RESEARCH ARTICLE

Convex and Concave Model 3D Printing for Designing Right-side Bronchial Blocker for Infants

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Abstract: It is technically challenging for pediatric anesthesiologists to use bronchial blocker (BB) to isolate the lungs of infants during thoracoscopic surgery. Further, BB currently sold in the market cannot match the anatomical characteristics of the infants, especially on the right main bronchus. It may easily cause poor exhaustion of the right upper lobe, which leads to interference with the thoracoscopic surgical field. The two dimensional reconstruction data of 124 normal infants' airways were extracted from the medical image database of Beijing Children's Hospital for statistical analysis. After using linear fitting and goodness-of-fit test, a good linear relationship was detected between infant age and various parameters related to aid in designing a new BB for infants (R^2=0.502). According to the growth and development rate of infants, the DICOM files of airway CT scan of 7 infants aged 30, 60, 90, 120, 180, 270, and 360 days were selected to print non-transparent convex and transparent concave 3D models. The non-transparent convex model was precisely measured to obtain the important parameters for BB design infants only, to complete the design of BB, to generate the sample, and to verify the blocking effect of produced sample in transparent concave three-dimensional (3D) model.

Keywords: Three-dimensional printing; Infant; Bronchial blocker; Airway management

1. Introduction

When animal experiments fail to satisfy design requirements or the clinical trials are hard to conduct, 3D printing can aid in designing medical devices and consumables[1-4]. For example, during an infant's thoracoscopic surgery, it is required to block the bronchus and collapse the lung of surgery side to generate a full operation field for the operator. However, it is problematic for animal models to express these delicate operations. Our 3D printing model will fully display bronchi in practice to provide reference and guidance for designing

new-style bronchial blocker (BB)[5,6]. Nevertheless, the BB currently sold in the market cannot nicely match the anatomical characteristics of the infants. The BB is an important medical consumable for airway management during thoracoscopic surgery and general anesthesia in infant patients. BB can block the bronchi of the surgical side and prevent the contamination of the healthy lung tissues by blood secretions or tumor cells from the surgical side of the lung. In addition, it may help to drain residual air from the surgical side of the lung.

There are three key points to consider when designing BB. First, the transverse diameter (TD) of the

inflatable cuff of BB infants only determines that BB can enter and seal the bronchus[7]. Second, the longitudinal diameter (LD) of cuff may protect the right upper lobe (RUL) opening without obstruction[8]. Finally, the length of the catheter body (LCB) needs to suit the infant's airway anatomy[9]. If it is too long, it is rather difficult to control and if it is too short, it cannot reach the bronchus. Therefore, how to obtain the above-mentioned measurement data are a crucial technological issue of this study (Figure 1).

The strategy to measure infant's airway parameters under two-dimensional (2D) CT scan airway reconstruction is to select the section with the greatest and clearest tracheobronchial view for measurement[10]. Nonetheless, this section may not be the perpendicular section of the airway. Due to the position of the infant, the measurement value may be too large. At the same time, comparatively small measurement data, such as TD and LD, and computer software point measurement are relatively susceptible to manual measurement error (Figure 2)[11]. Similar measurement problem may also affect three-dimensional (3D) airway reconstruction[12].

The common non-transparent convex 3D printed model can measure these anatomical data with comparatively high accuracy and facilitate accurate

measurements repeatedly (Figure 3)[13]. These are indispensable parameters for the design of the inflatable sealing cuff for BB infants only although it can be costly when more cases are measured. Furthermore, the non-transparent convex 3D printing model cannot reflect the internal conditions of trachea and bronchus and the actual sealing effect of the sample cannot be verified. Hence, the goal of this study is to apply 3D printing technology to design new BB for infants in a more accurate and efficient manner.
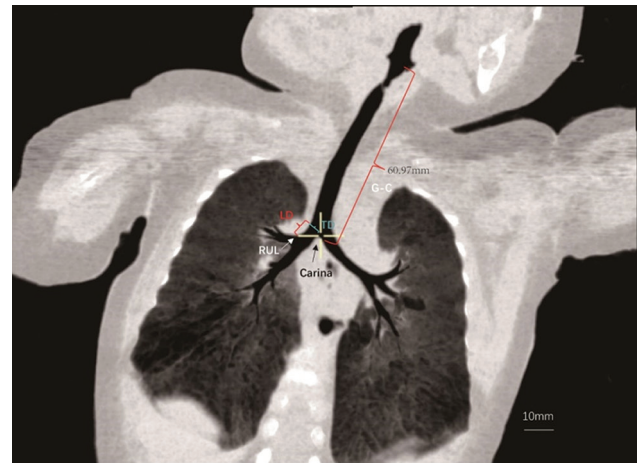

Figure 2. The strategy of measurement using airway CT scan on infants. Abbreviations: TD, transverse diameter; LD, longitudinal diameter; LCB, length of the catheter body; RUL, right upper lobe.
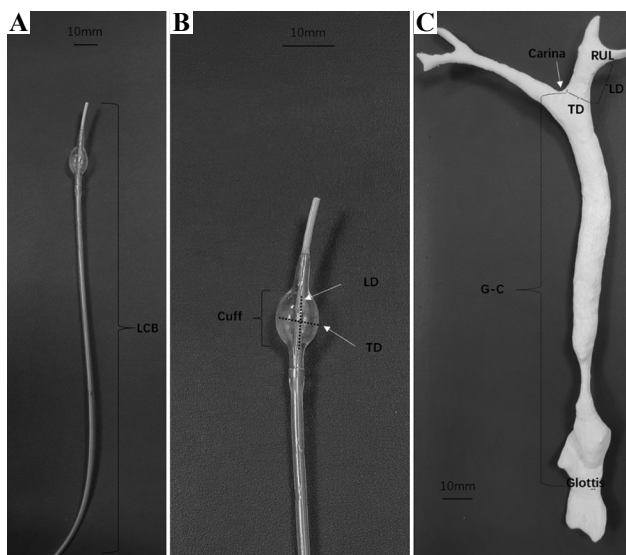

Figure 1. Key points to designing bronchial blocker. (A) The catheter body of BB infants only on trial-produced sample. Abbreviation: LCB, length of the catheter body. (B) The inflatable cuff of BB infants only on trial-produced sample. Abbreviations: TD, transverse diameter; LD, longitudinal diameter; Cuff, inflatable cuff of BB). (C) Locations of important design parameters in a 3D printed airway model. Abbreviations: LCB, length of the catheter body; RUL, right upper lobe; G-C, distance from glottis to carina, LD. To match up with distance from upper margin of right upper lobe opening to carina; TD, to match up with the diameter of the right main bronchus.
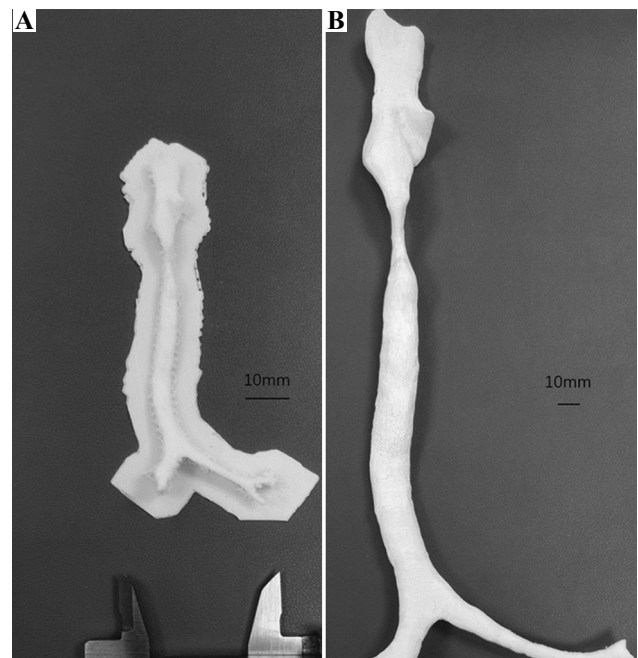

Figure 3. Common convex 3D printing models of airway of an 1-month-old infant weighed 5 kg. (A) 3D printed 1:1; (B) 3D printed 1:3.

2. Methodology

2.1. The research strategy of this study

We confirmed that the research involving experiments on human subjects met the ethical standards of the Helsinki Declaration in 1975. The research was approved by the Ethics Committee of Beijing Children's Hospital, Capital Medical University. All infants' parents had informed and signed the consents. First-two-dimensional CT airway reconstructions of 124 normal infants (non-premature) aged 5–390 days were selected from Beijing Children's Hospital medical image database. The following key data are measured under a computer program: (i) TD: The diameter of the right main bronchus for designing TD of inflatable cuff; (ii) LD: The distance from the upper margin of RUL opening to carina for designing LD of inflatable cuff; and (iii) G-C: The distance from glottis to carina for determining length of the catheter body. Second,

data analysis was performed to look for probability centers with the aid of normal distribution by age and body weight. The cases nearest to the mean value in each subregion were selected. These overlapping cases are the target cases for convex-concave 3D printing. Finally, the transparent concave 3D models were precisely measured to obtain the important parameters for BB design infants only, to complete the design of BB, to generate the sample, and to verify the blocking effect of produced sample in transparent concave 3D models (Figure 4)[14].

2.2. Statistical analysis of data: Linear fitting and goodness-of-fit test

Multivariate analysis was used to identify correlations between the continuous numeric data[15], including the association between the sex, age, weight of the patient and GC, TD, and LD of their CT airway reconstructions. Standard least squares regression was used with log transformation[16,17].
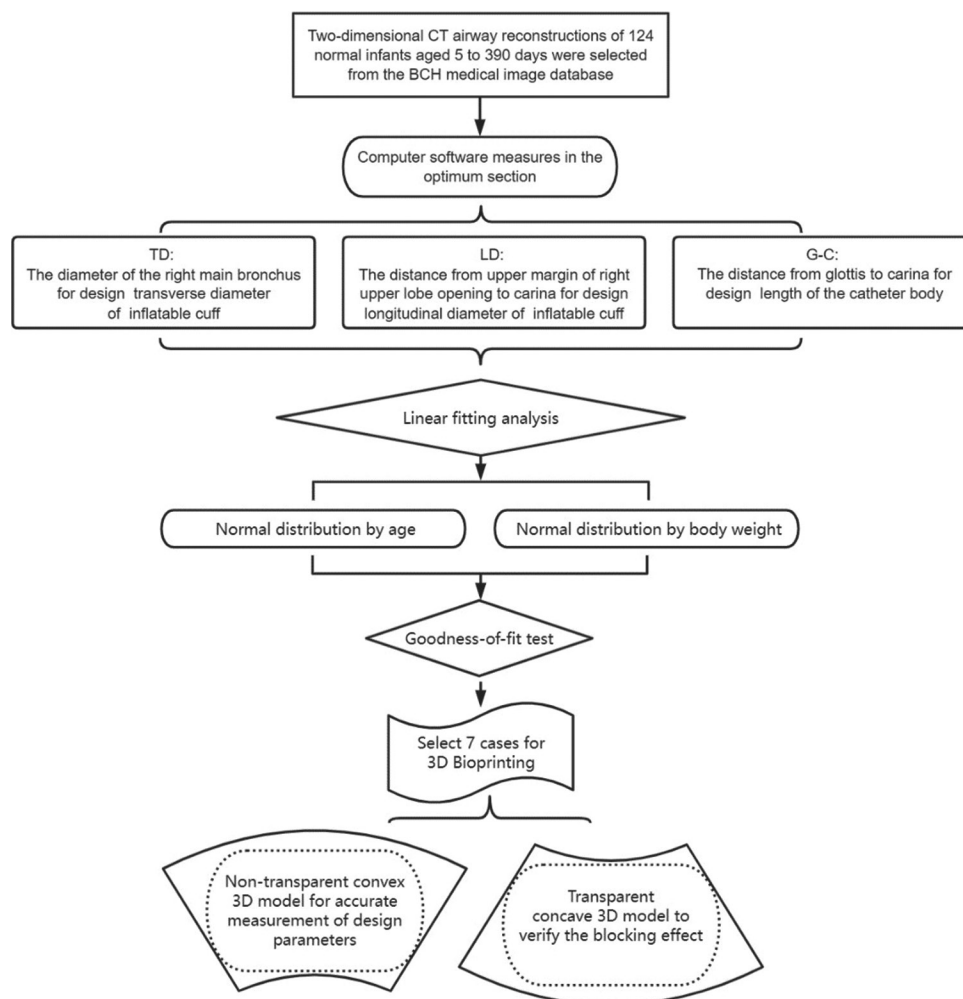

Figure 4. The research strategy of this study.

2.3. The 3D model printing of infant's airway

The 3D printing data came from DICOM files of CT scan[18]. According to the growth and development rate of infants[19], the DICOM files of airway CT scan of 7 infants aged 30, 60, 90, 120, 180, 270, and 360 were selected from the medical image database of Beijing Children's Hospital. The slice thickness was 0.625mm and the pixel spacing was 0.4883 mm. The model was set in the center of the printer platform. The settings were as follows: (i) Print nozzle diameter was set to 0.2 mm; (ii) print height was set to 0.1mm; (iii) the wall thickness was set to 2 mm; (iv) the bottom thickness was set to 1 mm; (v) the filling density was set to 50%; (vi) print speed was 10.0mm/s; (vii) the nozzle temperature was set to 20°C; (viii) the support type was set to floor support; and (ix) the model size ratio was set to 1:1. The set slice file is saved in G-code format and printed. The printing material of convex models polylactic acid (PLA) with a diameter of 1.75 mm and fused deposition modeling (FDM) was used to obtain the required model. After printing, the model was processed by removing support, polishing, and smoothing. SLA laser curing layer printing was adopted in concave models printing, the material was transparent resin, the printing resolution was 0.01mm, and the molding speed was 100g/h[20,21].

"Convex" is the 1:1 3D models of the external contour of the infant's airway, reflecting the actual size of the infant's trachea and bronchi. Convex models can contribute to the design of the size and length of the inflatable cuff by more accurately measuring the key dimensions and sizes of the infant's convex airway models. "Concave" refers to the printing of the infant's airway inner cavity which simulates the real size of the infant's trachea and bronchial cavity structure, and is used to test and verify the compatibility between the new-style infant's BB designed in this study and tracheobronchial inner cavity of infants.

FDM printing (using PLA for convex models) is more economic and faster than SLA printing with highly transparent photosensitive resin. The most important role of the convex model is to measure and to reflect the external contour of the infant's airway for research purposes. Using FDM printing helps save money and printing time[20,21]. Nevertheless, SLA printing with highly transparent photosensitive resin is used in the concave models to enable a more direct view of the blocking state of the new-style BB inside the airway and to assess the sealing effect. Therefore, it is worth spending more research, financial support, and time on this printing model.

This study had entrusted a qualified medical catheter manufacturer (Shenzhen Medoo Medical Tech. Co., Shenzhen Guangdong, China) to produce trial-produced BBs. The body of BBs catheter material is nylon 11 with characteristics including light weight, corrosion resistance, not easy to fatigue cracking, good sealing, and small resistance. The soft inflatable cuff material is thermoplastic elastomer, which is a type of polymer material with both rubber and thermoplastic properties. It exhibits high elasticity of rubber at room temperature and can be plasticized at high temperature.

3. Results

3.1. Correlations between the continuous numeric data

A single-level liner model showed a higher value in the R^2 of G-C (0.456 vs. 0.330), TD (0.206 vs. 0.175) and LD (0.170 vs. 0.160) of the age, compared with the weight (Figure 5). The regression equation showed an R^2 of 0.47, 0.23, and 0.19 in the multivariate model of G-C, TD, and LD, respectively. With the log values of the predictors as shown in Table 1, age was a significant predictor of G-C (logworth 6.48, $P < 0.05$) and TD (logworth 1.78, $P < 0.05$). However, weight was not a significant predictor for all three models (logworth 0.13, 0.37, and 0.423, $P > 0.05$) (Figure 5 and Table 1).

3.2. The non-transparent convex and transparent concave 3D printing models of infant's airway

According to the growth and development rate of infants[22,23], the DICOM files of airway CT scan of seven infants aged 30, 60, 90, 120, 180, 270, and 360 days were selected to print non-transparent convex and transparent concave 3D models (Figure 6).

3.3. The important parameters for designing BB infants only from measuring convex 3D models and CT scan image

The important parameters for designing BB infants only were obtained from measuring convex 3D models and CT scan image. G-C (Distance from glottis to carina for designing the location of barycenter on BB) is 70.347 ± 6.254 mm, TD (TD to match up with the diameter of the right main bronchus) is 5.189 ± 1.036 mm (n = 7). LD (LD to match up with distance from upper margin of RUL opening to carina) is 6.325 ± 1.725 mm (n = 7) and T-G (Distance between incisor teeth and glottis) is 44.580 ± 3.698 mm (n = 124) (Figure 7).

3.4. The trial-produced sample of BB infants only in a concave 3D printing model

According to the important design parameters mentioned above, the samples of BB infants only were successfully trial-produced. In the sample, the inflatable cuff is equipped with a LD of 6 mm and a TD of 5 mm. The wall of cuff has the adaptability of 25% expansion to adjust to the individual differences of different infants. Meanwhile, the barycenter of the BB should be 120 mm away from the distal end of the catheter (Figure 8).
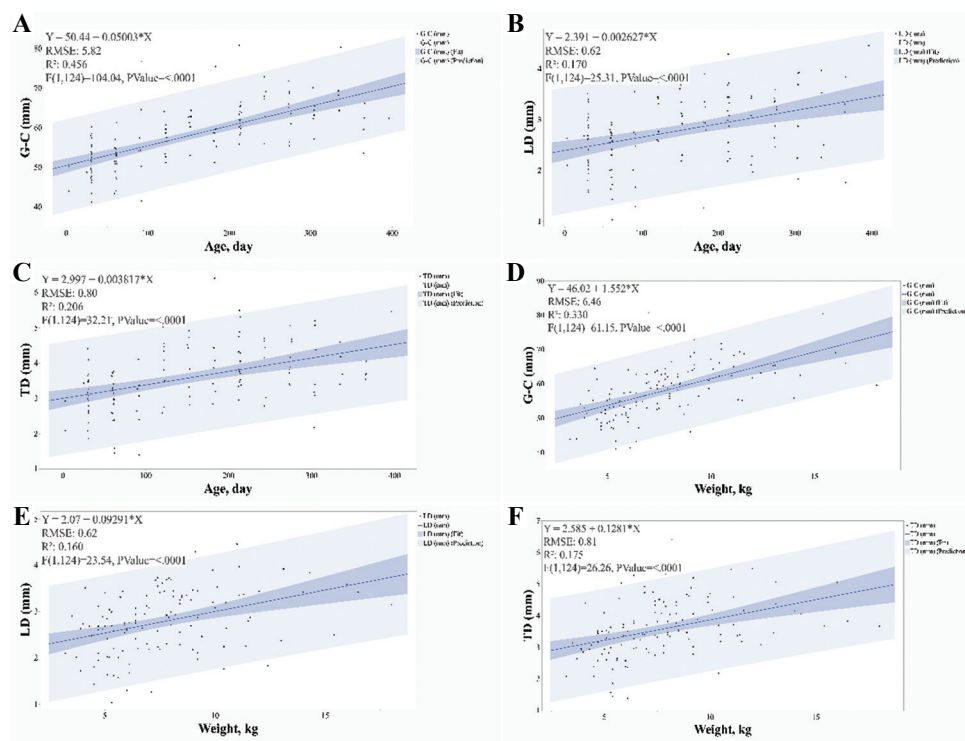
Figure 5. A single-level linear model of G-C, TD, and LD of age and weight. (A) The single-level linear model of G-C of age. (B) The single-level linear model of TD of age. (C) The single-level linear model of LD of age. (D) The single-level linear model of G-C of weight. (E) The single-level linear model of TD of weight. (F) The single-level linear model of LD of the weight. Abbreviations: G-C, distance from glottis to carina; TD, transverse diameter; LD, longitudinal diameter.

Table 1. Multivariate analysis of sex, age, and weight of the patient as well as G-C, TD and LD

Dependent variable	Independent variable	Coefficient	LogWorth	*P*	R²	Adjusted R²	RMSE
G-C* (mm)					0.47	0.46	5.78
	Sex	1.06	1.23	0.059			
	Age (day)	0.05	6.48	0.000**			
	Weight (kg)	0.11	0.13	0.734			
TD* (mm)					0.23	0.22	0.79
	Sex	0.14	1.202	0.06286			
	Age (day)	0.00	1.779	0.01662*			
	Weight (kg)	0.03	0.37	0.42661			
LD* (mm)					0.19	0.17	0.62
	Sex	0.05	0.646	0.3772			
	Age (day)	0.00	1.117	0.0763			
	Weight (kg)	0.04	0.423	0.2257			

G-C*, distance from glottis to carina (mm); TD* (transverse diameter), to match up with the diameter of the right main bronchus (mm); LD* (longitudinal diameter), to match up with distance from the upper margin of the right upper lobe opening to carina (mm). *$P<0.05$, **$P<0.01$

3.5. Verification of blocking effect of the trial-produced sample of BB infants only in the concave 3D printing model

The concave 3D printed models were used to verify the blocking validity of the trial-produced sample. The inflatable cuff of BB was placed between the opening of the RUL of the right main bronchus and the carina, simulating the situation of the right lung isolation during thoracoscopic surgery in infants. After inflation of cuff, ink was added into the concave 3D printed bronchial model to observe whether there was a serious leakage of the inflatable cuff and whether it blocked the RUL opening at 0, 15, 30, 60, and 120 min. The experiment demonstrated no visible leakage at 15 min, and slight leakage at 30, 60, and 120 min. A silk thread through the
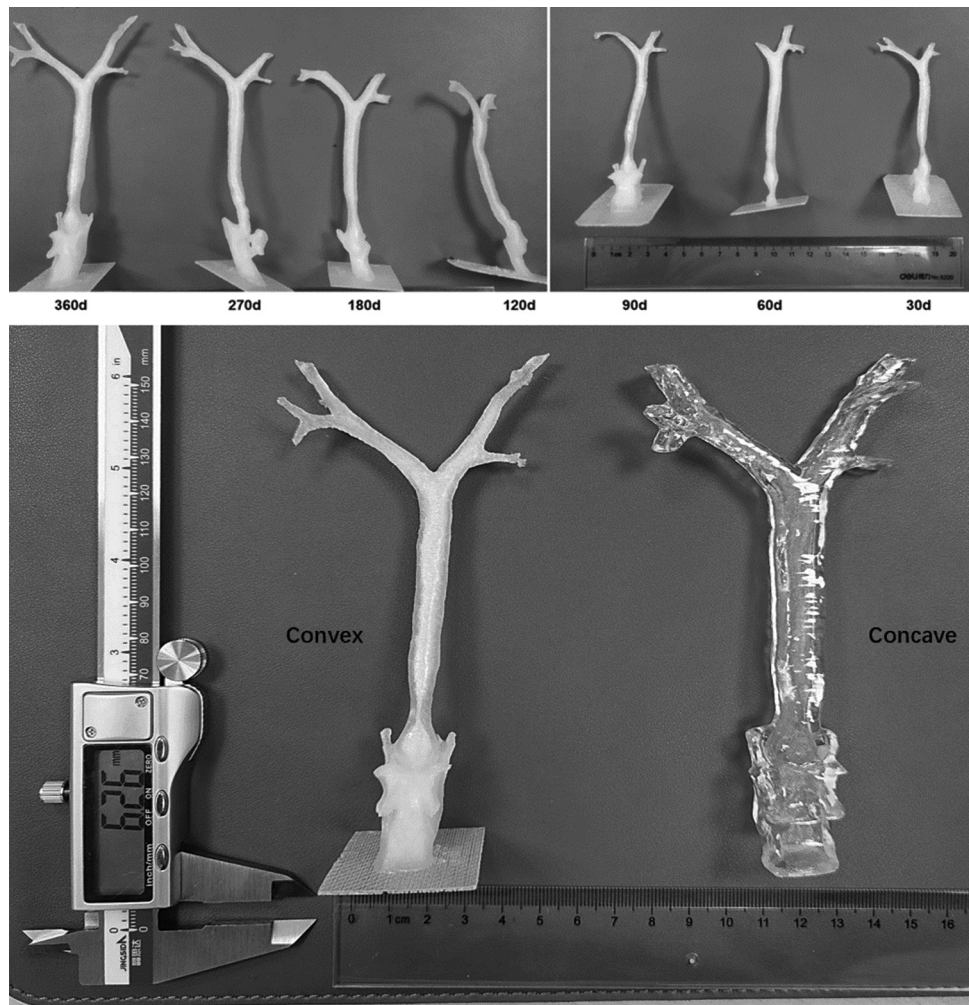
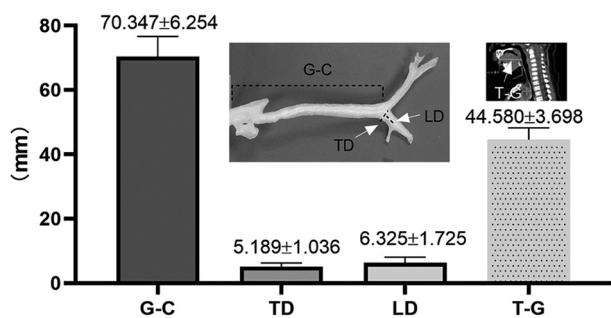**Figure 6.** The convex and concave 3D printing models of infant's airway.

Figure 7. The important parameters for designing BB infants only from measuring convex 3D models and CT scan image. Abbreviations: G-C, Distance from glottis to carina for designing the location of barycenter on BB; transverse diameter, to match up with the diameter of the right main bronchus (mm); longitudinal diameter, to match up with distance from the upper margin of the right upper lobe opening to carina; T-G, distance between incisor teeth and glottis.
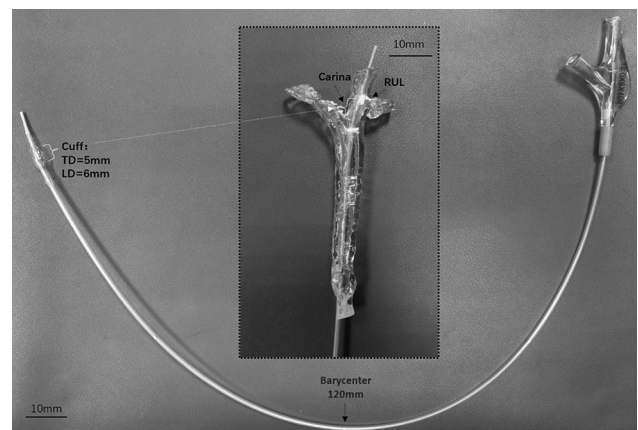
RUL opening of the concave 3D printed model was used to confirm that it is unobstructed (Figure 9).

Figure 8. The trial-produced sample of BB infants only in a concave 3D printing model.

4. Discussion

The difficulty in designing the right bronchus for infants lies in how to attain more realistic anatomic data of the
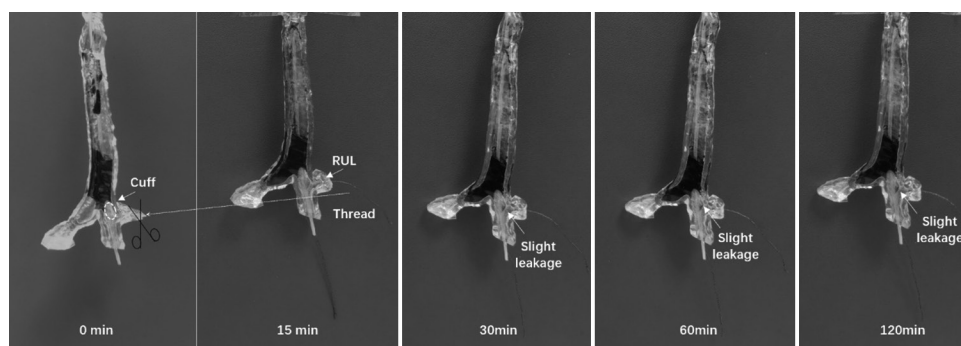
Figure 9. Verification of blocking effect of the trial-produced sample of bronchial blocker infants only in the concave 3D printing model.

infant bronchus. One of the approaches to solving this issue is computer measurements in 2D or 3D reconstruction of the infant's normal CT scan airway[24,25]. This method is comparatively reliable in measuring long distances, such as incisor teeth to glottis (T-G) and glottis to carina (G-C). Nonetheless, when measuring small anatomical structures, such as the distance from the opening of the RUL to the carina (LD) and the inner diameter of the right main bronchus (TD), the measurement error tends to be relatively larger. High-precision 3D printing based on CT scanning DICOM files and repeated measurement of 3D printed models can provide more realistic measured values[26-28]. However, 3D printing in every case would be expensive and environmentally unfriendly[29].

The findings of this study, illustrated in Figure 5, showed that airway CT measurement parameters of infants were linearly fitted according to the age in days and body weight, accompanied by normal distribution and linear relationship. As shown in Table 1, goodness-of-fit test and linear fitting were conducted according to the age in days, which have a better linear fitting degree[30-32]. At the same time, it was also proven that TD ($R^2 = 0.23$) and LD ($R^2 = 0.19$) of imaging measurements did not reach the corresponding linear fitting degree with G-C ($R^2 = 0.47$), suggesting that imaging measurements may have larger measurement errors in these two small measurement parameters. The next step was to extract typical cases according to the age of the day for 3D printing to obtain more accurate measurement values.

Seven typical cases were selected for 3D printing. The growth and development rate of infants from birth to 120 days is swift[33], and then progressively slows down. Therefore, in the selection of typical cases in this study, the interval of the first 4 months was 30 days, and the patients of 180, 240, and 360 days were selected for 3D printing after 6 months (Figure 6).

Convex and concave 3D models were printed for each typical case (Figure 6)[34,35]. Convex was used for precise measurement of infant airway parameters and the concave was used for validation of samples. As shown in Figures 7-9, the objective was to design a BB with a more suitable anatomical structure that is simpler to operate

and less likely to fall off at the minimum cost for infant patients. These studies are not feasible in animal studies that work with rhesus monkeys[36], and in clinical trials that do not meet ethical requirements[37].

5. Conclusion

3D printing can assist in the design of medical devices or consumables suitable for special populations such as infants. By measuring the parameters obtained from the 3D printed convex models, we determined that the infant's BB adopts a soft low-pressure inflatable cuff with a LD of 6 mm and a TD of 5 mm and has the adaptability of 25% expansion to adapt to the individual differences of different infants. In addition, the barycenter of the BB should be 120 mm away from the distal end of the catheter, so that the barycenter of the catheter should be in the infant's airway as far as possible to facilitate the manipulation, and it is not easy to shift or fall off due to gravity during the operation. We have obtained a Chinese utility patent authorization (ZL 201820428821.9). We tested the effectiveness of the right bronchial occlusion using concave 3D printed models. The test results indicate that the anticipated design requirements are satisfied. However, this research has the following limitations, which need to be addressed in future studies: (i) We were unable to measure the thickness of the infant's tracheobronchial walls with the use of the current facilities and technology; (ii) although the designs of infant BB and intravascular catheter share overlapping material requirements, the safety of infant BB still needs to be carefully evaluated in the next clinical study.

Acknowledgments

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Conflict of interest

There are no conflicts of interest to declare.

Author contributions

X.D. and W.W. are radiologists responsible for gathering DICOM data from pediatric CT scans and taking measurements under computer software. W.M. and F.X. proficiently explore 3D bioprinting technology. Z.M. and X.Z. are overall responsible for pediatric anesthesia management, designed project, and validation.

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