Anatomy-driven design of a prototype video laryngoscope for extremely low birth weight infants

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Abstract. Extremely low birth weight (ELBW) infants frequently require endotracheal intubation for assisted ventilation or as a route for administration of drugs or exogenous surfactant. In adults and less premature infants, the risks of this intubation can be greatly reduced using video laryngoscopy, but current products are too large and incorrectly shaped to visualize an ELBW infant's airway anatomy. We design and prototype a video laryngoscope using a miniature camera set in a curved acrylic blade with a 3×6-mm cross section at the tip. The blade provides a mechanical structure for stabilizing the tongue and acts as a light guide for an LED light source, located remotely to avoid excessive local heating at the tip. The prototype is tested on an infant manikin and found to provide sufficient image quality and mechanical properties to facilitate intubation. Finally, we show a design for a neonate laryngoscope incorporating a wafer-level microcamera that further reduces the tip cross section and offers the potential for low cost manufacture. [DOI: 10.1117/1.3517457]

Keywords: intubation; laryngoscopy; extremely low birth weight infants; remote light source; imaging system.

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1 Introduction

Every year, about 4 million babies are born in the United States. In 2006, 30,792 newborns had birthweights of less than 1000 grams [extremely low birth weight (ELBW)], with 6666 of these having birth weights less than 500 g.[1] 85 to 90% of infants in this weight range require endotracheal intubation, the insertion of a tube into the airway, for the purpose of mechanical ventilation and/or delivery of medication such as exogenous surfactant.[2] Intubation is difficult to perform, and even more difficult to learn. Using the standard laryngoscope, the device used to visualize the airway during intubation, only one individual at a time can be in the correct position to visualize the vocal chords, through which the tube will be passed. Problems are compounded in ELBW infants due to their tiny size and relatively anterior placement of the larynx. Research at the University of California, San Diego (UCSD) Department of Pediatrics has shown that successful intubation in this population requires an average of three intubation attempts, and can take up to ten attempts.[3] Problems associated with these multiple attempts can include hypoxia, bradycardia, blood pressure changes, and increased intracranial pressure.[4] The laryngoscope has seen a recent innovation with the addition of video imagers. Typical nonvideo laryngoscopes can have a flat, illuminated blade set at 90 deg to the handle (Miller) or a curved blade set against the handle (Macintosh). Both styles require that the operator create a direct line-of-sight view of the vocal chords. Intubation of ELBW infants typically uses the smallest size Miller blade laryngoscope, size 00, with cross sectional dimensions at the tip of about 10×1 mm. Video laryngoscopes include an imager set in the tip, which allows for indirect viewing around curves. Early systems used a coherent fiber bundle in the tip with the actual sensor in the handle, while most systems now have a camera in the tip. The physician can view the airway on a monitor, improving the view of the larynx.[5] The clinician can both see around curves as well as get a magnified view of the larynx. Additionally, multiple people are able to visualize the airway, helping other members of the resuscitation team to perform their jobs, and assisting new doctors in learning the procedure.

Our goal was to create a prototype video laryngoscope suitable for use in ELBW infants, satisfying several constraints. First, the blade tip needed a 2 to 3 mm by 6 to 7 mm cross section, with a length, curvature, and shape suitable for infant anatomy, rather than scaled down adult anatomy. The blade needed to be mechanically strong enough to hold its shape while controlling the tongue of the patient. Finally, an imager of adequate quality and resolution had to fit within these spatial constraints and also be provided with sufficient lighting to operate without excessive heating at the inserted tip.

2 Imaging System

Existing video laryngoscopes use either a small video camera or a coherent fiber bundle to transmit the image of the airway. We identified a commercially available microimager, the Medigus (Omer, Israel) IntroSpicio charge-coupled device (CCD) camera, as a promising sensor. The imager package is square in cross section and only 1.8 mm per side, which fits within the size constraints. The camera has an f/5.99 lens with effective

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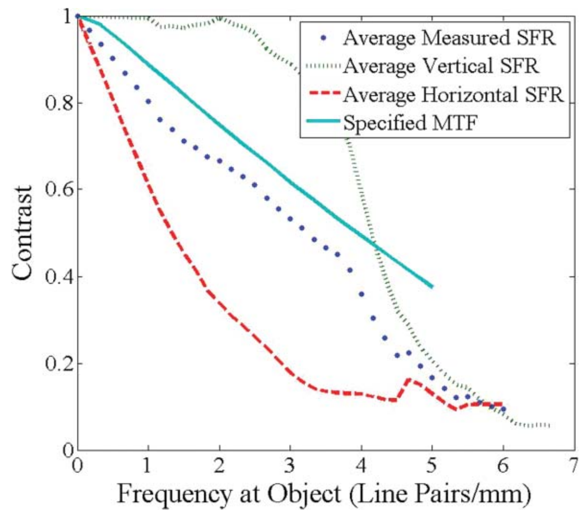

Fig. 1 Modulation transfer function of the imaging system with the object at a 2.2-cm range.

focal length of 0.712 mm. We conducted an initial characterization of the camera, taking images of a standard United States Air Force resolution target at varying distances. We found the overall resolution characteristics by measuring the contrast of each set of line pairs (normalized to the values of dark regions) and finding the highest resolvable spatial frequency (Figs. 1 and 2). The images were displayed in an oval format, 300 pixels high and 350 pixels across, and demonstrated sufficient resolution for working distances less than 5 cm, appropriate for the application requirements.

We found a necessary scene illumination of about 6000 lux at the scene (at 4 cm), or about 130 lux at the sensor, from the equation[6]:

$$E_{\text{image}} = \frac{\pi}{4} E_{\text{object}} \left(\frac{1}{(1+m)F} \right)^2$$

The simplest solution for the light source would be a white-light LED adjacent to the image sensor. However, we found that

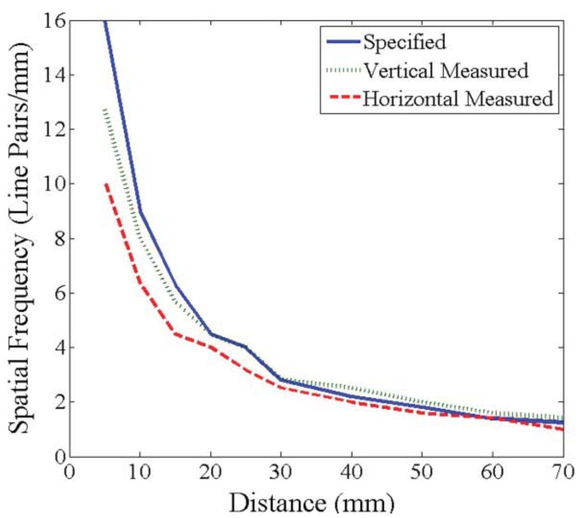

Fig. 2 Maximum resolvable spatial frequency (at the object plane) versus object distance.

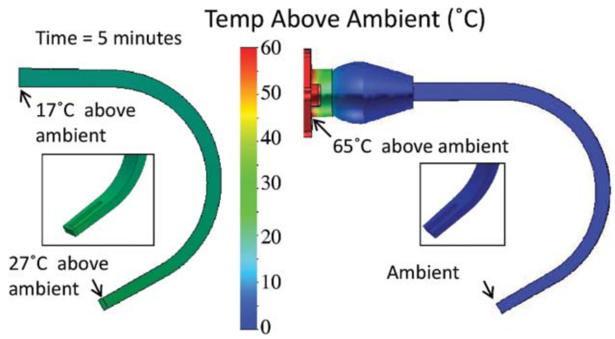

Fig. 3 Temperature distribution model for tip-mounted and remote handle-mounted LED sources.

available LED sources up to 25 lumens output required 1 to 2 W to operate, which needs to be thermally isolated or conducted away from the sensitive tissue in the ELBW infant's throat. Temperatures above 43.5°C can potentially cause thermal damage to the skin.[7] However, a laryngoscope comes into contact with even more delicate tissue. Injuries to the tongue[8] and oropharynx[9] have been seen from laryngoscopes left on too long, even at temperatures below this threshold.

To determine whether a tip-mounted LED would be safe, we created a mechanical model of this configuration using Solidworks (Concord, Massachusetts) design software, placing an LED source directly connected to a solid aluminum blade to maximize heat conduction from the tip, as shown in Fig. 3. We modeled a Luxeon III (Quadica Developments, Brantford, Ontario) white-light LED with a thermal resistance of 17°C/W and operating at 1.6 W. The heat transfer coefficient to the air is assumed to be 15 W/(m^2*K). Peak LED temperature was found using the thermal resistance model.[10] The operating time depends on whether the operator needs to make repeated attempts, or whether the laryngoscope might be left "on," but an operating time of at least five minutes was required. In this model, after five minutes of continuous operation, the tip temperature had risen to 27°C above ambient temperature, well over the tissue damage threshold.

2.1 *Remote Light Source Laryngoscope*

The alternative is to locate the LED source in the laryngosope handle, attached to a fiber bundle or transparent light pipe, to direct light to the tip. We chose a light pipe as the simplest option, and after experimenting with multimode plastic fiber waveguides, we determined that the optimal design was to construct the entire blade out of acrylic to act as a light pipe. We added a Fraen (Reading, Massachusetts) light injector lens between the LED and light pipe to increase coupling efficiency, and used a curved and tapered shape for the light pipe. The thermal model in Fig. 3 also shows the remote LED configuration, mounted at the base of an acrylic blade. In this model, the power of the LED was increased to 3.9 W to account for light transmission losses (the power level for a high-powered LED flashlight). The model did not include a heat sink for the LED, and so the temperature at the LED rose to 65°C above ambient (confirmed by experimentation). Even so, the calculated temperature distribution shows that there is a negligible transmission of heat to the tip, which remained within less than 1 deg of ambient.

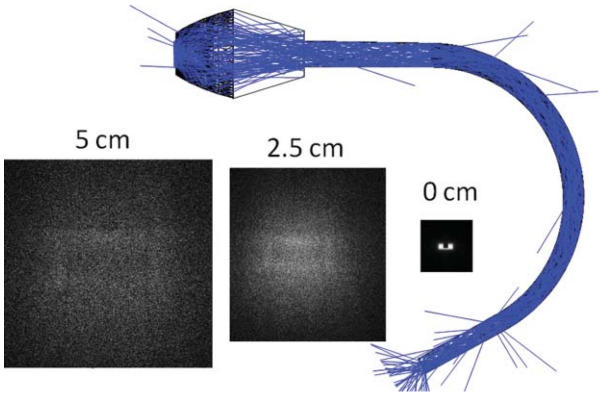

Fig. 4 Optical simulation of light pipe efficiency showing light distribution for several distances from the tip.

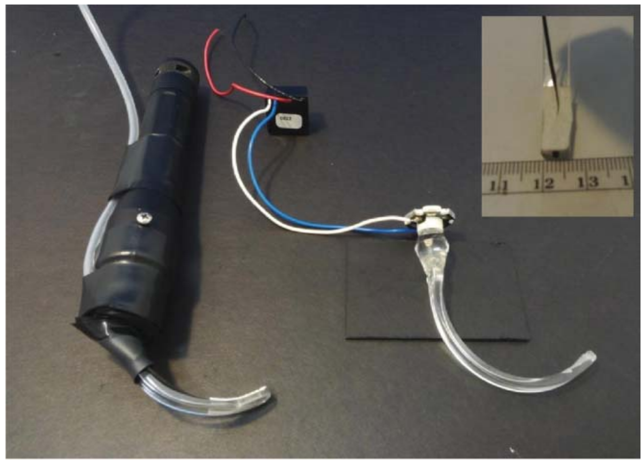

Fig. 5 The full prototype is shown on the left and the LED, lens, and light guide assembly is shown on the right, with the tip shown with a ruler for scale (inset).

It is possible for thermal injury to occur due to more distant parts of the laryngoscope,[11] so future versions of this device would necessarily include additional heat sink material to lower the temperature of any part of the device that could potentially come into contact with the patient. With the remote light source design, the LED is in the handle, making the placement of heat sink material simple.

We created a detailed optical model of the light pipe using Zemax (Bellevue, Washington) ray-tracing software to estimate losses and predict the uniformity of light output. Figure 4 shows the light path of this design, with the inset showing the light distribution at the tip, modeled as a diffuse surface, with a total efficiency of 30%.

2.2 *Prototype Fabrication and Test*

The light pipe was fabricated from an Optix brand acrylic sheet by Plaskolite (Columbus, Ohio). The overall fabrication procedure was determined experimentally. First, the 0.25-in. acrylic sheet was cut to 0.5-in. strips to have the correct aspect ratio. The edges were then sanded and flame-polished with a hydrogen-oxygen torch to be smooth. The blanks were heated for 18 minutes in a 180°C oven. At this point, the blanks were pliable and able to be stretched into a taper, where the center met the size specification. The stretched piece was then set to a mold of cardboard covered with felt to reduce mark-off. After cooling, the blade was cut to the correct length, and then drilled with a groove for the placement of the camera.

The finished blade was attached with Norland (Cranbury, New Jersey) optical adhesive to the Fraen lens. We used an Inova (Boulder, Colorado) X0 LED flashlight as the basis for the device, providing both the LED and the handle. The full device is seen in Fig. 5. The light distribution was bright enough, and covered a wide enough field of view ($\mathrm{NA} = 0.6$). We measured actual efficiency at 22 to 28% due to minor surface defects and variability in the fabrication process. Figure 6 shows the light distribution at 1 cm, both simulated and measured.

This device worked well in the optics laboratory, but went through several designs based on feedback from medical personnel. The first prototype featured a straight blade at a 90-deg bend, emulating the Miller blades typically used with ELBW infants. However, the non-line-of-sight nature of the video laryngoscope opened up new design opportunities. Rather than needing to maintain an angle where the clinician can directly view the larynx by pulling up on the handle, the blade is designed with a curved shape to allow for the anterior placement of the infant larynx. During intubation, the endotracheal tube is supported with a stylet (vinyl-coated wire) that helps the clinician guide it to the larynx and which is removed as the tube is inserted. This wire is bent into a curved shape suitable for the current patient. Therefore, a more curved blade shape was possible, and after several iterations we ended with a prototype blade with the 130-deg angle shown in the earlier illustrations. The overall curve is similar to a Macintosh blade, but this design has no sharp curves. The cross section of the device is compared to a

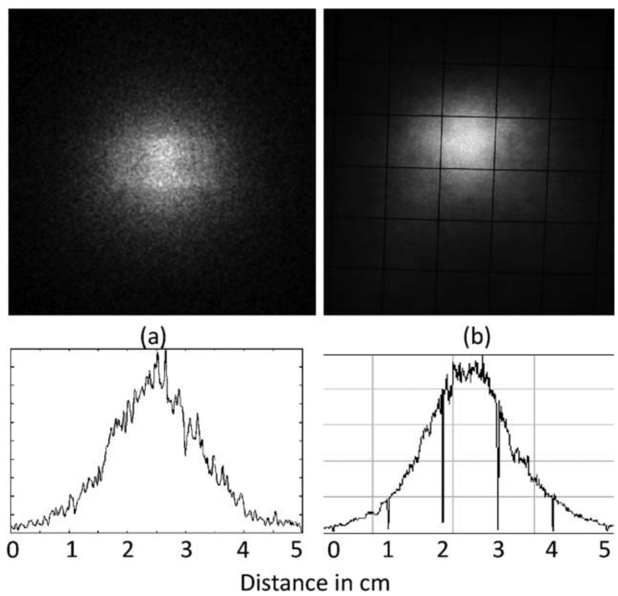

Fig. 6 (a) Simulated and (b) measured light distribution over a 5×5-cm area at 1-cm distance.

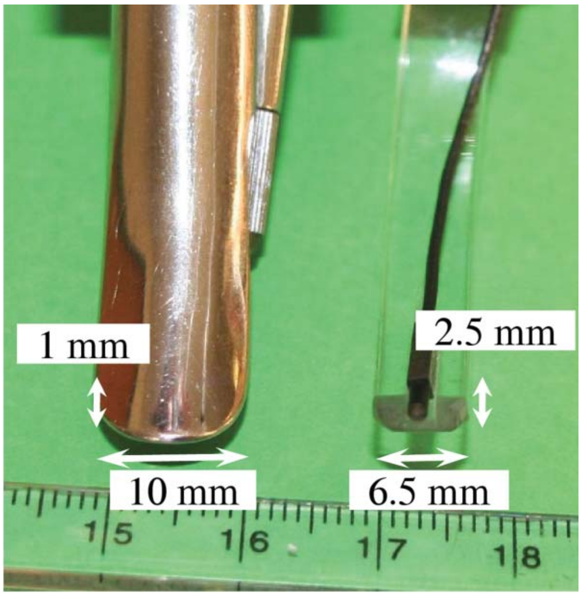

Fig. 7 Prototype blade compared to Miller 00 blade.

Miller 00 blade in Fig. 7. While the Miller blade is thinner, it is also much wider. It is also important to note that the 1 mm thickness is curved, with a total depth of 3.5 mm.

Evaluation was done with a Premi-Blue Neonatal Simulator infant manikin (Gaumard, Miami, Florida), as shown in Fig. 8. This manikin was chosen because it emulates the difficult airway of a very preterm infant. The standard Miller 00 blade and a 2.5 endotracheal tube completely fill the airway, preventing direct visualization. About 20 operators attempted intubation using the prototype device. The final, curved prototype laryngoscope allowed for rapid and sure intubation on the infant manikin. The blade as a light guide design provided sufficient illumination without tip heating, and the acrylic blade was physically strong enough to keep the tongue out of the way for the procedure, helped by a textured lower surface. With the camera 1 cm from the larynx, the monitor-displayed image was more than 20× actual size. Each operator evaluated the view to be comparable to those achieved by commercial video laryngoscopes.

Fig. 8 The prototype being used to intubate an infant manikin.

3 Future Direction

Our working prototype of a neonatal laryngoscope, made using readily available components, served its purpose as an initial working model to verify the utility of a video laryngoscope for ELBW neonates. However, the Medigus camera used in the prototype leads to a high system cost. This was judged to be a barrier to manufacture and widespread deployment of such specialized instruments. However, extremely low cost microimagers are being mass produced for cellphones and other consumer products.

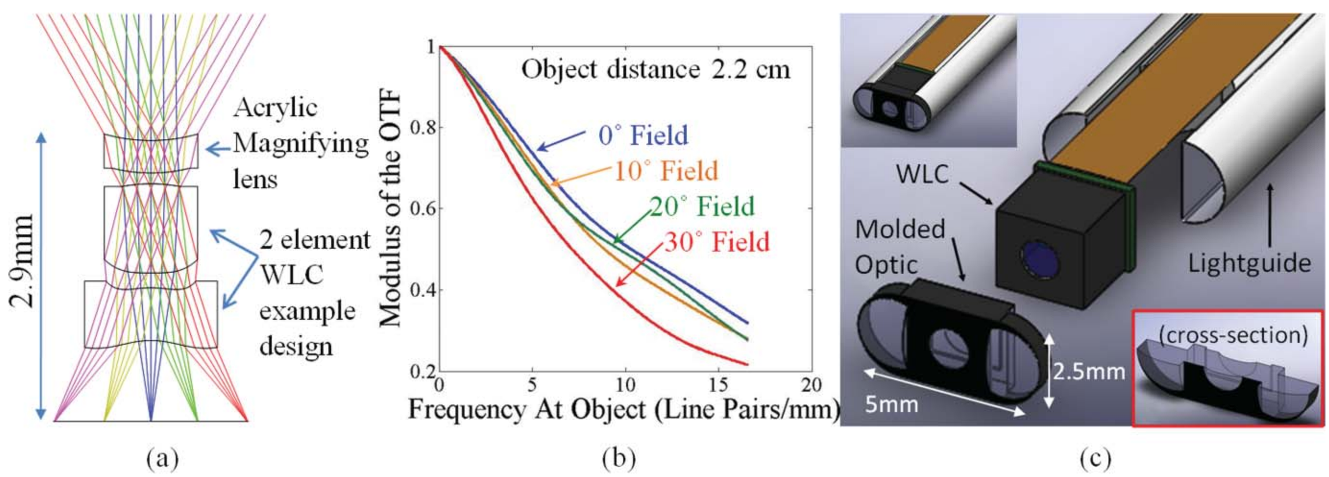

Fig. 9 (a) Raytrace diagram and (b) MTF for the modified WLC imager. (c) Shows the conceptual drawing of the entire laryngoscope tip, including the WLC, light pipe, and molded optic.

Wafer level cameras (WLCs) are microimagers where multiple lens elements are fabricated on wafers, stacked and fused onto a wafer containing the complimentary metal-oxide semiconductor (CMOS) image sensors, then finally diced into individual cameras for surface mounting onto ribbon connectors. This reduces both the manufacturing costs and footprint of the complete device without reducing performance.[12] WLC systems can also allow for advanced functions such as stereoscopic vision through the use of two cameras.

As the last step in this project, we wanted to design a WLC-based neonate laryngoscope. Currently available WLC imagers are wide angle cameras designed to operate at long object distances (several meters), and the nature of the process makes it prohibitively expensive to customize a microimager to work at the short (centimeter) object distances we require. However, the working distance of a wide angle imager can be reduced by adding a single element in front of the long-distance imager. Figure 9(a) shows the layout and performance of a two-element WLC lens with the addition of a single molded aspheric lens, with both the magnification and focus adjustment needed to bring the object working distance from infinity to approximately 2 cm for the WLC.

These preliminary optical simulations indicate that the wavefront aberrations introduced by the aspheric magnifying lens are low enough to maintain the standard resolution of the WLC at the short working distance. A 0.3-mm-thick magnifying acrylic singlet lens with aspheric curvature on both sides will introduce 0.015 waves root mean squared (RMS) of aberration on axis, 0.023 waves RMS of aberration at 50% field, and 0.089 waves RMS of aberration at the full 60-deg field of view of a WLC camera. A well-aligned magnifying singlet will introduce less than 3% reduction in MTF over the full field at 56 cycles/mm (1/4 Nyquist for 2.25 μm pixels). Negligible loss of relative illumination and no change in distortion can easily be achieved. The simulated MTF shown in Fig. 9 compares favorably to the measured MTF of the prototype device. The change from an f/5.99 lens to an f/2.8 lens increases the light sensitivity of the imager by a factor of 4.5, and a lower power LED can be used.

Figure 9 also shows how the overall mechanical system can be integrated. Just as in the current prototype, the electrical connection for the imager runs along the light pipe. Here, the asphere for the imager is molded into a cover that also incorporates lenses to shape the output light distribution from the light pipe. The overall tip has a 2.5×5-mm cross section. This approach may provide a short-term path to affordable neonate laryngoscopes.

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