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Intuguard – A Novel, Thin and Hard Dental Guard for Intubations, Rigid Endoscopies, and Transoral Procedures That Eliminates Transfer of Impact Forces to the Teeth

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Abstract

Background: Dental injuries from intubations and transoral endoscopic surgical procedures are still frequent and represent one of the primary reasons for legal claims against anesthesiologists and hospitals. The lifetime cost of an avulsed or chipped or tooth can be $5,000 to $20,000 because a chipped tooth may ultimately fail and require a dental implant [1]. In many cases, the patient incurs this cost outside of the window of insurance coverage, impacting the doctor-patient relationship and potentially leading to litigation. In attempts to prevent dental injury during intubations and transoral endoscopic surgical procedures, inexpensive pre-shaped dental guards are provided on anesthesia carts. These dental guards are made of relatively soft materials such as Ethylene-Vinyl Acetate (EVA), tend to have poor fit, and are easily dislodged during a procedure. They also undergo plastic deformation or even fracture when severely loaded, and therefore provide inadequate dental protection. The goal of this laboratory study was to identify a better material and dental guard design that minimizes the transfer of forces to the teeth.

Methods: 24 dental guard prototypes with a range of design parameters were crafted from a thermoplastic polymer, fitted to faux dentitions, and systematically tested for their force dampening features to identify a dental guard with optimal characteristics capable of preventing force transmission to the faux teeth by a rigid laryngoscope.

Results: Among the dental guard design parameters, two were found to impart the most significant force dissipating capacity: extending the dental guard onto the palate region of the oral cavity, and adding a flap portion to the guard with a center cusp that extended over the gingiva-teeth intersection. Dental guards with these design elements had much lower force transmittance compared to the standard hospital-issued dental guards.

Conclusions: In the present study we challenged the widely used soft EVA-based mouth guard concept by introducing a meticulously engineered hard thermoplastic polymer based device. In contrast to the standard guard that transfers significant forces to the teeth, the optimized guard design emerging from this study suppressed force transfer, thanks to a superior polymer [2], strategically placed perforations, and a stabilizing palate extension. The dental guard can be custom fitted in a minute and remolded if needed. We believe that this device could save patients from dental injuries, and protect anesthesiologists, otolaryngologists, and hospitals from lawsuits.

Keywords: Dental protection; Mouth guards; Intubation; Transoral surgery; Rigid endoscopy

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Introduction

There is still a lack of consensus on the actual rates of dental trauma from endotracheal intubations and rigid endoscopic procedures (rigid laryngoscopies and esophagoscopies) [3-13]. The most common injuries are enamel fractures involving the upper incisors, along with exfoliation of teeth [14], crown and root fractures, damage to crown and bridgework, and extensive tooth mobility. There are many factors that can increase the risk for a dental injury [15]. Difficult intubations and multiple intubation attempts can increase the risk for injuries about twentyfold [16]. Dental guards are considered problematic with tracheal intubation procedures, as bulky dental guards can interfere with the limited amount of space available [17].

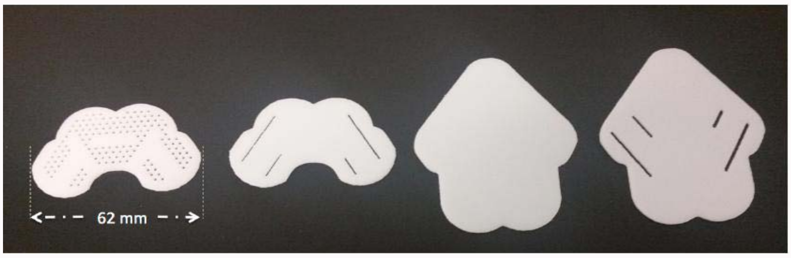

Figure 1: Images of 4 of the 24 intubation guard prototype designs.

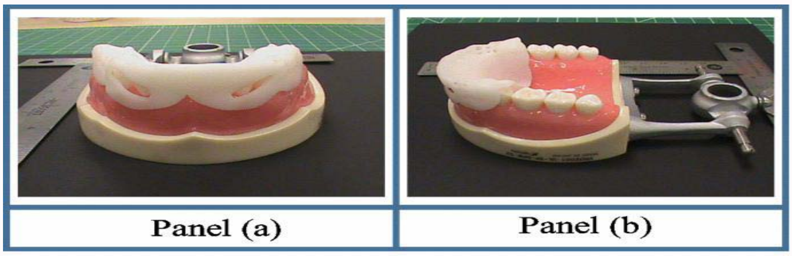

Figure 2: Example of intubation guard prototype fitted onto faux maxillary dentition; panel (a) frontal view panel (b) side view.

In attempts to lower the incidence of dental injuries during endotracheal intubations and rigid endoscopic procedures, dentist-made guards in EVA or acrylic or soft pre-shaped "one fits all" appliances [18-21], have been offered to the patients, but the protection provided is at best marginal. Ideally, one would like to use a material that has better mechanical properties, is relatively inexpensive, and can be quickly custom-shaped with excellent conformal fit to a patient's dentition, either by the patient or by personnel in the operating room. One such material is polycaprolactone, a thermoplastic polymer that can easily be shaped into a dental guard thanks to its relatively low melting point of about 333K [22].

Given the physical properties of polycaprolactone, one would expect that dental guards made from polycaprolactone should be able to better dissipate the forces applied during intubation or transoral procedures compared to the low-cost EVA guards on anesthesiology carts. Our hypothesis was that it should be possible to increase the force dissipation ability of this material by introducing small perforations or slits in strategic positions. The shape of these perforations or slits would undergo reversible deformations in the area where force is applied. These localized deformations of the contours of the perforations and slits would contribute to dissipation of forces by redirecting them horizontally into the void spaces in the polymer, thereby decreasing the force that is transmitted to the underlying faux teeth. To verify this hypothesis, a systematic evaluation of different dental appliance designs with varying shapes, sizes, and placements of perforations and slits was conducted with the objective to identify a design that maximizes the overall force dampening ability of the dental guard.

Methods

This study was carried out entirely in a laboratory setting involving faux denitions. Therefore, the study is not subject to any IRB approval.

Dental guard prototypes were made from 1.6 mm thick injection-molded sheets of polycaprolactone with a number-average molecular weight of 47500 ± 2000, and a weight average molecular weight of 84500 ± 1000. The material had a Young's modulus of 470 MPa (1 mm/min) and 430 MPa (10 mm/min) according to ASTM Test D412-8, and a tensile strength of 29.11 MPa.

The sheets were cut into small coupons of varying shapes, approximately 10 cm^2 to 20 cm^2 in area, and different patterns of small perforations or slits were placed in the coupons. 24 different dental guard prototype coupons were fabricated to optimize the design with regards to force dissipation and fitting, for transoral surgeries as well as endotracheal intubations. These prototypes embodied a diverse set of force-dissipating features. The prototypes varied primarily in five broad design parameters: 1) The number of teeth physically covered when the prototype was fitted to the maxillary arch of the faux dentition; 2) The length of guard extension over the gingiva-teeth intersection; 3) The length of guard extension onto the palate; 4) The physical dimensions of the force absorbing slots at the anterior edge of the appliance; and 5) Both the location and number of perforations. Examples of four of these prototypes are shown in Figure 1.

The prototype coupons were placed for 30 seconds - 60 seconds into warm water at a temperature of approximately 333K until the polymeric material softened and became pliable. The softened material was draped over the maxillary dentition of a set of faux teeth so that the material assumed a conformal shape with the dentition. Upon cooling to room temperature, the material hardened and slightly contracted, giving a tight fit resistant to dislodging by instruments or intubation tubes. Figure 2 shows such a dental guard prototype fitted over faux teeth.

For measuring the effect of forces on the typodont, two experimental setups were created. First, an intubation laryngoscope was mounted to a device that allowed us to simulate the effect of forces when the anterior maxillary teeth are used as a fulcrum during insertion of the instrument. 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 [19,21]. When the central incisor teeth were purposely used as a fulcrum to achieve entry of the intubation laryngoscope, visual observation revealed that the most severe forward deflection of faux

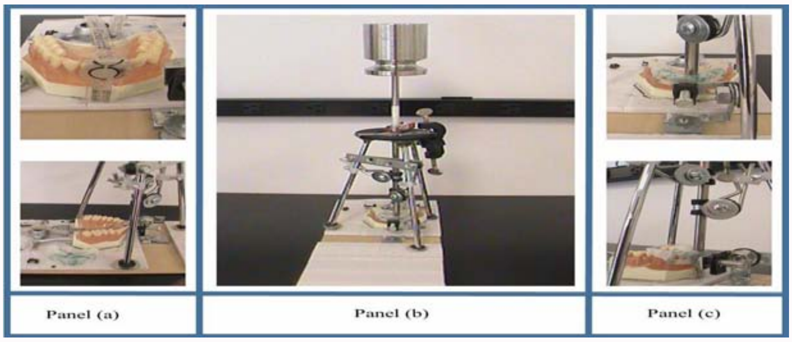

Figure 3: Custom built test apparatus to evaluate the dental protective capacity of the various intubation guard prototypes.

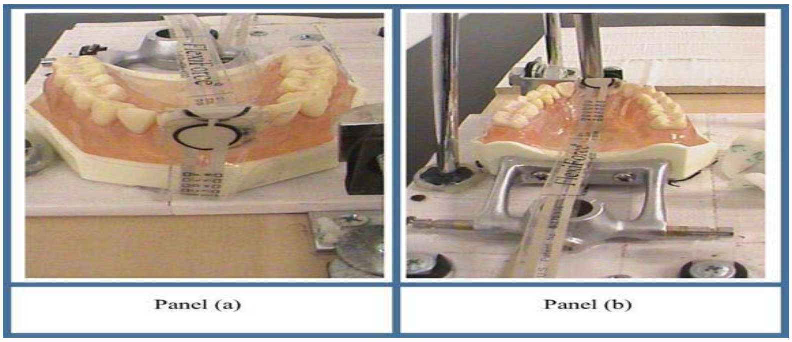

Figure 4: The maxillary half of a typodont outfitted with two Tekscan® pressure sensors; panel (a) front view, panel (b) rear view.

teeth occurred in the area centered between the incisor teeth at the gum-teeth intersection.

The insight gained from theses preliminary experiments were used to identify the proper placement of pressure sensors for more quantitative measurements in a custom-built apparatus shown in Figure 3. Thin pressure sensors (Tekscan®, South Boston, USA) were placed at different positions along the faux dental arch based on the visual observations from the simulated intubation mentioned above. Force measurements were also obtained with the sensor placed at various points along the gingiva-teeth intersection to better understand the force distribution at a distance from the point of impact. In this custom-built test apparatus, a 2.268 kg cylindrical stainless steel weight was supported on a 3.175 mm diameter stainless steel tube. The tube was balanced on top of a vertical steel rod whose bottom end rested on a small area of the typodont. This apparatus made it possible to pressure-load one or more teeth along the faux maxillary dental arch with a reproducible force (Figure 4). Next, the sensors were placed between the typodont and one of the dental guard prototypes that had been draped over the typodont, and the pressure-loading experiment was repeated on the same positions of the typodont. Comparing the pressure readings of the sensors before and after placing the protective dental guard over the typodont made it possible to quantify how much of the applied force was dissipated by the dental guard and how much of the applied force was transmitted to the faux teeth or gum section underneath.

Results

Five design variables were investigated for the 24 intubation guard prototypes included in this study: 1) The number of teeth physically covered when the prototype was fitted to the maxillary arch of the faux dentition; 2) The length of guard extension over the gingiva-teeth intersection; 3) The length of guard extension onto the palate; 4) The physical dimensions of the force absorbing slots at the anterior edge of the appliance; and 5) both the location and number of perforations included in the guard design.

Among these five design parameters, two were found to impart the most significant force dissipating capacity to the guard: extending the dental guard onto the palate region of the oral cavity, and a flap portion of the guard having a center cusp that extended over the gingiva-teeth intersection. Dental guards with these design elements had much lower force transmittance compared to the standard hospital issued dental guards. The amount of forces transmitted to the incisor tips and the intersection of gum and teeth varied dramatically as the type, size, and placement of perforations or slits was systematically altered. In control experiments with faux teeth protected by the standard anesthesiology cart guard available in many hospitals, the sensors registered peak forces of 2.75 N at the incisor tips and 1.91 N at the gum-teeth intersection. With most of the 24 prototypes placed onto the faux dentitions, the peak forces decreased significantly, and in some cases, the sensor at the incisor tips registered a reading of zero with only very low forces registering on the gum-teeth intersection.

The first set of prototypes (Series A) varied in the design details of the anterior flaps with a center cusp. Starting with a solid flap area, the design was modified by introducing rectangular slots, perforations, or combinations thereof. Series B varied from covering premolar to premolar teeth versus covering canine to canine teeth in an attempt to find a good compromise between protection of teeth and ease of fitting. As the number of teeth covered increased, a smaller amount of force was transmitted, but the increasing length of the guard made it more difficult to achieve a good custom fit. Ultimately, a compromise had to be made between the degree of force dissipation and ease of fitting.

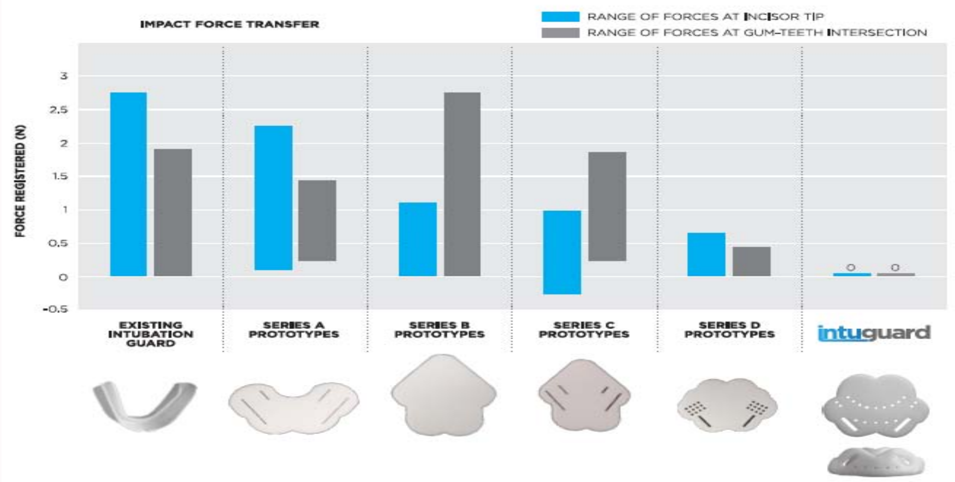

Figure 5: The standard dental guard for intubations (far left) that currently is present in anesthesia carts all over the world displays significant force transfer through the material, down to the teeth it should protect. A number of engineered designs and materials were developed in this study and superior version, from a force transfer standpoint, is shown to the far left, displaying zero force transfer through the guard to the teeth.

The third set of prototypes (Series C) yielded data that served as the basis for defining a range of the physical dimensions of the rectangular open spaces (slots) in the guard's anterior. The primary purpose of the rectangular slots is to allow the polymer to deform and stretch into the open slot areas when pressure is applied to the guard. This deformation absorbs and redirects some of the applied forces within the intubation guard rather than transmitting all the forces to the underlying dentitions. Comparing the effect of a number of aspect ratios and overall sizes of the slots led to an optimum design of the slots that minimized the force transmission through to the incisors. Among the series of guards with different slot designs, the maximum peak force that transmitted was a mere 0.74 N. Interestingly, for one of the embodiments of this series the force transmission to the incisors was slightly negative. In this case, less force registered on the sensor when pressure loaded with the weight than with just the guard present. In other words, the act of pressure loading the guard of this design likely caused the appliance to release the applied stress by physically bowing slightly outward, away from the sensor, thereby giving a negative pressure reading on the sensor. Based on the force transmission trends observed and the insights gained from the set of 24 different intubation guard prototypes, a final set of 7 guard prototypes (Series D) was manufactured. Each prototype of this set embodied one or more of the identified force dissipative features as determined from the previously generated force transmission data. A summary of the ranges of force sensor readings at the incisor tips and the gum teeth intersection for the prototypes in series A through D is provided in Figure 5. Among the final set of 7 prototype designs of series D, one particular design stood out as it very effectively prevented force transmission to both the incisor tips as well as to the gum-teeth intersection. A Computer-Aided Drawing (CAD) and a photograph of this optimized dental guard design are shown.

This design incorporated two front flaps separated by a forward cusp, two side flaps, and a rear palate extension. Furthermore, this design introduced rectangular slots in the front flaps, and two sets of larger circular perforations to improve comfort and to create more of a snug fit to the dentition. When a patient creates suction during the fitting process, these perforations are critical for form fitting around the dentition. Thus the material can more easily drape over the molars ultimately achieving a very secure and snug fit to the maxillary dental arch. The palate extension assures that the guard does not move during intubation. This optimized prototype balances dental protection and ease of fitting and is shown in Figure 2 fitted to faux dentitions. The slots and the palate extension were found to be crucial design elements of the optimized prototype.

Discussion

Dental guards for protecting teeth during intubations and surgeries must fulfill several critical criteria: They need to be easily molded after softening in hot water and be pliable enough to work for any dentition, even if there are missing or significantly misaligned teeth. The material needs to harden fast and to be thin, not to compromise the access to the airway by intubation laryngoscopes and rigid endoscopes. The material must be tough and non-compressible, in order not to easily break or bend under both significant high peak (intubations) and long lasting constant pressure (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 new intubation guard design reported in this paper focused on meeting the criteria.

The mock intubation laryngoscopy procedures revealed that the central incisor teeth were at the greatest risk for damage. High forces at this location can be particularly damaging because of the potential of avulsion of one or more teeth. These findings lead to the conclusion that an optimized intubation guard must not only be made of a strong and thin material but also be designed in such way that it supports the teeth with a stabilizing palate extension to avoid mobilization of the dentition during the procedure.

The experiments with the intubation guard prototypes convincingly showed that the transmitted forces were significantly smaller than those allowed through to the underlying teeth by a typical dental guard included in standard medical carts. The insights gained from the first series of five prototypes (series "A") led to a modified set of guards (Series "B"). One of the designs in series "B" did not allow any force transmission at all to the central incisors. Similarly, no force transmitted through to the gingiva-teeth intersection with a slightly modified design of series "B". The peak-transmitted forces in series "B" were significantly smaller than those for the prototypes comprising

Series "A". In Series "B", the peak force measured on the incisors was 1.13 N compared to 2.3 N for Series "A". The third set of prototypes was prepared and tested to optimize the physical dimensions of the rectangular slots in the guard's anterior (series "C"). In this series, one of the prototypes gave a negative reading on the incisor tips, indicating that the guard was bowing away from the incisors when placed under the load.

The best performing overall guard design was one of the designs in a final set of prototypes (Series "D") that included all of the force dissipating features identified in series "A", "B", and "C". This optimized mouth guard gave simultaneous readings of zero at both the incisor tips and the gum-teeth intersection. All force transmission was mitigated as indicated by both sensors. The design of this guard included a portion that extended onto the hard palate of the oral cavity, a portion that extended over the gingiva-teeth intersection, and symmetrically covered eight teeth when fitted to the dentition. Also, the anterior rectangular slots were symmetrically placed. This design and all of the delineated features made up the final design of the intubation guard and resulted in the issuing of a U.S. patent [23]. The optimized dental guard emerging from the present study has yet to be evaluated clinically, but given the remarkable ability to dissipate forces in laboratory studies, one would expect this new design to outperform the simple guards used in previous clinical settings.

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