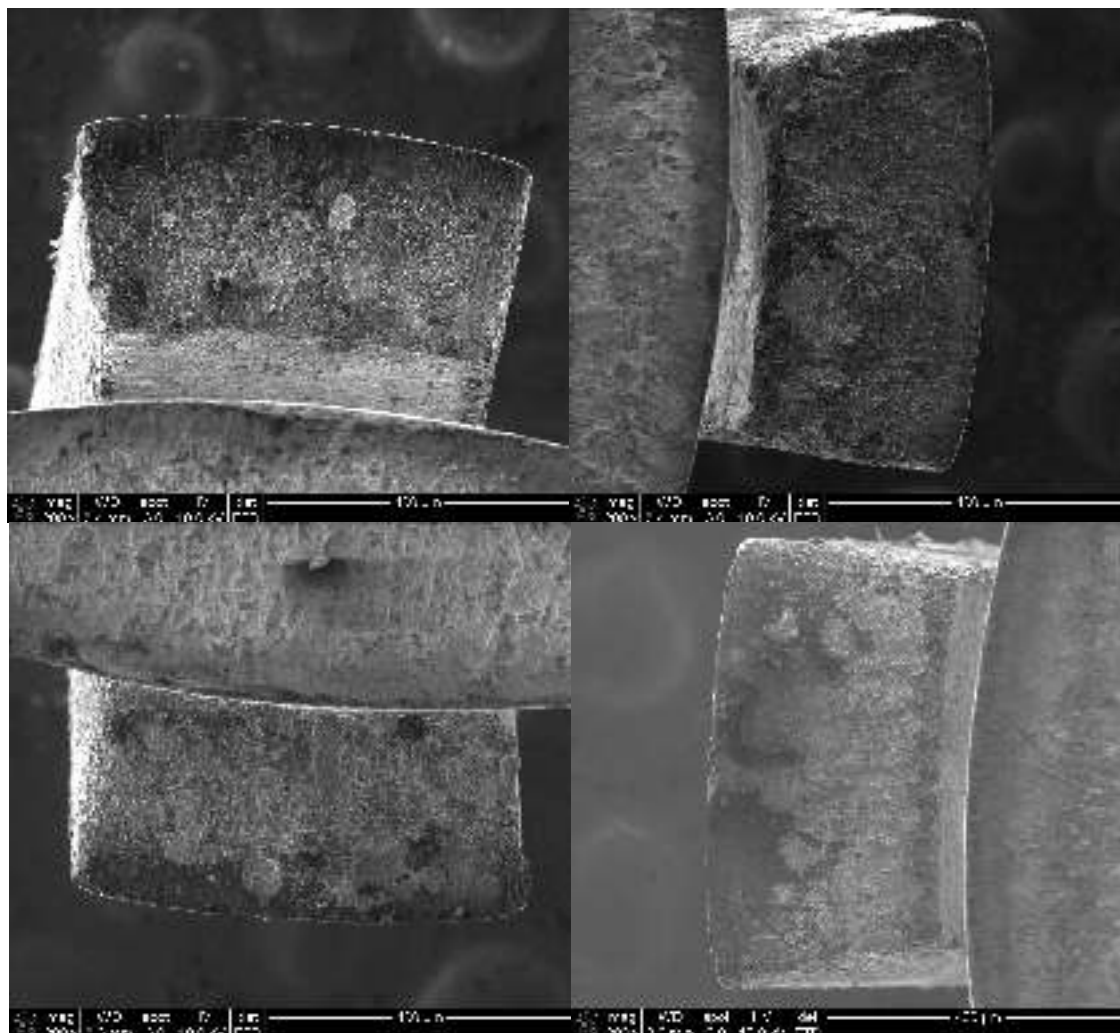


Used Smileloc #6 (02-004)

Inner Flaps

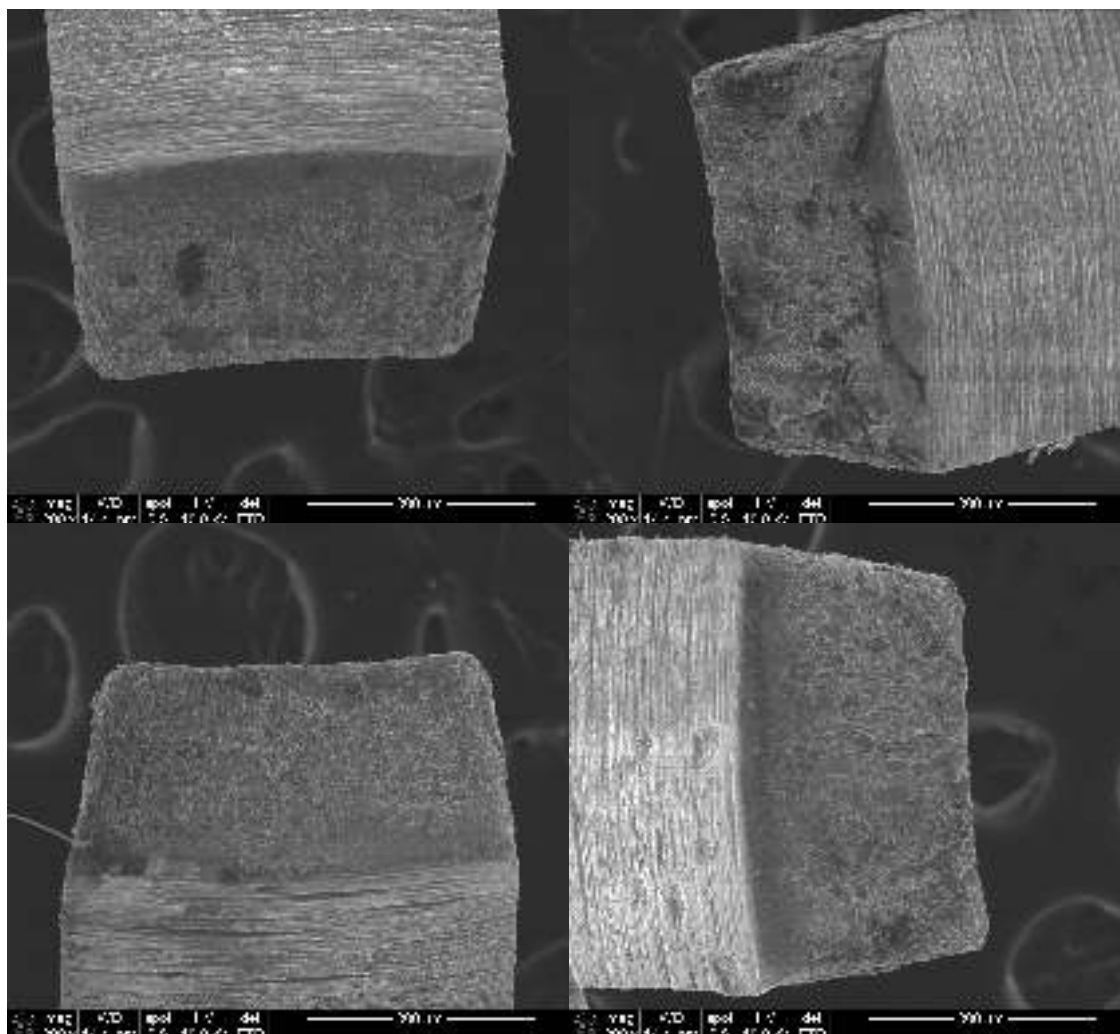


Outer Flaps

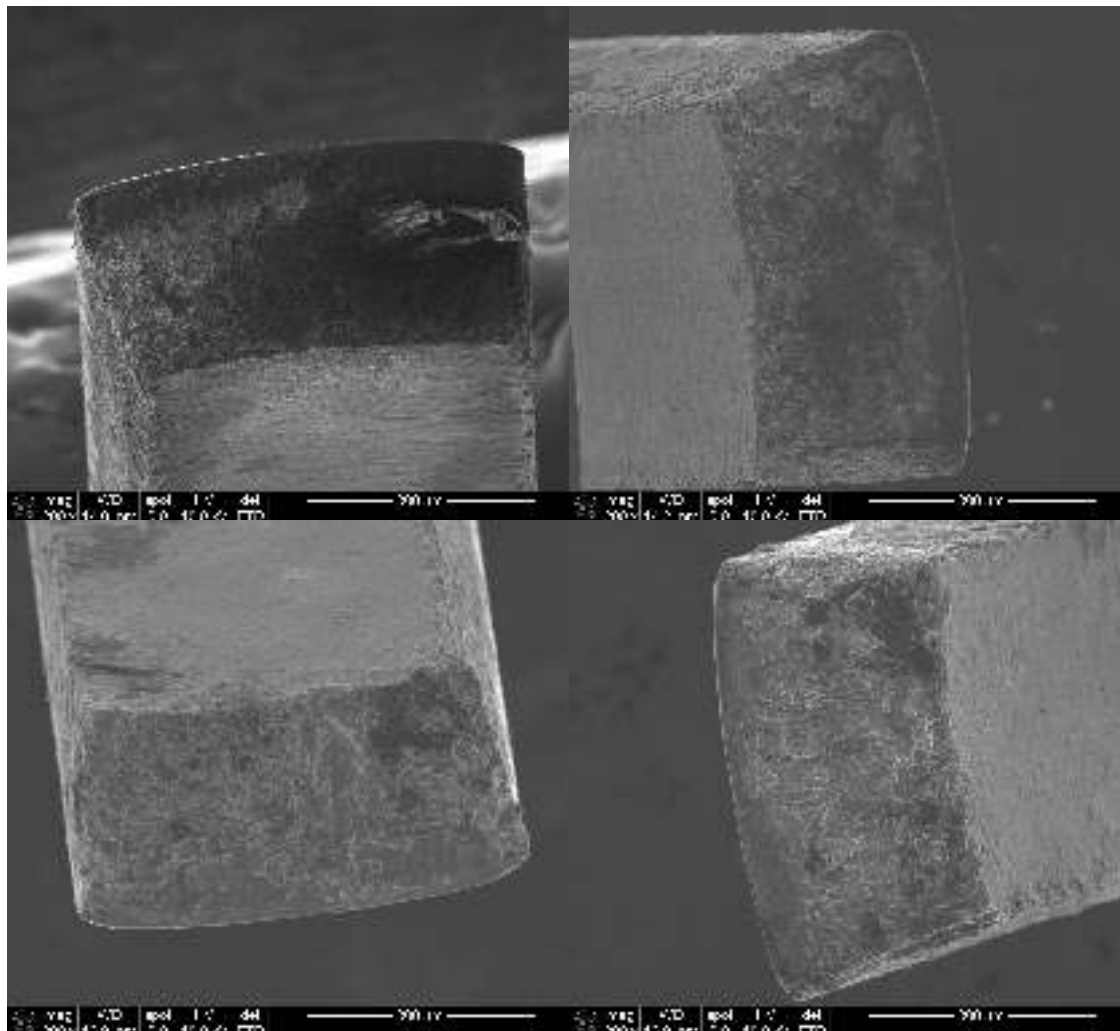


Used Smileloc #7 (02-009)

Inner Flaps

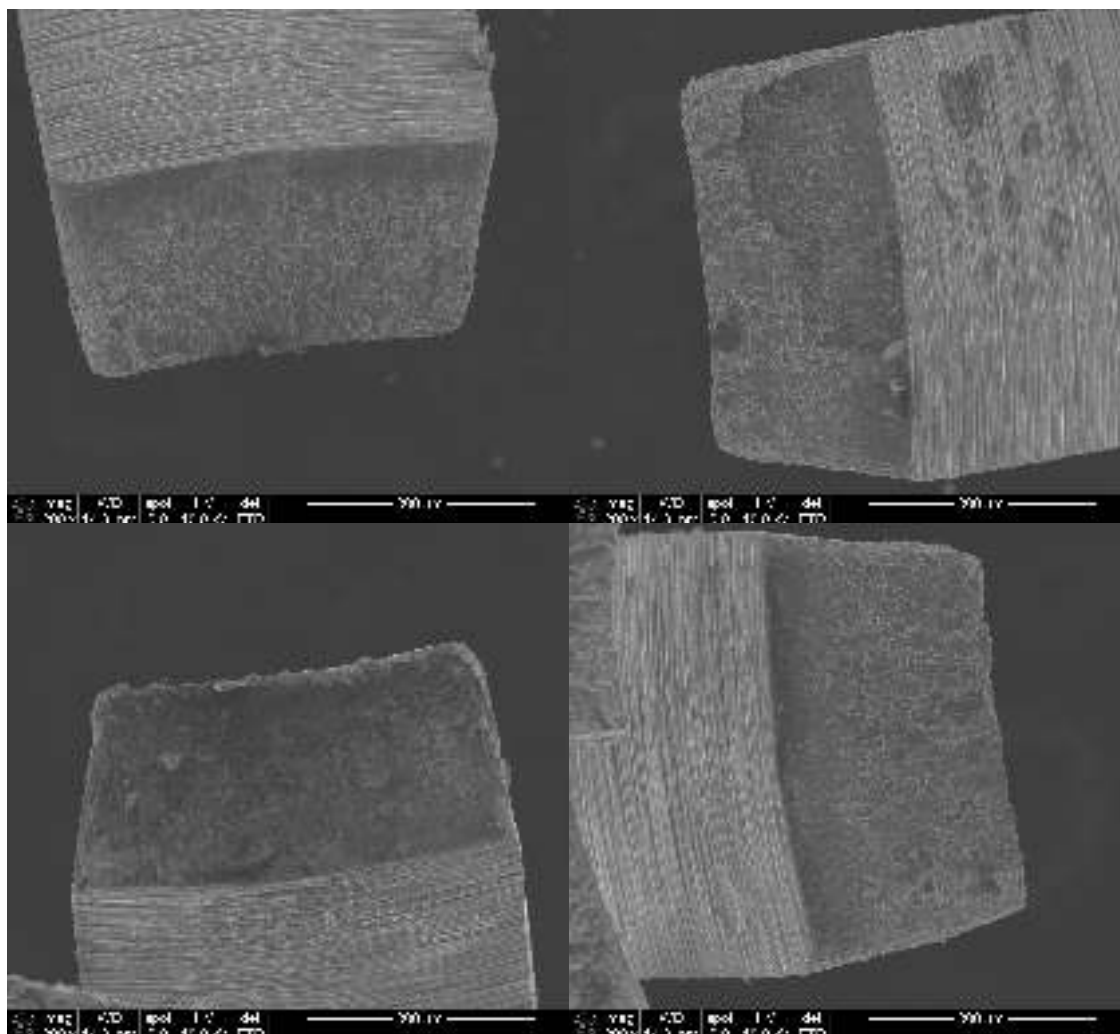


Outer Flaps

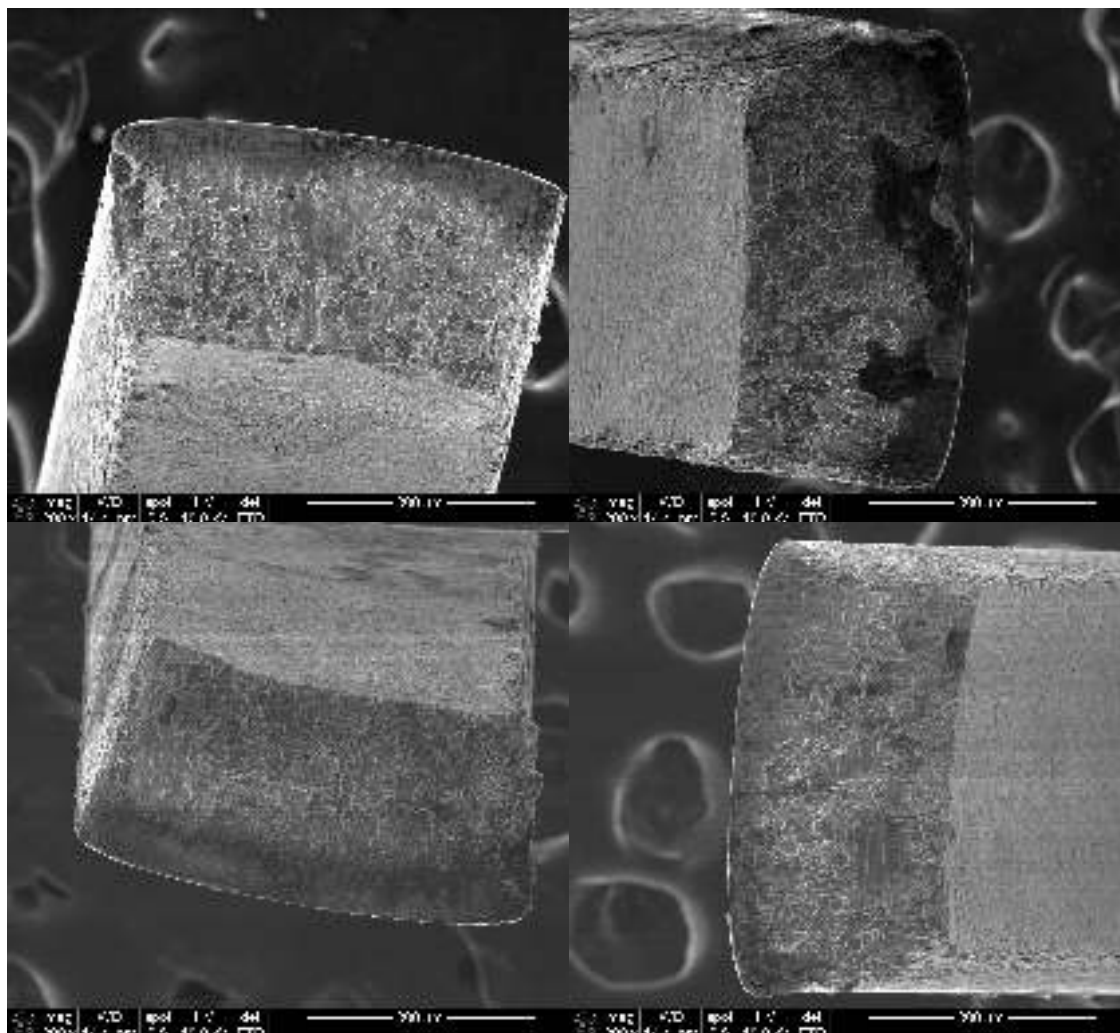


Used Smileloc #8 (02-010)

Inner Flaps

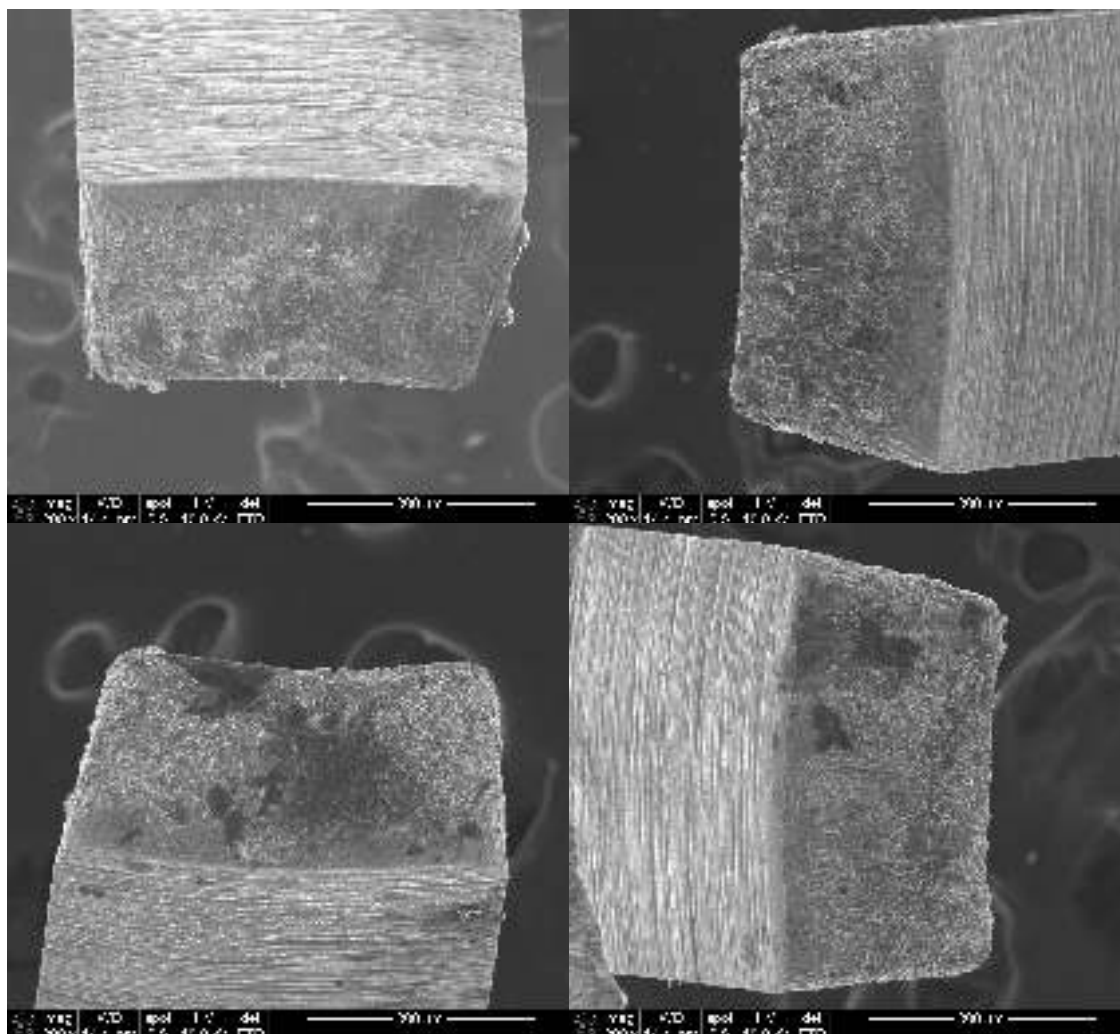


Outer Flaps

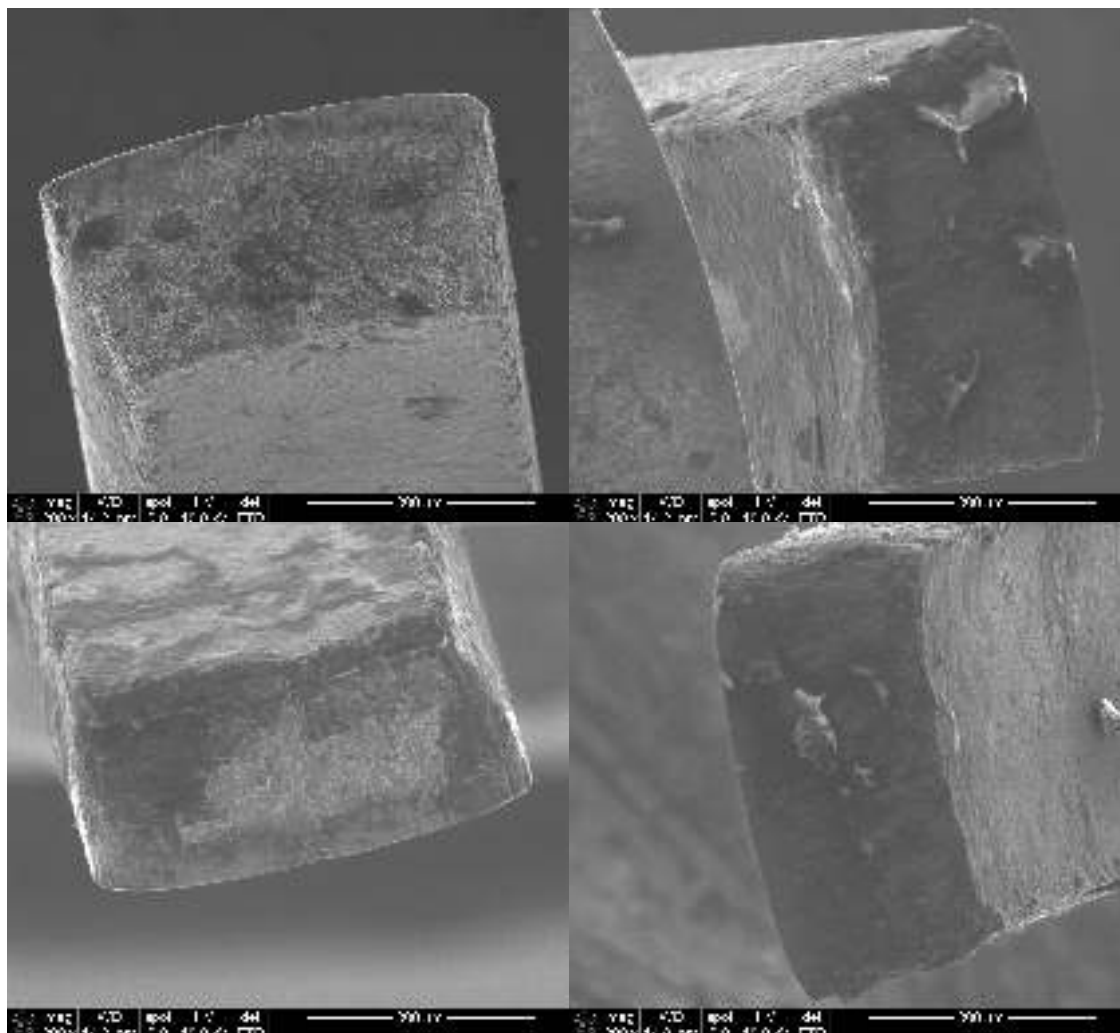


Used Smileloc #9 (02-012)

Inner Flaps

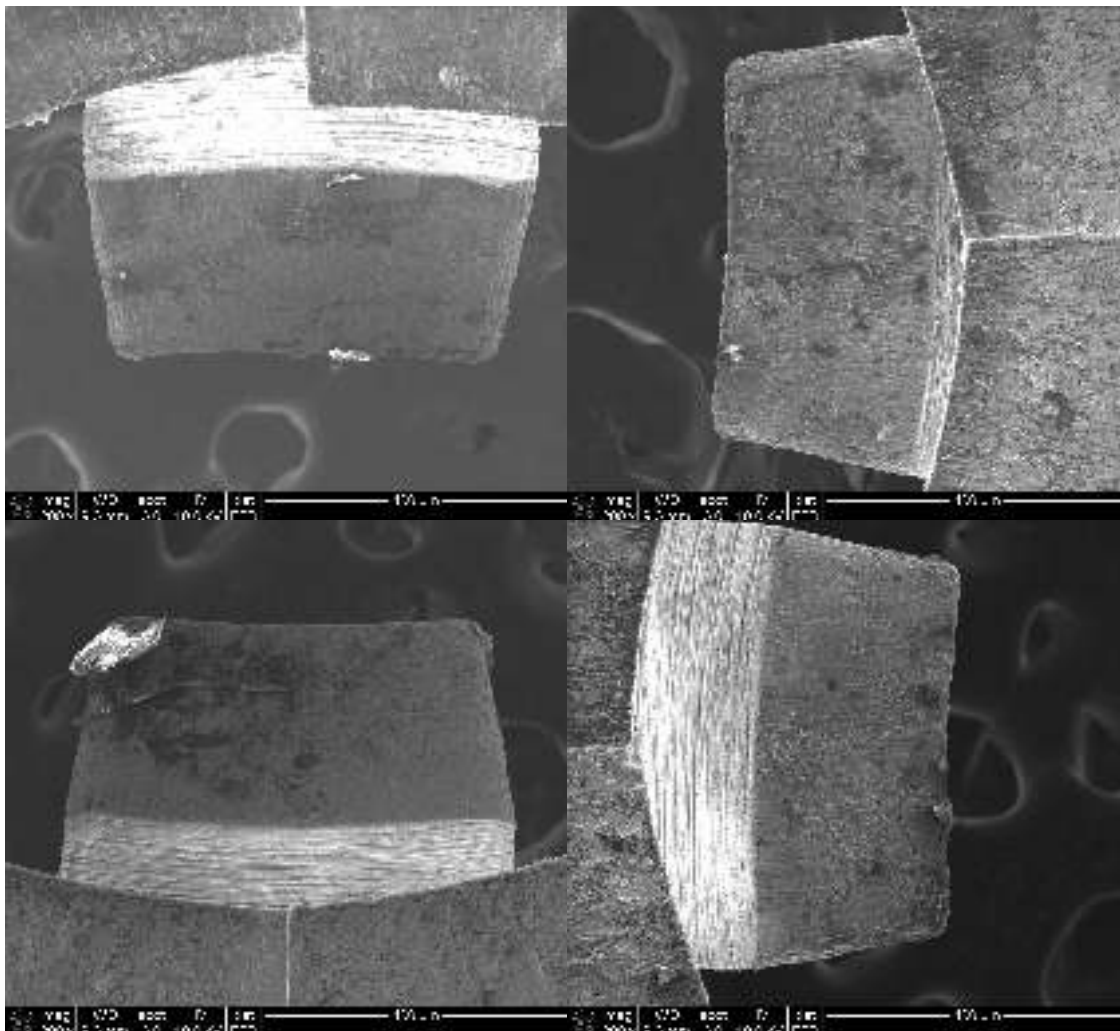


Outer Flaps



Used Smileloc #10 (02-005)

Inner Flaps



Outer Flaps

