Background

The Slide® Nylon is a Mandibular Advancement Device used in the treatment of mild to moderate sleep apnea and snoring. Only the Slide family of products places all of the adjustable components over the occlusal plane of the teeth, away from all the oral tissue. This provides maximum patient comfort and ease of adjustment. The Slide Nylon is an FDA-cleared, patent-pending device.

Executive Summary

Strength testing of the Slide Nylon was performed for retraction, compression, and lateral forces. **In all cases, the Slide Nylon stood up to the forces normally experienced in oral appliances use.** Testing in-lab proceeded until failure conditions were presented to understand the extra window of safety realized with the Slide Nylon device. What follows is a summary of the tests procedures and results.

Mandibular Retraction Force Testing

The primary force the Slide Nylon is expected to withstand in order to maintain the desired mandibular advancement is the resulting retraction force applied by the user's lower jaw. To test the component's ability to withstand these forces, the Slide Nylon rail and groove components were additively manufactured on plates in the same manner as they would be on the Slide Nylon splint; the largest spacer (8mm) was then applied to the rail. These test articles were loaded into a tensile tester, which applied a force in the direction shown below until the parts demonstrated failure.

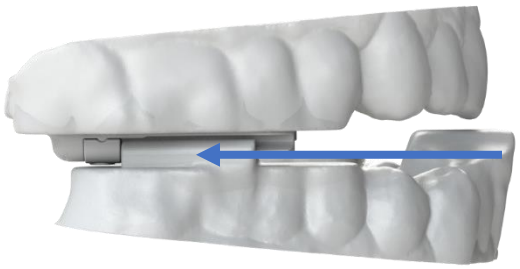

Figure 1 - Direction of mandibular retraction force experienced by the Slide Nylon.

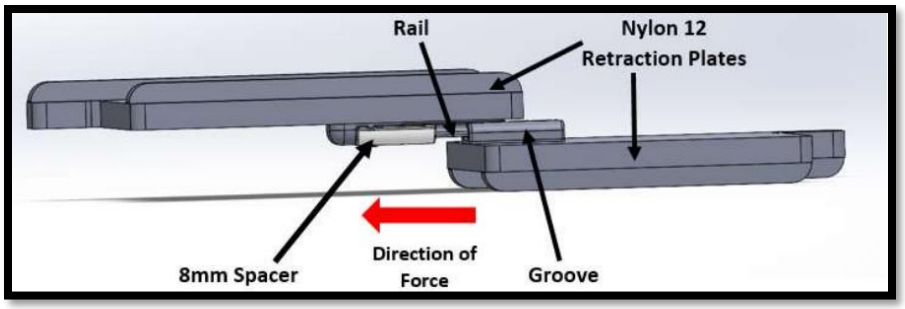

Figure 2 - Directional force applied to rail and groove components in tensile tester.

The retraction force at maximum protrusion would be expected to be in the range 15-20N. The Slide Nylon withstood forces averaging 482N before a component exhibited failure.

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Masticatory Compression Simulation and Testing

The Slide Nylon was subjected to masticatory compression forces to evaluate the performance of the occlusal components (specifically, the rail and groove parts). **The maximum masticatory force applied by humans is expected to be around 700N.** A benchtop test using a tensile tester was used and **the Slide Nylon rail and groove components was subject to forces in excess of 900N, and no component failure was observed.**

The above forces were further analyzed as part of a simulation on the individual rail and groove parts. A simulated force of 700N was applied and the von mises stress concentrations over each component were measured and recorded, as well as the deflection experienced by each component:

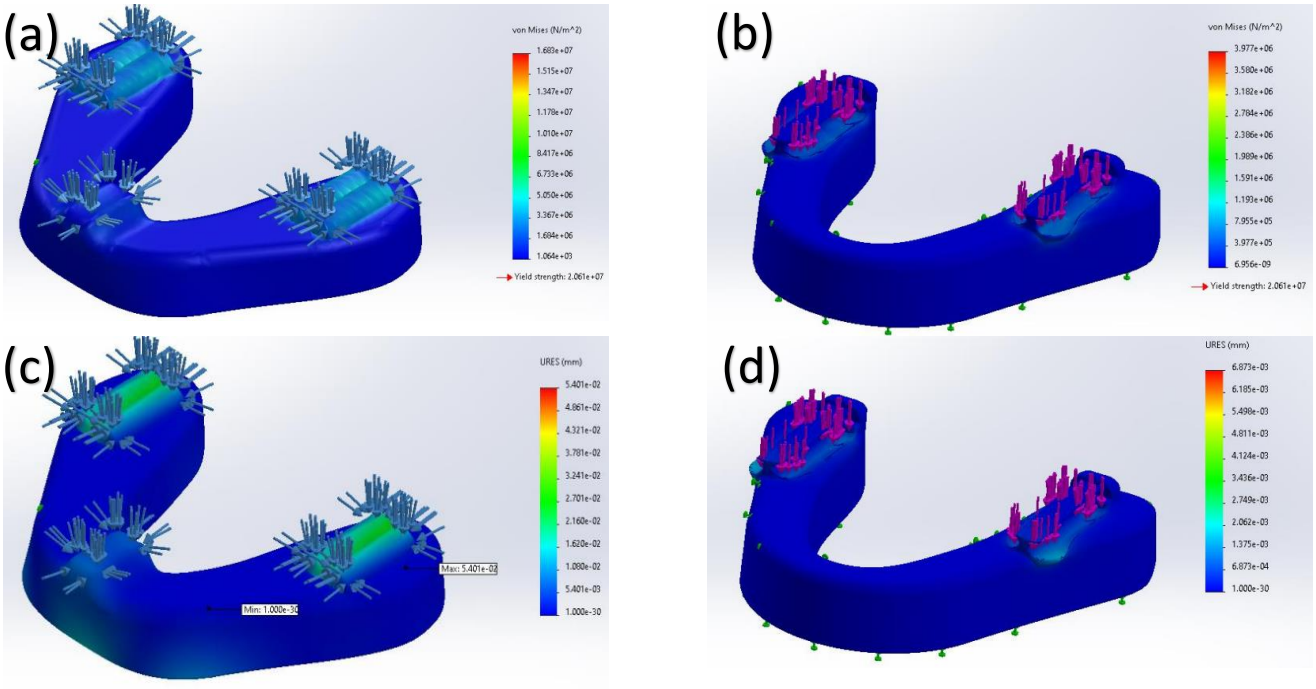

Figure 3 - The maximum von mises stress (MPa) is 16.83 for the mandible splint (a) and 3.97 for the maxilla splint (b). The maximum displacement (mm) is 0.054 for the mandible splint (c) and 0.00687 for the maxilla splint (d).

In both the rail and groove components, masticatory compression will not crush or destroy the Slide Nylon. The yield strength (stress required before permanent plastic deformation) of the material is 20.61 MPa, while the maximum stress experienced in the assembly is 16.83 MPa. When high stresses are experienced, the product will deform slightly, but the structural conditions of the product will not be compromised.

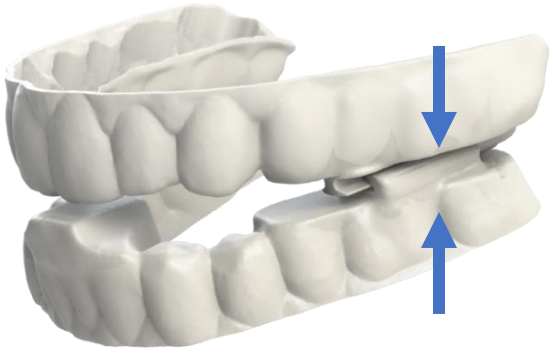

Figure 4 – Direction of masticatory compression upon the Slide Nylon.

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Bruxism (Lateral) Force Testing

Patients that have obstructive sleep apnea often suffer from bruxism as a secondary side effect. By activating the jaw muscles and grinding the teeth, oxygen is sent to the jaw muscles. When a patient has been successfully treated for their sleep apnea, their bruxism symptoms may also subside. Regardless, it is important for an oral sleep apnea appliance to be able to withstand reasonable forces expected during bruxism. Bruxism forces include both clenching/compression forces (discussed above), as well a lateral (side-to-side) forces.

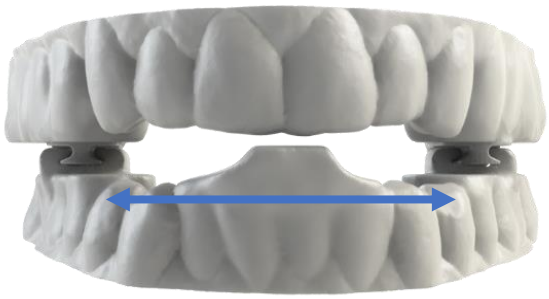

Figure 5 - Lateral movement expected with bruxism.

To test the component's ability to withstand these forces, the Slide Nylon rail and groove components were additively manufactured on plates in the same manner as they would be on the Slide Nylon splint; the largest spacer (8mm) was then applied to the rail. These test articles were loaded into a tensile tester vertically, and a force was applied pushing the rail down across the groove until the parts demonstrated failure (See Figure 6).

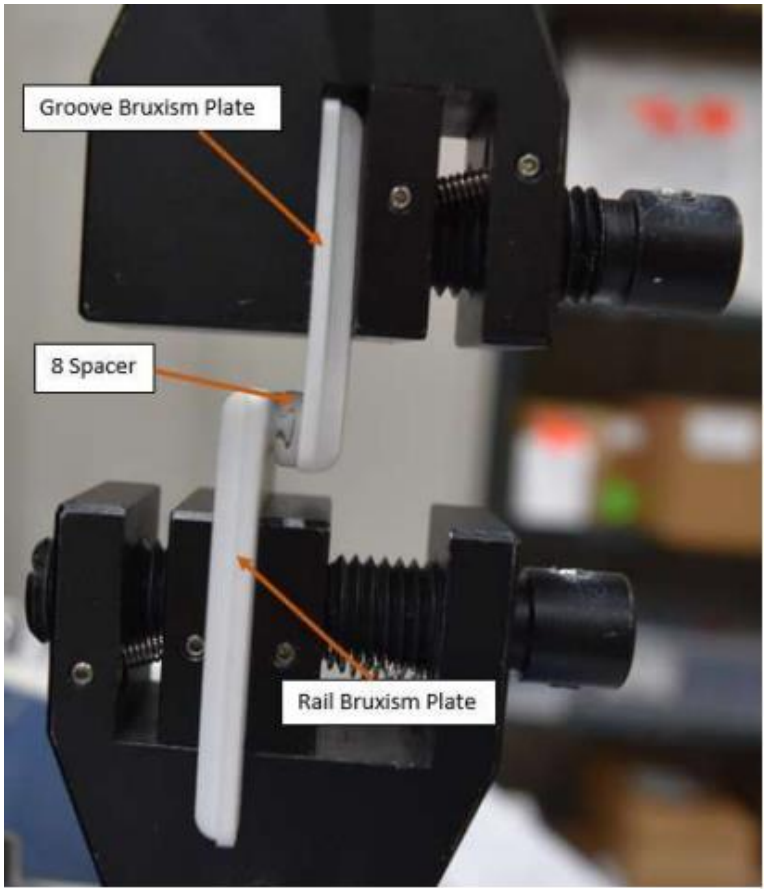

Figure 6 - Bruxism lateral force test setup.

The Slide Nylon rail/groove withstood an average of 436N in bruxism. Bruxism is a force without a well-documented lateral range for comparison. However, in addition to being able to withstand these lateral forces, the Slide Nylon is also designed with some clearance between the rail and groove components, which is intended to facilitate minor side-to-side movements before any significant force is even being translated to the components. Extremely heavy bruxers may experience a decreased device lifetime.

Closing

In-lab strength testing of the Slide Nylon demonstrated that it stood up to the retraction, compression, and lateral forces normally experienced in oral appliances.

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