Communication

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A New Lighting System for Surgical Vision Optimization in Barbed Pharyngoplasty for OSA

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Abstract: Obstructive Sleep Apnea (OSA) surgery is now a viable solution in selected patients and the "remodelling" palatopharyngeal surgery is the most common one. Recently it becomes less invasive with the introduction of Barbed Sutures (BS). An optimization of surgical technique is represented by Barbed pharyngoplasty (BP), that requires surgical precision and needs efficient and precise oropharyngeal visualization. Consequently, the lighting system is of pivotal importance in BP. The aim of this work is to describe the first experience on the use of a new lighting system, called Klaro™ in BP for OSA. We evaluated the Klaro™ system in 15 consecutives BP for OSA in comparison with conventional headlamp illumination. The visualization of palatopharyngeal muscle in the bottom of the tonsillar fossa, entry and exit needle, such as needle tip were statistically better with Klaro™ than headlamp illumination both for surgeon and resident ($p<0.05$). No significant differences for the visualization of the posterior pharyngeal wall and uvula were reported. The Klaro™ lighting system allows a satisfied illumination of oral cavity and oropharynx in the majority of cases. We encourage to use of Klaro™ not only in BP for OSA, but also in all oral and pharyngeal surgeries, including tonsillectomy and oncological surgery.

Keywords: barbed pharyngoplasty; lighting system; surgical vision; oral cavity: klaro

1. Introduction

Obstructive Sleep Apnea (OSA) is a growing health concern involving about one billion people worldwide; it is characterized by episodes of vibration and collapse of upper airways during sleep resulting in noise production (snoring), airflow decreasing (hypopnea) or cessation (apnea), oxygen desaturations, fragmentation of sleep, daytime sleepiness [1]. The first-line treatments that are frequently employed in moderate and severe OSA are continuous positive airway pressure (CPAP) and/or mandibular advancement device (MAD) [2,3]; however failure in long-term adherence to both treatments was reported in 25–50% of cases [4].These factors led to significant advances in OSA and snoring surgery management over the past few years. In patients who do not tolerate or do not have good results with first lines treatments, OSA surgery is now a viable solution, thanks to newer, less invasive, or morbid treatments that also increase patient compliance [5]. Among the surgical

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procedures for OSA treatment, palatopharyngeal surgery is one the most common performed [6]. To preserve pharyngeal function and improve breathing space, oropharyngeal surgery for OSA has progressed from a significant removal of "redundant" soft tissue (resection techniques) to less invasive reconstruction techniques.

To reduce surgical procedures' invasiveness and increase oropharyngeal stiffness in the last years Vicini et al. [7] made popular a new suturing technique known as Barbed sutures Pharyngoplasty (BP), which allows a knot-free tissue closure and an uniform distribution of tensile closure force [8].

BP requires more surgical precision from the surgeon, following precise vectors in a submucosal plane during the procedure [9].

Generally, the surgeon illuminates the operating field with his conventional headlight (photophore), but often this is not enough to achieve an optimal and uniform illumination of the entire surgical area. In addition, due to the depth of the oral cavity and often the narrow mouth of patients, it is difficult for trainees to correctly view all the steps of surgical procedures performed by the first surgeon.

In transoral surgical procedures the surgeon is often forced to assume uncomfortable positions for a long time [10], with difficult exposure of the operating field and poor sharing of the procedure with assistants and trainees [11].

A new device called Klaro™ (Figure 1) has been recently introduced to the market for the illumination of anatomical cavities during surgical operations. The Klaro™ (Vivo Surgical Private Limited, Singapore) is a sterile and disposable surgical lighting device for deep cavities.

This work aims to describe our experience using Klaro™ as an additional illumination tool, especially in BP for OSA, to facilitate surgeon's work and residents' learning curve.

Figure 1. Klaro™ device.

2. Materials and Methods

2.1. Patients' selection

We used the Klaro™ device in 15 consecutives patients (13 males, 2 females; median age 49,1±9,87 years old) affected by moderate-severe obstructive OSA, who underwent BP at the Unit of Integrated Therapies in Otolaryngology at Campus Bio-Medico University Hospital Foundation from January to May 2022.

The inclusion criteria were OSA patients older than 18 years old, with a confirmed circular palatal collapse at drug-induced sleep endoscopy assessment, who refused or did not tolerate nasal CPAP therapy as first-line treatment. Furthermore, all the patients enrolled in the study showed good nasal patency, small tonsils (tonsil size 1 and 2 according to Friedman Staging System), BMI less than 30 kg/m2, and ASA < 2. Patients with age more than 70-year-old, with severe medical comorbidities, Mallampati grade IV were excluded from the study.

2.2. Surgical Procedure

The surgical technique used was Alianza Barbed Pharyngoplasty. It is performed under general anesthesia with orotracheal intubation; the patient is placed in supine position, and a Boyle-Davis mouth gag is used to expose the oropharynx.

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It uses barbed absorbable sutures that allow suspending palato-pharyngeal structures to anatomical non-collapsible landmarks (posterior nasal spine, pterigoideal hamulus, pterigomandibular raphe) [12].

We used two interlaced unidirectional barbed threads (Medtronic V-Loc™ 180, size 2–0 or 3–0, length 30 cm, mounted on taper-pointed 26-mm semicircular needle, absorption in 180 days, tensile strength 65% at 21 days) to obtain a bidirectional suture: each needle is passed in the looped-end of the other suture, then gentle traction is applied to tighten a "flat knot."

To prevent the two looped ends left protruding in the oral cavity a tiny (3 mm) incision in the mucosa over the Posterior Nasal Spine (PNS) is made sink them in.(8)

2.3. The illumination device

The Klaro™ consists of a flexible high-intensity LEDs bar that can be bent by the user so that it conforms to the shape of the retractor blade to provide optimum stability during the procedure.

It is powered by a battery pack that can be attached to the surgical drapes and guarantees autonomy of 4 hours. The Klaro™ is characterized by four lighting intensity adjustable levels, wide-angle lighting (from 155° when it is unbent to 340° when bent), and it maintains a safe working temperature under 38°C throughout the 4 hours of use. The Klaro™ is registered and approved in several international territories, including the US FDA, European Union's (EU) CE Mark, and Singapore's Health Science Authority (HSA).

2.4. Mounting the Klaro™ device on tongue retractor

The device is provided with 4 Retractor Loops and 2 Mini Retractor Loops that enable the user to fasten the Klaro™ LED strip easily and quickly onto most surgical retractors in the market (Figure 2).

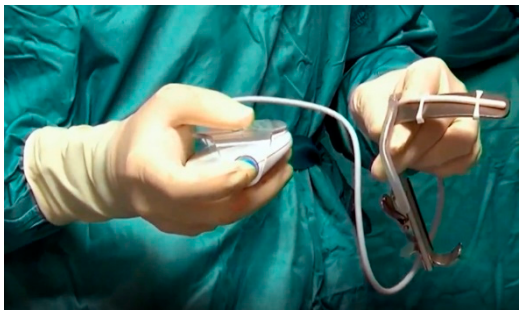

Figure 2. KLARO™ device applied on the tongue retractor.

2.5. Study Design

On each patient, the procedure was performed by an expert surgeon: on one half of the palate with the headlamp and the other half with Klaro™ illumination system; the residents attended the surgical procedures, which were filmed with a 70° rigid endoscope and transmitted on the screen (Figure 3A,B).

For the illumination system evaluation, we asked both the first surgeon and residents about the quality of vision of critical structures (Uvula, Posterior Pharyngeal Wall, Palatopharyngeus muscle, penetration and exit point of the needle, and Needle tip), grading it with a score from 1 to 3 (1 = poor vision, 2 = moderate vision, 3 = good vision).

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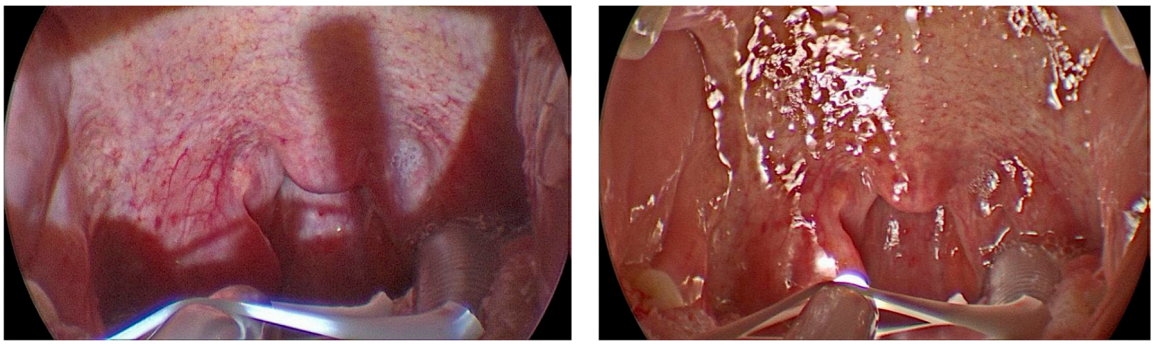

(**a**) (**b**)

Figure 3. (**a**) Oropharynx lighting with headlamp; (**b**) Oropharynx lighting with KLARO™.

2.6. Statistical analysis

The comparison between Klaro™ and headlamp was made using a Wilcoxon's signed rank sum test. Statistical significance was set at a p-value < 0.05, and the data were analysed using R version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Intraoperative quality of visualization of anatomical structures according to the surgeon: headlamp vs Klaro™

The quality of visualization was statistically significantly better with Klaro™ versus Headlamp identifying the palatopharyngeal muscle fibers at the bottom of the tonsillar fossa, allowing to perform delicate manoeuvres such as entry and exit with the needle at the same point. No significant differences were reported for the visualization of the posterior pharyngeal wall and uvula (Table 1).

Table 1. Intraoperative quality of visualization of anatomical structures according to the surgeon: headlamp vs Klaro™.

	HEADLAMP (n°15)			**KLARO™ (n°15)**			**p-value**
	Good	*Moderate*	*Poor*	*Good*	*Moderate*	*Poor*	
Uvula	10	5	0	13	2	0	0.08
Posterior Pharyngeal Wall	9	6	0	11	4	0	0.16
Palatopharyngeus muscle	6	4	5	8	4	3	0.04
In and exit point	6	7	2	9	5	1	0.04
Needle tip	7	5	3	10	4	1	0.02

3.2. Intraoperative quality of visualization of anatomical structures according to the residents: headlamp vs Klaro™

The quality of visualization on the screen was statistically significantly better with Klaro™ versus Headlamp to identify the fibres of the palatopharyngeal muscle and to recognize the entrance and exit point of the sutures and the needle tip (Table 2). The uniformity of vision and the absence of shadows on the screen during the use of Klaro™ made the image more uniform and enjoyable (Fig 3 A,B). Also, the residents did not report significant differences for the visualization of posterior pharyngeal wall and uvula.

Table 2. Intraoperative quality of visualization of anatomical structures according to the surgeon: headlamp vs Klaro™.

	HEADLAMP (n°15)			KLARO™ (n°15)			p-value
	Good	*Moderate*	*Poor*	*Good*	*Moderate*	*Poor*	
Uvula	8	5	2	9	5	1	0.16
Posterior Pharyngeal Wall	9	5	1	11	3	1	0.16
Palatopharyngeus muscle	3	8	4	5	9	2	0.04
In and exit point	6	6	3	8	6	1	0.04
Needle tip	5	7	3	8	6	1	0.02

4. Conclusions

The KLARO™ lighting system is a good and comfortable illumination device for oropharyngeal surgery that improves the surgeon's ergonomics, providing a better visualization for observers learning of surgical procedures; the uniform illumination device allows to identify the anatomical landmarks performing barbed pharyngoplasty accurately.

The KLARO™ lighting system is easily adaptable to the retractors thanks to its flexibility and adequate hooking systems, even if sometimes, especially in patients with Mallampati IV and/or reduced mouth opening can be cumbersome. Our experience with KLARO™ is focused on barbed pharyngoplasty for OSA, but we encourage to use of Klaro™ in all oral and pharyngeal surgeries, including tonsillectomy and oncological surgery.

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Conflicts of Interest: The authors declare no conflict of interest

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