Intuguard: A high-performance dental guard for rigid laryngoscopy, intubations, and endotracheal surgical procedures

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Numerous legal claims against anesthesiologists and hospitals arise from dental injuries that occur during intubations and transoral endoscopic surgical procedures. Although some hospitals and medical practices may use low-cost mouth guards in an attempt to protect the teeth of their patients, many medical professionals tend to shy away from using such protective guards for intubations, since these guards are bulky and obstruct access. Furthermore, they tend to get dislodged during procedures. Even when guards are used, dental injuries are prevalent, as most of the inexpensive guards that can be found on surgical carts are not providing adequate protection and have poor fit.

Akervall Technologies, Inc. has developed a revolutionary new intubation guard product based on a proprietary high-performance material. This material comes in form of a 1.6 mm thin, flat tray that can be softened by immersion into hot water and easily fitted to the patient's dentition prior to the medical procedure. Once inserted, the material quickly cools and assumes a perfect conformal fit around the teeth, rivaling the fit of a very expensive mouth guard made in a dental laboratory, but at a fraction of the cost.

The design of the intubation guard is based on an extensive research and development effort in order to minimize the transfer of forces on the incisor tips and the gum-teeth intersection, giving unprecedented protection during intubation and transoral surgical procedures. This break-through technology of the intubation guard was awarded a patent (U.S. Patent 9,302,063).

There is still a lack of consensus on the actual rates of dental trauma during intubation and transoral surgical procedures, as reported in the literature cited and as stated in a recent review article on dental trauma during intubation (Ansari, 2016). The lifetime cost of a chipped tooth is $15,000 - $20,000. This high cost is associated with the fact that in many cases a chipped tooth ultimately fails and requires a dental implant many years after the injury. Besides the high treatment costs, these types of dental trauma may also damage the doctor-patient relationship, end up in legal proceedings against the clinic or hospital, or malpractice suits against the medical professionals involved. The most frequent injuries on record are increased mobility of teeth and fractures of the enamel of the upper incisors. Also, in many cases, exfoliation of teeth is reported, along with crown and root fractures, or damage to crown and bridgework. (Chadwick et al. 1998).

Many medical instruments can cause dental injuries , for example rigid laryngoscopes and esophagoscopes, oropharyngeal airways, bite blocks, suction devices, props and mouth gags. Jaw clamping during light anesthesia can also cause dental trauma. Patients who are at high risk for a dental injury are people who suffer from periodontal or gum disease, have protruding upper incisors or previously traumatized or isolated teeth. Furthermore, patients who have caries, restorations, veneers, crowns, bridgework and implants are at high risk.

Some medical practices or hospitals use dentist made guards in EVA or acrylic, but these devices are rather costly and require time-consuming fabrication and fitting. More often than not, soft pre-shaped "one fits all" mouth guards are used. These inexpensive pre-shaped dental guards are made of relatively soft and compressible materials such as ethylene-vinyl acetate (EVA). Such “one-size fits all” dental guards do not fit well and can get easily dislodged during a procedure, obstructing the instruments and potentially blocking the airway. They also deform when force is exerted on them by an instrument. When high force is applied, they may even completely fail and break.

All these problems are solved by the new Intuguard. This new protective device, while still being relatively inexpensive, is made from a material that has superior mechanical properties. It can be quickly custom-fitted to a patient's dentition, either by the patient at home, or immediately before the procedure by personnel in the medical facility.

The fitting procedure is greatly facilitated by the patented design of the guard that has small perforations or slits in strategic locations. Furthermore, these perforations and slits are very effective in dissipating forces applied by instruments. When the guard experiences forces exerted by an instrument, the perforations and slits allow local deformations to occur that deflect the forces away from the underlying teeth. Consequently, the guard is a very effective force dampening device that protects teeth even when a lot of force is being applied.

To examine the performance of the guards in a laboratory setting, a typodont (a set of faux teeth) and an intubation laryngoscope were used. In these experiments, the anterior maxillary teeth were used as a fulcrum during insertion of the laryngoscope. This experimental approach was selected, since a recent paper (Ray, B.R., Khanna, P., Anand, R.K., Baidya, D.K. J., 2013. Dental guards: An alternative solution for loose teeth. Anaesthesiology Clinical Pharmacology; 29; 424–425.) stated that using the maxillary teeth as fulcrum represents the most common incorrect execution of intubation laryngoscopy through which the central incisors are most likely to be damaged. The intubation laryngoscope was mounted to a device that allowed the application of precisely measured and reproducible forces. (Figure 1). Pressure sensors were mounted in the critical locations of the typodont where the laryngoscope was expected to apply the largest forces.

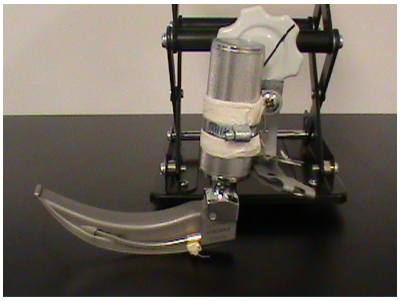

Figure 1. *Intubation laryngoscope mounted to a device that can apply precisely reproducible impact forces.*

Force measurements were conducted using Tekscan pressure sensors placed along the faux dental arch. Additional force measurements were also performed with the

sensor placed at various postitions along the gingiva-teeth intersection. A custom-built test apparatus was used where a 3.175 mm diameter stainless steel tube loaded with a 2.268 kg cylindrical stainless steel weight applied pressure onto specific locations of the typodont (Fig.2).

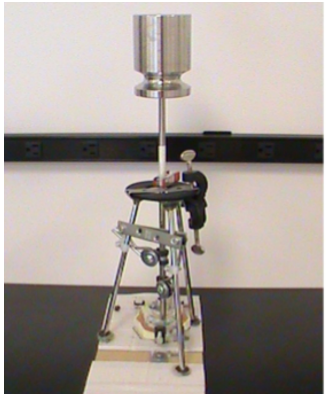

Figure 2. *Custom built test apparatus to evaluate the dental protective capacity of the various intubation guard prototypes.*

When the central incisor teeth were purposely used as a fulcrum to achieve entry of the intubation laryngoscope, the most severe forward deflection of teeth occurred in the area centered between the incisor teeth at the gum-teeth intersection. Therefore, pressure sensors were placed in these critical locations, as shown in Figure 3.

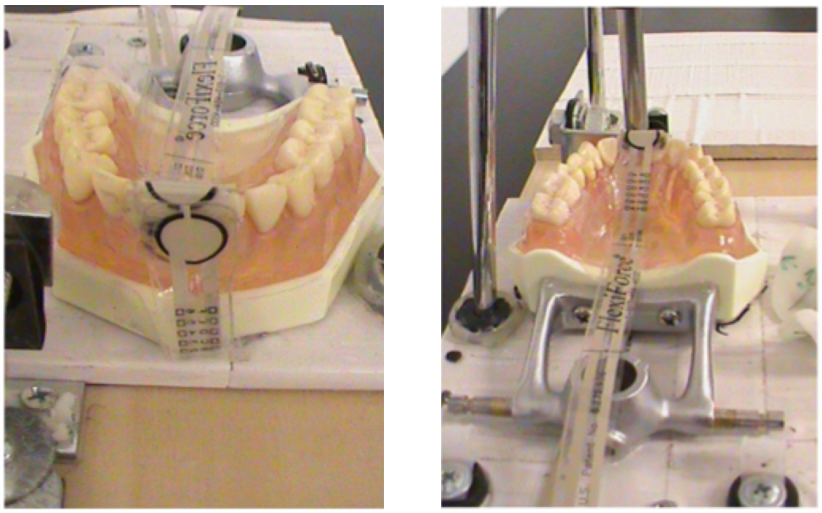

Figure 3. *Maxillary half of typodont outfitted with two Tekscan® pressure sensors; left panel is a front view of the outfitted typodont, the right panel a rear view.*

To prove the effectiveness of these new intubation guards in a clinical setting, the guards were fitted to the maxillary dentitions of 594 patients that were scheduled for transoral surgical procedures. Before the fitting process, the patients' teeth were examined for risk factors such as loose teeth, fillings or crowns, and any patient that

was found to exhibit any one of these risks was excluded. After completion of each endoscopic procedure, the patient's teeth and dental guards were examined for evidence of physical damage or defect. Among the 594 patients, only two dental injuries were identified during the postoperative assessment (ongoing study, data not yet published). The results of this study attests to the effectiveness of the guard and its ability to dissipate the forces applied by the rigid endoscopic instruments that were often sustained for several uninterrupted hours.

Four different intubation guard prototype designs were tested, and for each of these designs several variables were examined such as a) the number of teeth physically covered when the prototype was fitted to the maxillary arch of the faux dentition; b) the length of guard over the gingiva-teeth intersection; c) the length of guard extension onto the palate; d) the size and shape of the slits at the anterior edge of the guard; and e) the location and number of circular perforations.

Among these design variables, the number of teeth covered and the length of the guard extension onto the palate played the most important role in force dissipation, and ultimately one particular design emerged that was so effective in force dissipation that the sensors at the incisor tips and on the gum-teeth intersection registered a reading of zero (Figure 4).

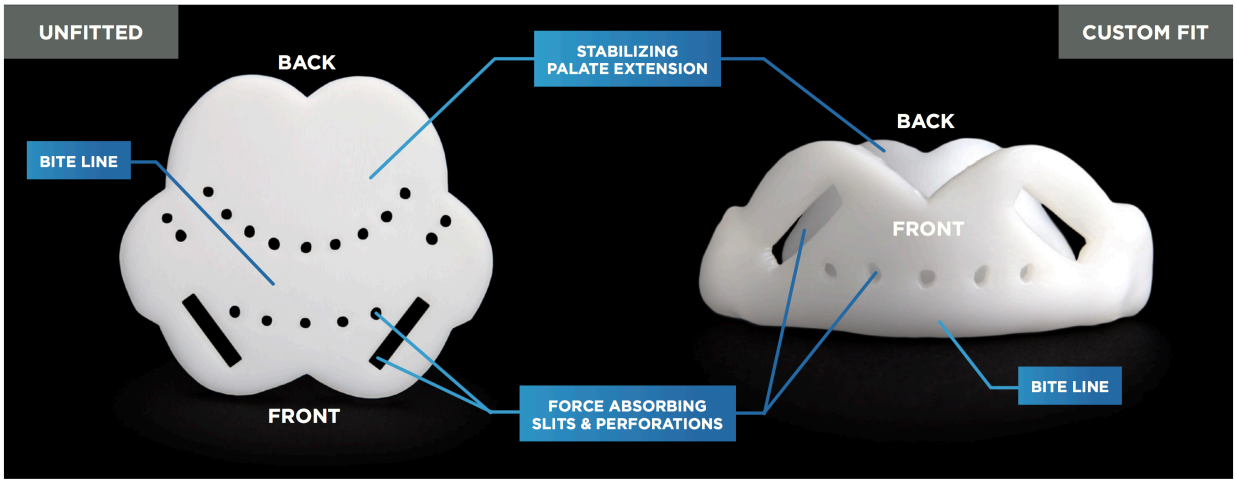

Figure 4. *Intuguard in unfitted and fitted state.*

One important feature of the Intuguard is the stabilizing palate extension that assures that the guard does not get dislodged from the teeth during intubation. In control experiments with faux teeth protected by the standard medical cart guard

available in many hospitals, the sensors registered peak forces of 2.75 Newtons (N) at the incisor tips and 1.91 Newtons at the gum-teeth intersection (Figure 5).

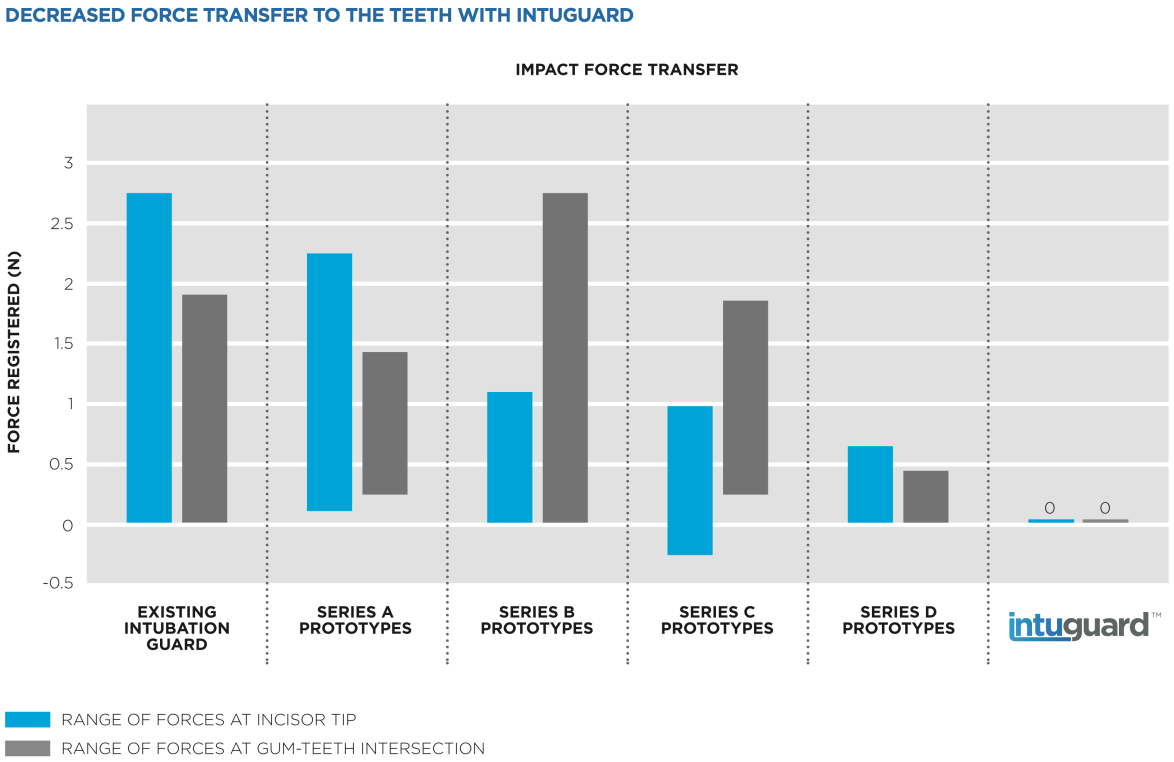

Figure 5. *Peak force transfer to teeth with existing hospital intubation guard, the four prototypes studied, and the ultimate version of Intuguard.*

Intuguard therefore fulfills several important requirements for effective protection of teeth during intubation and transoral surgical procedures. The flat tray of the Intuguard can be easily from-fitted to the teeth after softening in hot water. The guard will give excellent fit even if there are missing or significantly misaligned teeth. After fitting, the guard hardens in less than a minute. It is only 1.6 mm thick so that it does not hinder the access to the airway by intubation laryngoscopes and rigid endoscopes. The guard is made of a strong material that will not break or bend under intubations where high peak forces may be exerted, and also hold up under long lasting constant pressure encountered during rigid endoscopies. The commercially available disposable dental guards that are present on anesthesia carts in operating rooms all over the world do not meet these criteria. They are too soft, fit poorly, and cannot resist any significant pressure from instrumentations.

The Intuguard is thin, sturdy, and easy to fit at home or in the pre-op area. Patients can easily fit the dental guard by themselves before coming to the hospital for a procedure, thus overcoming the issue of taking time from the preoperative/per-operative routines. This cost-effective device could save patients from dental injuries and protect anesthesiologists, otolaryngologists and hospitals from lawsuits. The novel guard shows significantly less force transfer to the teeth and could become an effective tool for decreasing dental injuries.

ACKNOWLEDGEMENTS

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