

A Multi-Center Preference study of a Novel Oral Appliance Design and Material for Better Provider, Physician, Patient and Payer Acceptance

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Introduction

It has been said that PAP therapy is nearly 100% efficacious but chases adherence. The latest generation of CAD CAM oral appliances to the contrary, has excellent compliance and chases efficacy. The third recommendation of the AASM/AADSM joint guidelines recommends physicians prescribe OAT for patients who prefer it (mild and moderate OSA diagnosis or failed PAP therapy). Thus, it is essential for providers to select a device that patients prefer over CPAP and satisfies important clinical performance factors such as acceptable efficacy, precision, strength, size, ease of delivery and cleanability. In this way, all four of the major stakeholders in OSA treatment will be better satisfied, Patients, Providers, Physicians and Payers. This study tested the quality of patient and dentists' preferences of EVO, a novel iterative advancement device (NIAD), manufactured using artificial intelligent design, robotic manufacturing and the most advanced medical grade materials ever, from ProSomnus Sleep Technologies over legacy devices and PAP therapy.

Objectives

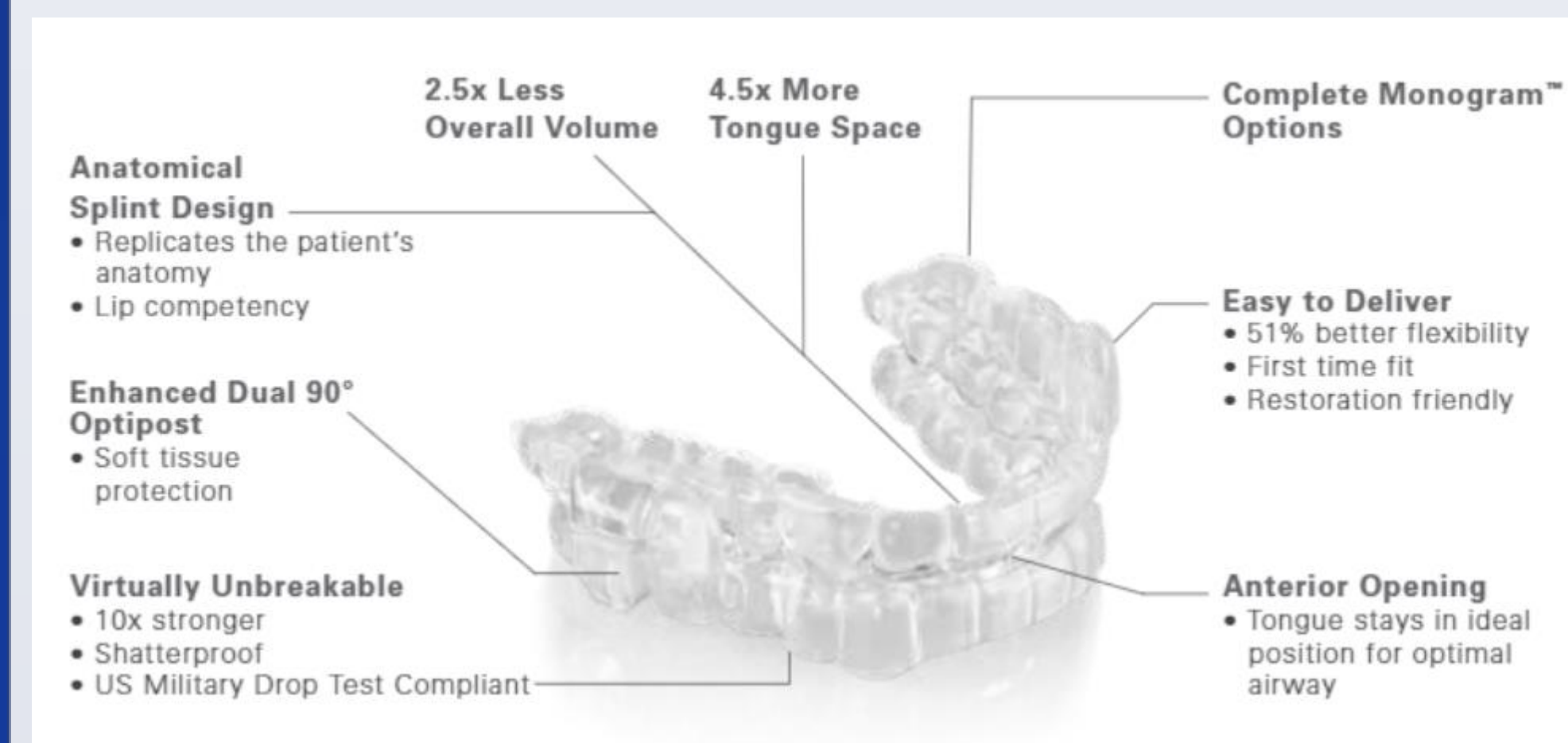
- Test patient preference for the NIAD against previously used oral appliances
- Test patient preference for the NIAD against CPAP
- Rate performance of the device for comfort based on features of the NIAD
- Determine material performance against other device materials
- Validate key design features with patients



Materials and Methods

Devices were manufactured from digital records of U/L impressions and bite registrations. 31 Patients (all with previous, some multiple OAs and 20 previous CPAP users) and 7 dentists were surveyed regarding a range of preferences about the NIAD material and device using a 0-10 scale. Samples were analyzed for stainability by mustard at 37C for 10 days against representative predicates using colorimetry. The NIAD device has specific features that were tested as shown below.

NIAD: The ProSomnus EVO Sleep and Snore device

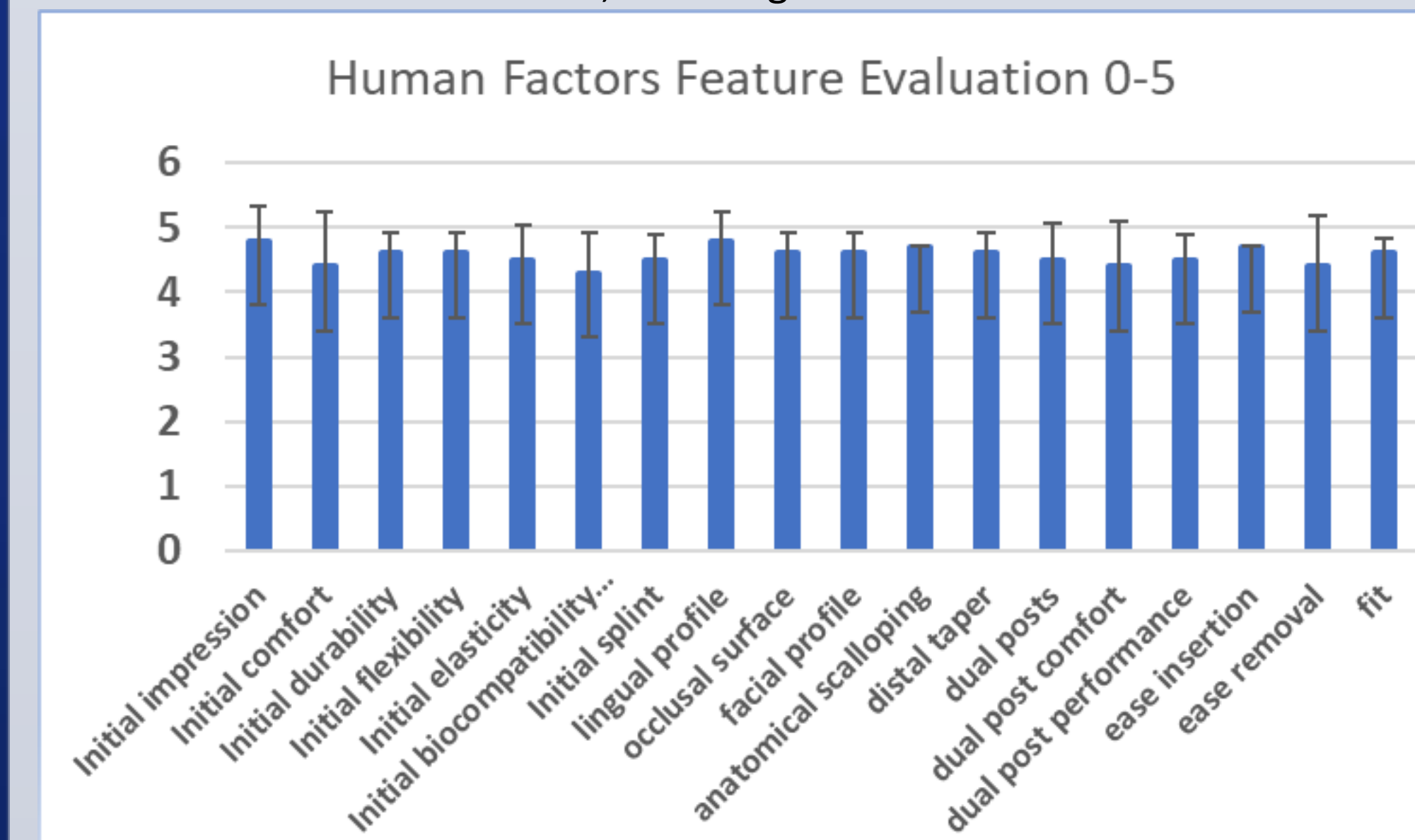


Specific Features to test

- Monolithic MG6™ material vs acrylic with liner
- True anatomical design (from patient's anatomy)
- Flex and fit of MG6 material vs hard acrylic, nylon and acrylic with liner
- Dual 90 degree post comfort
- MG6 flexibility in reference to ease of delivery, fit, and ease of removal

Results

Overall all acceptance of NIAD feature set 4.56 +/-0.43
Scored 0-5, 5 being most favorable



Results (continued)

Both doctors and patients were surveyed on their experience with the NIAD device.

Patient Survey Results

Survey Question	Response %
Preferred NIAD over CPAP	100%
Reported NIAD easier to keep clean than CPAP	100%
Would wear NIAD more than CPAP	100%
Preferred NIAD over the previous appliance(s) they had worn	100%
*(21 various soft liner devices with fulcrum straps, advancement tubes, screws, or anterior hook devices and 15 printed nylon appliances)	

Survey Question	Score
NIAD comfortable at delivery	9.2
NIAD smaller than other appliances I have worn	9.4
Contours more natural feeling	9.5
Easier to close my lips together	8.8
Confident device will not break if I grind	9.1
Confident in durability over time	9.1

Doctor Survey Results

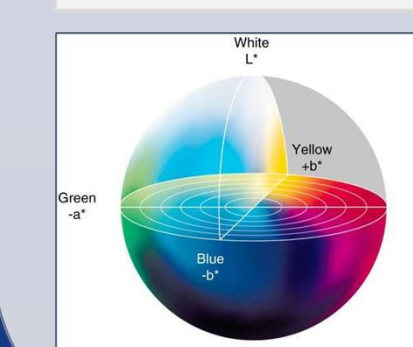
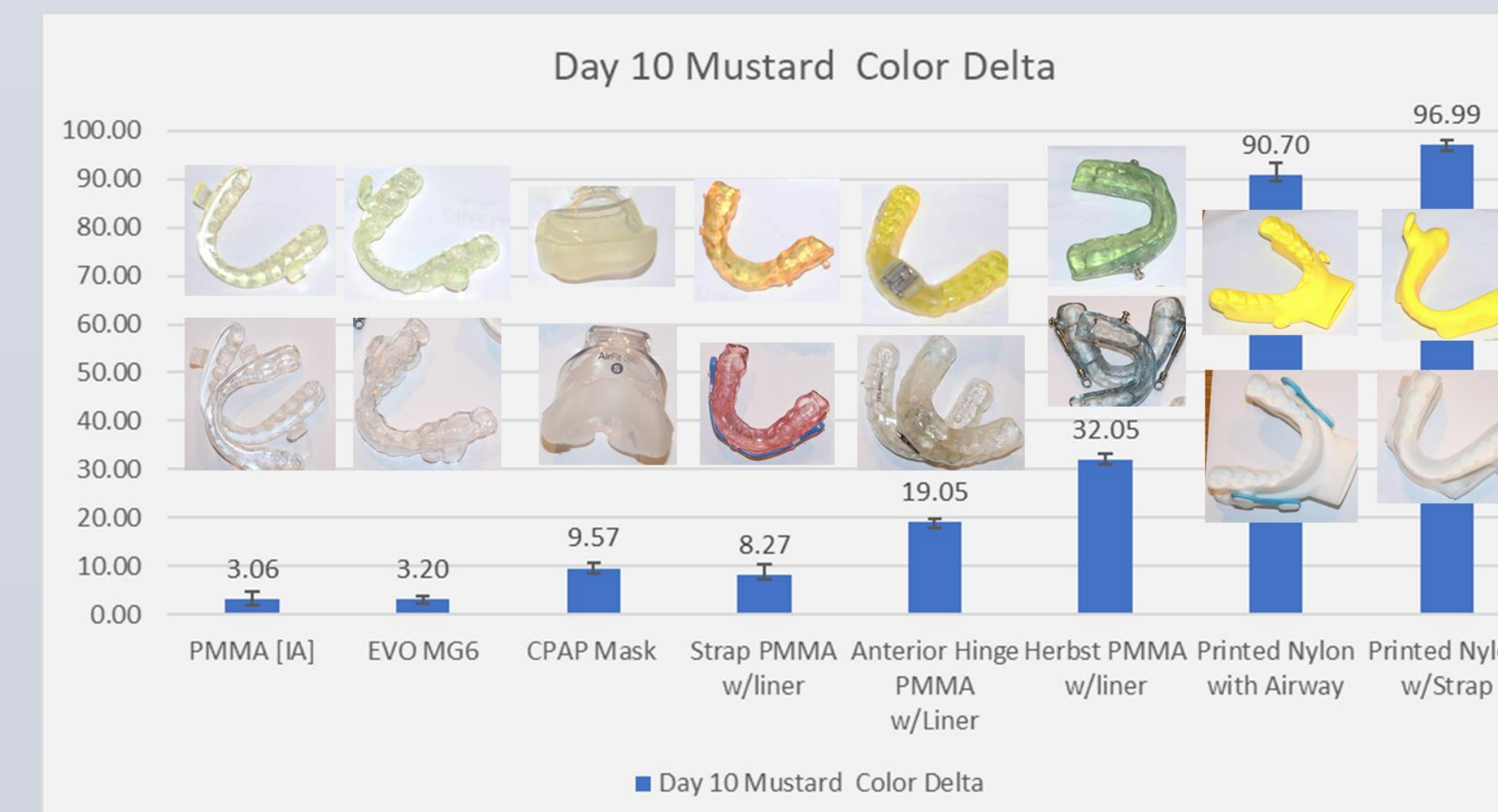
Survey Question	Response %
No adjustment interventions for fit at delivery,	81%
Would prescribe NIAD again	100%
Would recommend NIAD to their friends and colleagues	100%
Felt the precision is important	100%

* Average adjustment time was 3.1 min

Survey Question	Score
NIAD was easier to deliver than other devices	9.1
Retention was just right at delivery	8.7
Would use NIAD for patients with Bruxism	97
NIAD is safe for patients with Crowns and Veneers*	9.3
Would use NIAD on wider range of patients	9.8
NIAD would be easy to keep clean	9.8

*No crowns or veneers were removed or damaged during delivery

The NIAD MG6 material demonstrated less uptake of mustard resulting in a lower Delta E than all other devices with a soft lining or printed nylon, due to the low porosity of the surface structure



Samples had their color measured using a colorimeter capturing the E value, baseline values were subtracted from 10 day mustard soak value to calculate the Delta E, the color difference before and after staining

Conclusions

Patients preferred NIAD over CPAP and all other devices similarly designed for comfortable easy fit and delivery (soft liners and printed nylon) without compromising the comfort, cleanability or strength. Liner less milled devices outperform all other devices with less staining. The NIAD is similar to a current well studied (good efficacy, less side effects, precision, smallest, comfortable and compliant) iterative advancement device design from the same manufacturer with the addition of the new medical grade material application to enhance the patient, physician and payer experience.

Dentists reported that easy delivery and excellent retention, with no or very limited adjustments was accomplished. 100% added that they would use this device again, on a wider variety of patients (bruxers and multiple restorations) and would recommend to their colleagues.

Contact

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