

## Geometrical Facial Deformation According to Posture and Non-invasive Ventilation Mask Virtual Fit in Amyotrophic Lateral Sclerosis

### *Background*

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that eventually affects the respiratory muscles. In most cases of the slow progression of respiratory failure, noninvasive ventilation (NIV) is the first treatment option. NIV treatment provides a better quality of life and is, therefore, strongly recommended; however, its use must consider the type of ALS. Severe bulbar dysfunction limits NIV treatment. Aside from additional NIV options in ALS, including mouthpiece ventilation and intermittent abdominal pressure ventilation, prolonged use of a ready-made face mask is impractical for several reasons. Cognitive impairments can affect the maintenance of NIV. Hypersalivation and bronchial secretion disrupting ventilation can lead to poor NIV adherence. Pressure injuries are another clinical issue. The incidence of pressure injuries associated with NIV masks ranges from 10–31%. Long-term use of NIV face masks can result in pressure injuries at the contact area, and skin-protective patches may not prevent skin problems. Patients with bulbar ALS frequently have postural facial deformations, and these can lead to difficulties in wearing the NIV mask. No previous study has analyzed morphological differences in facial soft tissue according to posture in ALS.

### *Objective*

The aim of this study was to compare the deformations of the face in different postures in subjects with bulbar ALS and healthy participants. This study also virtually fitted an NIV mask to understand how the NIV mask interface affects the face in different postures.

### *Methods*

#### *Participants*

	Amyotrophic lateral sclerosis with bulbar involvement patients	Healthy participants
<b>Inclusion criteria</b>	<ul style="list-style-type: none"><li>• a patient with Amyotrophic Lateral Sclerosis, 16-60 years old</li><li>• a patient with respiratory difficulty</li><li>• a patient who requires or anticipates mechanical ventilation</li></ul>	<ul style="list-style-type: none"><li>• a volunteer without history of facial surgery or neuromuscular disease, 16-60 years old</li><li>• a volunteer without respiratory difficulty</li></ul>

	<ul style="list-style-type: none"> <li>a patient who visit out- or inpatient clinic at rehabilitation hospital</li> </ul>	
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>a patient who cannot scan due to respiratory instability</li> <li>a patient who cannot bear posture for 3D scanning</li> </ul>	<ul style="list-style-type: none"> <li>a volunteer with neuromuscular disease</li> <li>a volunteer with history of facial surgery or palsy</li> </ul>

### *Interventions*

The face is scanned with 5-camera unit 3D scanning system (3dMD, Atlanta, Georgia) in the sitting, supine, and lateral decubitus positions. Ten anatomical landmarks are located in the nasal root area for 4 points (sellion, glabella, left dacryon, and right dacryon) and in the oral area for 6 points (subnasale, SN; labial superius, LS; labial inferius, LI; cheilion left, CL; cheilion right, CR; and promentale, PM) where major skin deformations occur. Each subject should keep their mouth closed naturally during scanning. The amounts of change of a landmark position in the anteroposterior or lateral direction according to the posture change (from sitting to supine; from sitting to lateral decubitus) are measured.

### *Outcome measurements and statistical analysis*

Primary outcome measure: The change in position of anatomical landmarks

Change is reported as the mean displacement (mm) during the change in position from the initial position (sitting) to the subsequent position (supine & side-lying). The extent of facial landmark changes in different postures indicative of facial deformation in healthy subjects and subjects with bulbar ALS will be compared. A repeated-measures analysis of variance will be performed at a  $\alpha$  0.05 to assess the effectiveness of the group and posture. The Tukey-Kramer method will be used as a post hoc analysis for multiple comparisons of means at a  $\alpha$  0.05. All analyses will be performed using Minitab v.19 (Minitab, State College, Pennsylvania).