

Respiratory outcome after one-year treatment of obstructive sleep apnea with bibloc versus monobloc oral appliances: a multicenter, randomized equivalence trial

Åke Tegelberg¹, Eva Nohlert², Svenska Tandläkare-Sällskapet³, Anette Fransson⁴, Göran Isacsson⁵

Addresses:

¹ Department of orofacial pain and jaw function, Malmö University, Malmö, Sweden

² Centre for Clinical Research, Uppsala University, Västerås, Sweden

³ Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden

⁴ Postgraduate Dental Education Center and Faculty of medicine and health, Örebro University, Örebro, Sweden

⁵ Department of Orofacial pain and jaw function, Västmanland County Hospital Västerås, Sweden

Background: The benefit of bibloc over monobloc appliances in one-year obstructive sleep apnea (OSA) has not been evaluated in randomized trials. We hypothesized that these types of appliances are equally effective.

Methods: In this multicenter, randomized equivalence trial patients with OSA were assigned to either bibloc or monobloc appliance treatment. At baseline a one-night home respiratory polygraphy was done without respiratory support, and at one-year follow-up examination iterated with the appliance in place. The outcome was the change in the apnea-hypopnea-index (AHI) and the equivalence limits were set at ± 5 .

Results: Out of 302 patients 146 were randomly assigned to bibloc and 156 to monobloc. In 88 and 104 patients, respectively, were analysed per-protocol with a significant reduction of AHI with a mean change -16.7 (95% CI -19.4 to -14.1) in the bibloc and -11.8 (-14.9 to -8.7) in the monobloc and not significantly equivalent. The proportion of responders defined as AHI <10 at the follow-up was 68% and 65% for bibloc and monobloc, respectively.

Treatment related adverse events were generally mild and transient and occurred similar in frequencies between groups.

Conclusions: Bibloc and monobloc appliance treatment gave a significant positive effect in treating OSA. The treatment modalities were not statistically equivalent, with a numerically greater reduction with bibloc, and, were associated with a similar degree of adverse events.