



探討配戴新型下頷前移裝置 對患者呼吸中止症及睡眠品質之成效

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摘要

阻塞型睡眠呼吸中止症 (obstructive sleep apnea, OSA) 是一種高盛行率的睡眠相關呼吸障礙，其特徵為睡眠期間上呼吸道反覆塌陷，導致間歇性低血氧、睡眠片段化，並增加心血管與代謝相關風險。持續正壓呼吸器 (continuous positive airway pressure, CPAP) 雖被視為黃金標準治療，但其臨床療效常受限於患者耐受性及長期依從性不足。下頷前移裝置 (mandibular advancement device, MAD) 為一種客製化口腔內裝置，能於睡眠中前移並穩定下頷，已被國際臨床指引建議作為無法耐受或拒絕使用 CPAP 成人患者的替代療法。文獻顯示，MAD 對於輕至中度 OSA 患者能顯著降低呼吸中止低通氣指數 (apnea-hypopnea index, AHI)、減輕鼾聲強度、改善日間嗜睡，並提升健康相關生活品質。雖然 CPAP 在控制 AHI 的單夜效果上更為優越，但 MAD 具有較佳的長期依從性，因此在血壓調控及部分心血管預後方面展現不劣於 CPAP 的臨床效果。綜合而言，MAD 為一種極具可行性及以病人為中心的 OSA 治療選項。

研究目的與方法

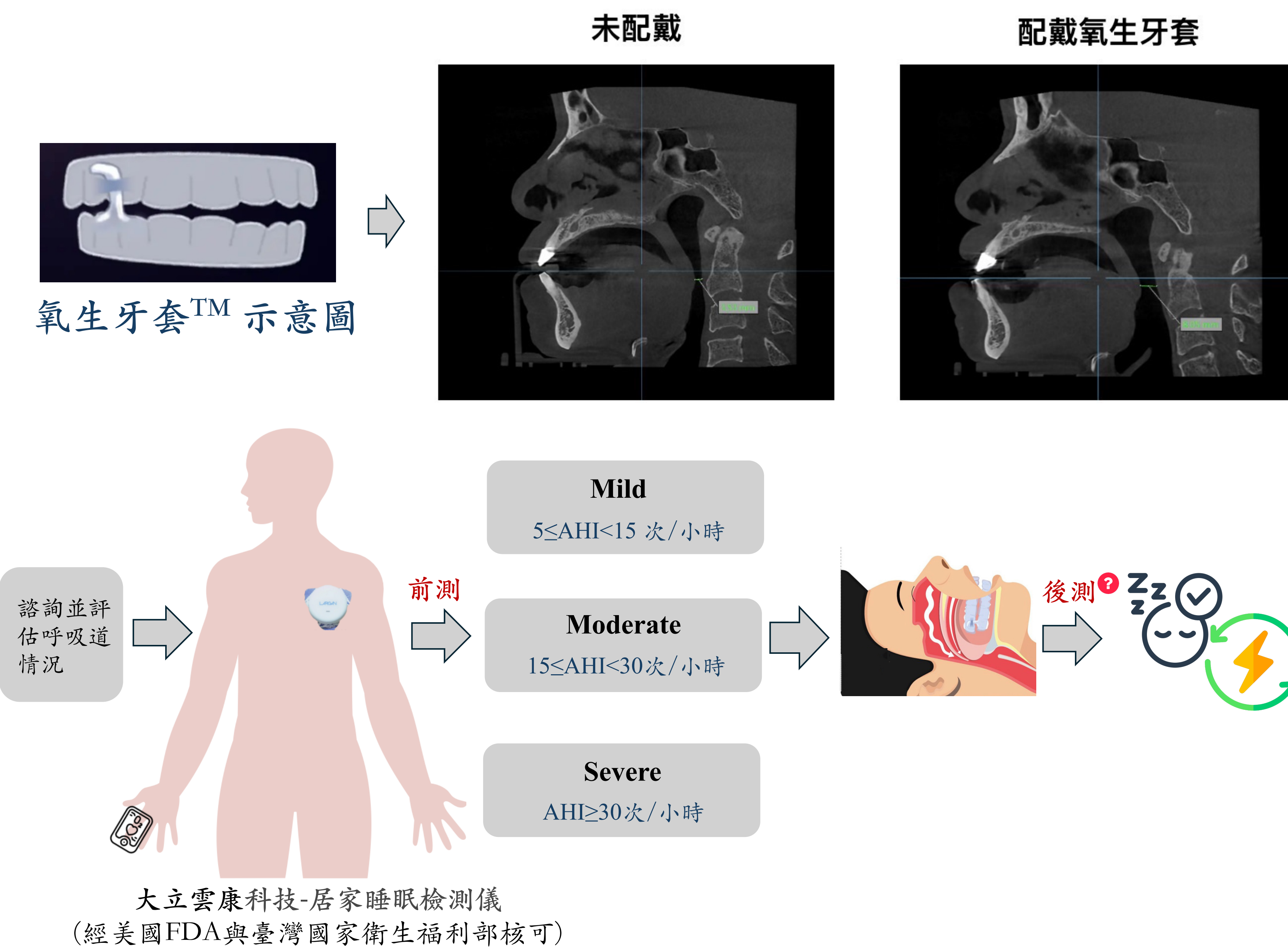


Figure 1. Conceptual Framework

假說一：配戴氧生牙套™ 後，可有效預防呼吸道塌陷，進而降低呼吸中止症生成機率。
假說二：氧生牙套™ 運用獨特的設計，相對現有 MAD 及 CPAP 更輕薄短小，病患依從性佳。

結果I -睡眠呼吸紊亂指數

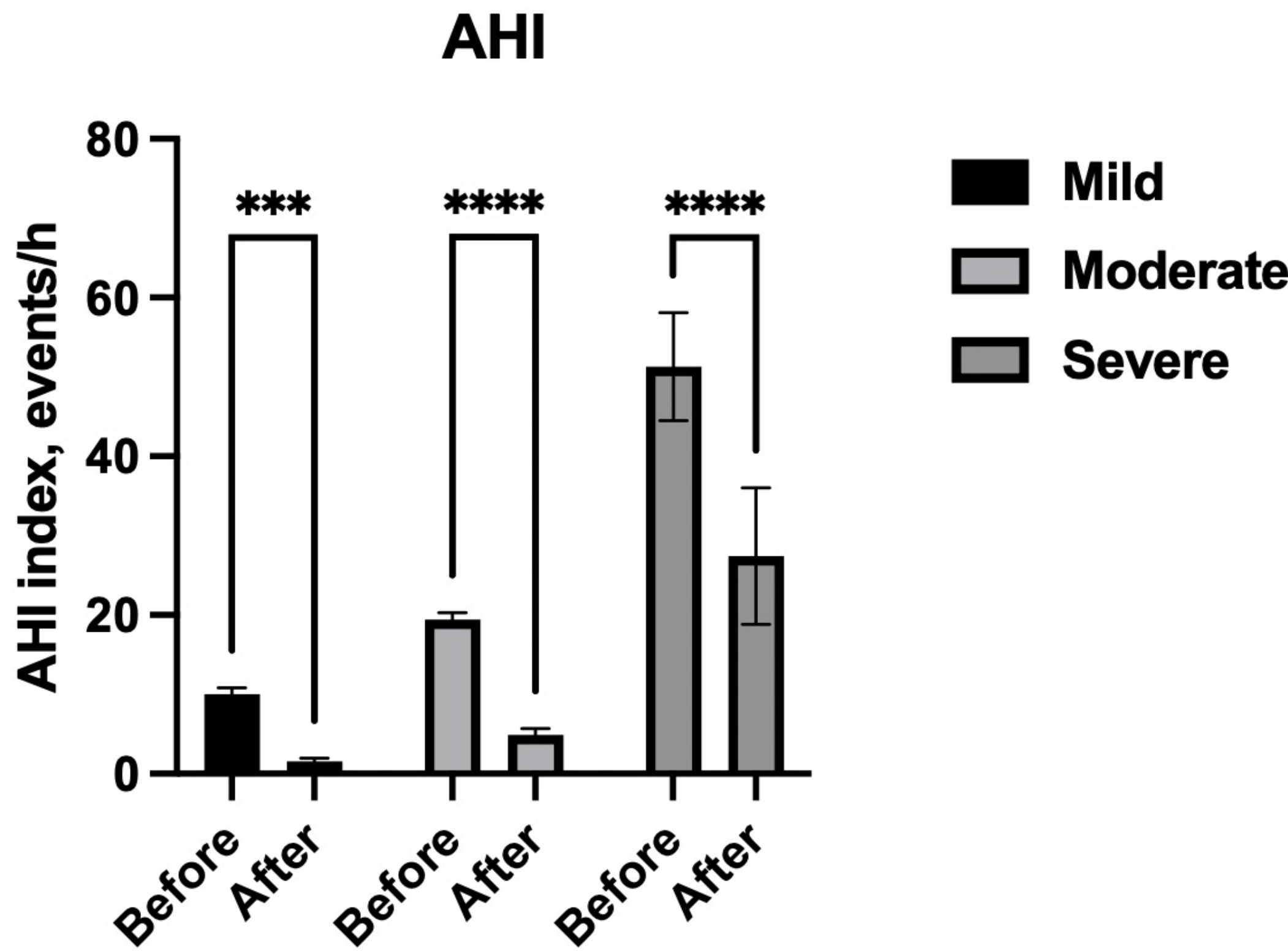


Figure 2. Effects of novel mandibular advancement device on Apnea-Hypopnea Index in sleep apnea patients. Values are presented as mean $\pm$ SEM (mild n=16, moderate n=13, severe n=13). AHI significantly decreased across all severity groups (paired t-test: ***p < 0.001 for all; confirmed with Wilcoxon signed-rank tests). Based on clinical criteria (treatment success defined as AHI < 10 events/hr or $\geq$ 50% reduction from baseline), a substantial proportion of moderate and severe patients achieved effective control.

結果II -血氧飽和度分析

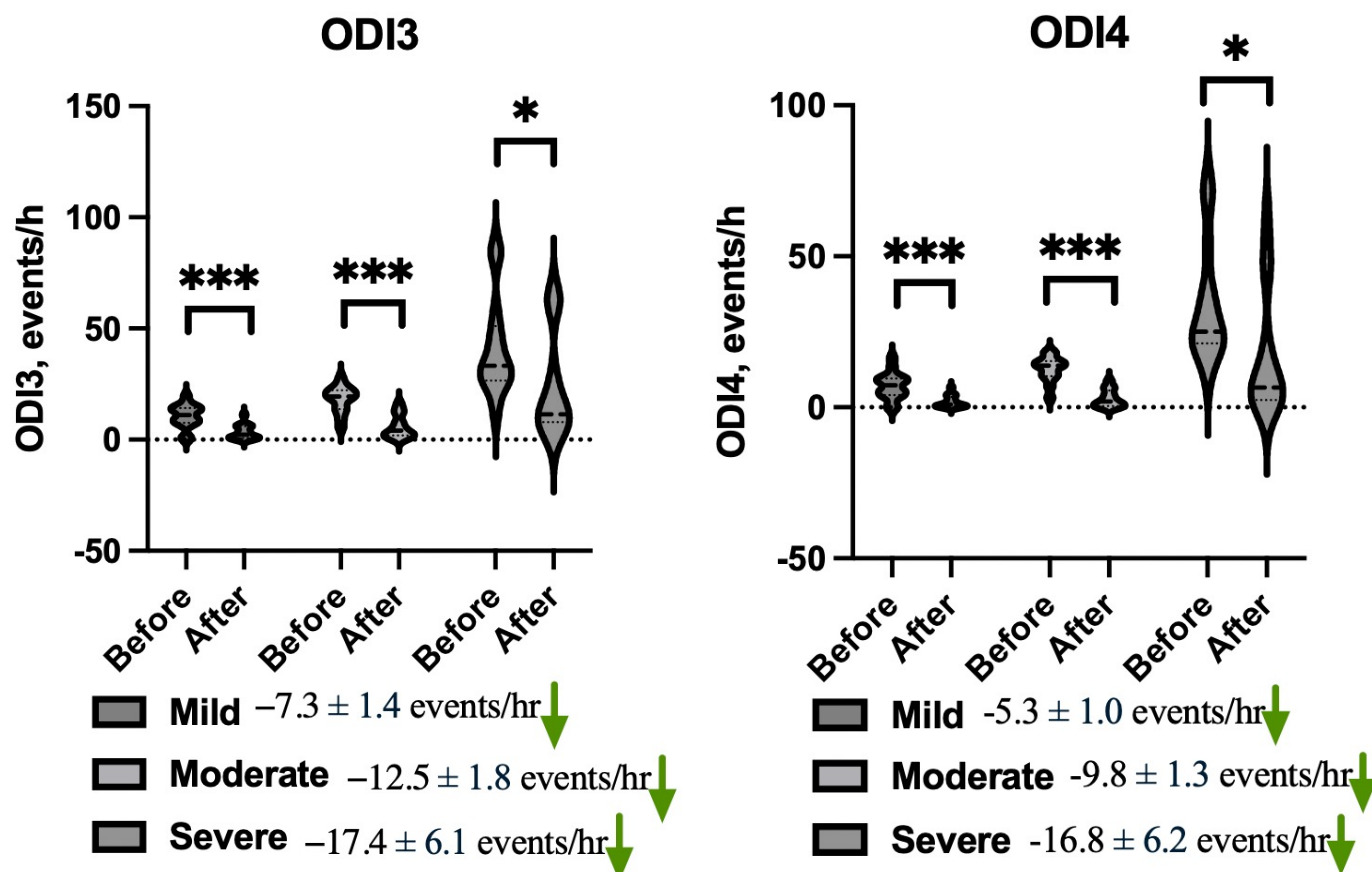


Figure 3. Effects of a novel mandibular advancement device on ODI3 and ODI4 in obstructive sleep apnea patients. Values are presented as mean $\pm$ SEM (mild n=16, moderate n=13, severe n=13). ODI3 and ODI4 significantly decreased across all groups (Mild ***p<0.001; Moderate **p<0.001; Severe *p<0.05). Statistical comparisons were performed using paired t-tests and confirmed with Wilcoxon signed-rank tests. Based on clinical criteria (ODI <10/hr or $\geq$ 50% reduction), a substantial proportion of moderate-to-severe patients achieved treatment success.

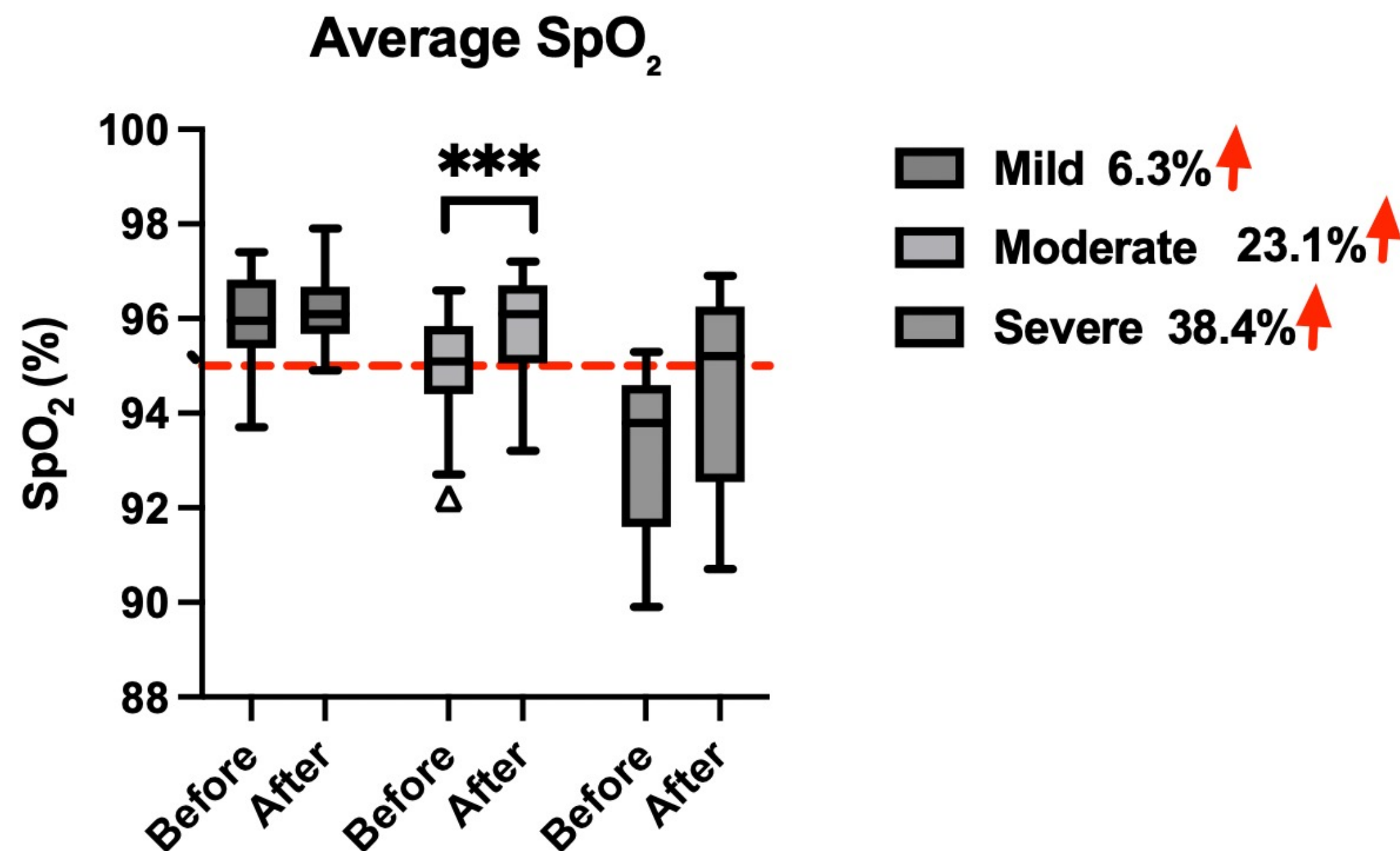


Figure 4. Effects of novel mandibular advancement device on the average blood oxygen saturation in obstructive sleep apnea patients. Values are presented as mean $\pm$ SEM, ***p < 0.001 compared with baseline. Paired t-test within each severity group (mild n=16, moderate n=13, severe n=13). Treatment success was further defined as achieving SpO₂ $\geq$ 95%, and responder rates before and after intervention were compared using McNemar's test.

結果III - 配戴率及依從性調查

Group	Compliant(%)	Non-compliant(%)	Other(%)
Mild	72.2%	16.7%	11.1%
Moderate	75%	16.7%	8.3%
Severe	86.7%	13.3%	-

Figure 5. Compliance with novel mandibular advancement device therapy among patients with obstructive sleep apnea after 6 months of wearing. Values are presented as percentages within each severity group.

結論

研究初步結果顯示，本實驗研發之創新下頷前移裝置能應用於不同嚴重度的阻塞型睡眠呼吸中止症患者中顯著改善呼吸中止指數，而血氧相關指標再配戴後均有往正向移動的趨勢。且受試者整體依從性佳，僅觀察到輕微且可管理之咬合與牙齒變化，顯示其短期安全性可被接受。此結果支持客製化 MAD 作為 CPAP 之外的臨床可行治療選項，特別適用於無法耐受或偏好替代方案之患者。同時，本研究突顯牙科專業於睡眠呼吸中止症中的潛在貢獻。未來仍需更大規模樣本與長期追蹤，以驗證其療效穩定性與長期安全性，並探討其不同臨床族群中的適用性。