3D models in paediatric ENT: a valuable aid for informed consent and patient reported satisfaction

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Background: Consent is an essential step in the surgical decision-making process. It is not just a professional and legal requirement—when performed properly, informed consent can increase a patient's understanding, satisfaction, and outcomes. Visual aids, in particular three-dimensional (3D)-printed models, are a useful clinical tool used in patient education and counselling, resulting in more effective comprehension and retention. In paediatrics, consent is sometimes challenging but is nevertheless essential, given any planned procedure requires the permission of a parent. To the best of the author's knowledge, this is the first study to explore the utility of 3D-printed models to assist with procedural consent in paediatric otolaryngology—an area which often involves navigating complex anatomy, challenging operations, and parent counselling.

Methods: We describe a case series of three paediatric patients requiring surgery for anatomical abnormalities—with CT scans performed as part of diagnostic work-up and 3D anatomical models fabricated from these images using computer-aided design. Consent was obtained from parents, with patient-specific 3D models used as an educational aid. Five-point Likert-scale questionnaires were completed by parents pre- and post-operatively to evaluate four domains (information, understanding, anxiety, satisfaction).

Results: Overall, in all three cases, the use of 3D models was associated with high ratings in the questionnaires of the surgeon's explanation and information, parental comprehension of disease and anatomy, and overall satisfaction. An improvement was also noted in parental anxiety and understanding when comparing counselling before and after with the 3D model.

Conclusions: 3D-printed anatomical models are a valuable tool for preoperative communication and consent—helping parents visualize their children's disease, improving comprehension, and reducing anxiety. This all contributes to better patient outcomes and satisfaction, particularly in the paediatric population which involves participation of parents/guardians.

Keywords: Paediatric; 3-dimensional imaging (3D imaging); informed consent; patient reported outcomes

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Introduction

Obtaining informed consent is an essential step in the surgical decision-making process. It is not simply a professional and legal requirement. When performed well, informed consent increases a patient's understanding of the surgery and has been shown to improve satisfaction and outcomes (1). Informed consent is defined by the Australian Commission on Safety and Quality in Health Care as a person's decision, given voluntarily, to agree to a health treatment. It is made following provision of accurate and relevant information about the treatment including alternative options, and is made with adequate knowledge and understanding of the risk and benefits of all treatment options (2).

The nature of paediatric surgery presents a unique situation where the consent-giver is usually not the patient. This dynamic can potentially make the consent process challenging, particularly in complex otolaryngological procedures. Complex anatomy and poor public understanding of head and neck anatomy or embryology are just some of the reasons that the consent process is challenging for both surgeons and patients in specific paediatric otolaryngology surgeries. For the patient and surrogate consent-giver to actively participate in the consent process, they need to understand the basics about their condition (3). In these circumstances, visual aids, in particular three-dimensional (3D)-printed models, have been demonstrated to be a useful clinical tool for patient education and counselling, resulting in more effective comprehension and retention (4-6).

3D models are becoming increasingly popular amongst surgical specialties worldwide (7). This is a rapidly developing field of surgery, with several authors already highlighting the benefits of 3D models in pre-operative planning and training (7). These models, whether virtual or physical, have already been widely adopted by otolaryngologists in head and neck reconstruction, intraoperative neuro-navigation, surgical planning, training and patient education (8). However, while several studies have mentioned the benefits of 3D models for patient education and consent in otolaryngology, to the authors' best knowledge, there is no study exploring the utility and effectiveness of 3D-printed models to assist with procedural consent in paediatric otolaryngology. The aim of this study is thus to evaluate the effectiveness and feasibility of 3D-printed models as aids in the informed consent process for complex paediatric otolaryngology procedures.

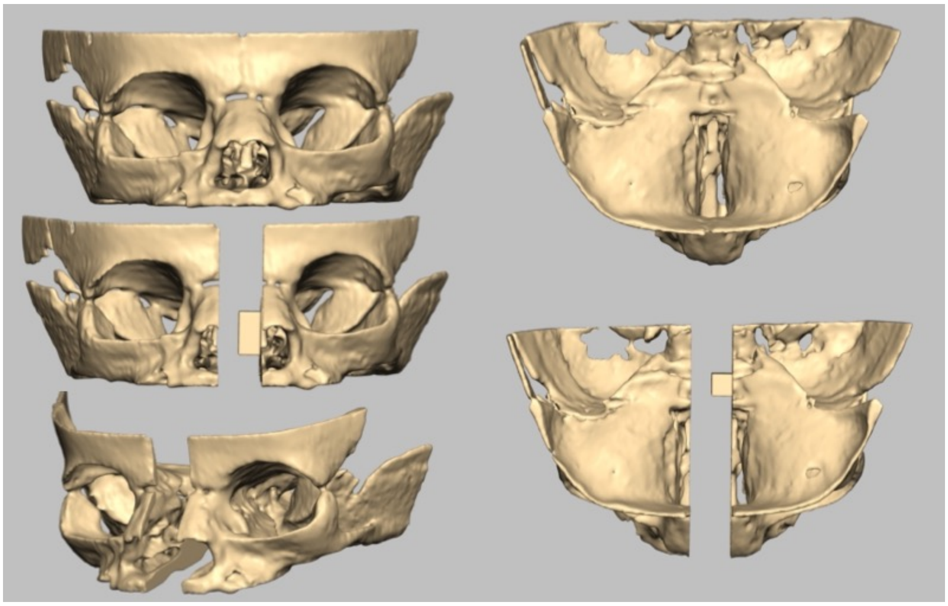
Methods

This study is reported according to the CARE reporting guidelines (available at https://www.theajo.com/article/view/10.21037/10.21037/ajo-24-38/rc). We describe a prospective case series of three paediatric patients requiring surgery for complex structural abnormalities at Perth Children's Hospital. All cases were performed by the same paediatric otolaryngologist who utilised the 3D models during the informed consent process. Images from a CT scan that was performed as part of routine diagnostic work-up were used to create 3D anatomical models using computer-aided design and additive manufacturing processes. This technology allows printing of a structure that can reproduce visuospatial and tactile features of a surgical technique. The models were produced at the point-of-care in a department with an ISO accreditation that encompassed the design and manufacture of medical devices, including 3D-printed models.

The 3D models were all designed using a similar methodology. CT data were processed using the medical modelling software package Mimics (Materialise® NV, Leuven, Belgium). One or more masks was created by thresholding based on Hounsfield units corresponding to the relevant tissue intensity (skull, soft tissue, teeth and teeth buds as necessary). The masks were cropped and manually edited to isolate the anatomical region of interest. A virtual 3D reconstruction of the anatomy was exported from Mimics as a 3D triangulated surface in the STL file format. The STL file was imported into Geomagic® Freeform® Plus (3D Systems, Rock Hill, South Carolina, USA) where it was edited to minimise 3D printing time. Sectioning of the model into parts to enable visualisation of internal structures was also undertaken as required. This cropped model was exported as a 3D triangulated surface in the STL file format.

The models for each case were printed on different 3D printers, reflective of the complexity of the model and the progression in technology between the 3 cases. The design and manufacture of these 3D-printed models at the point-of-care facilitated a rapid turn-around time, with finished models typically being made available to the treating surgeon within one day of the referral. The cost of production for each model varied between A$280 and A$680 depending on the complexity of the model and the printer/material used.

Informed consent for the corrective procedure was obtained from the person responsible, with these patient-specific 3D models used as an educational aid. A five-point Likert-scale questionnaires were completed by parents



Background	Elective C/S, 40^{+1}/40, desaturation + dusky episodes, unable to pass NGT
Dx	Bilateral dacryocystocoeles
Rx	Sinuscopy, bilateral inferior turbinoplasties, marsupialization of nasolacrimal duct cysts
3D model	Fused deposition modelling which creates a model consisting of opaque, hard plastic. The skull was sectioned and printed in two halves, which interlocked. This enabled the surgeon to separate the halves to indicate the location of the dacrocystocoeles and better explain the procedure to the parents

Figure 1 Case 1. Computer design of the 3D model and patient clinical information. 3D, three-dimensional; NGT, nasogastric tube; C/S, caesarean section; Dx, diagnosis; Rx, treatment.

pre- and post-operatively to evaluate the four domains of informed consent (information, understanding, anxiety, satisfaction). Data and figures were tabulated using Mircosoft excel.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and approved by institutional ethics board of the Governance Evidence Knowledge and Outcomes (approval No. 39832). Written informed consent was obtained respectively from the patients' parents for publication of this article and accompanying images

Results

Patient 1

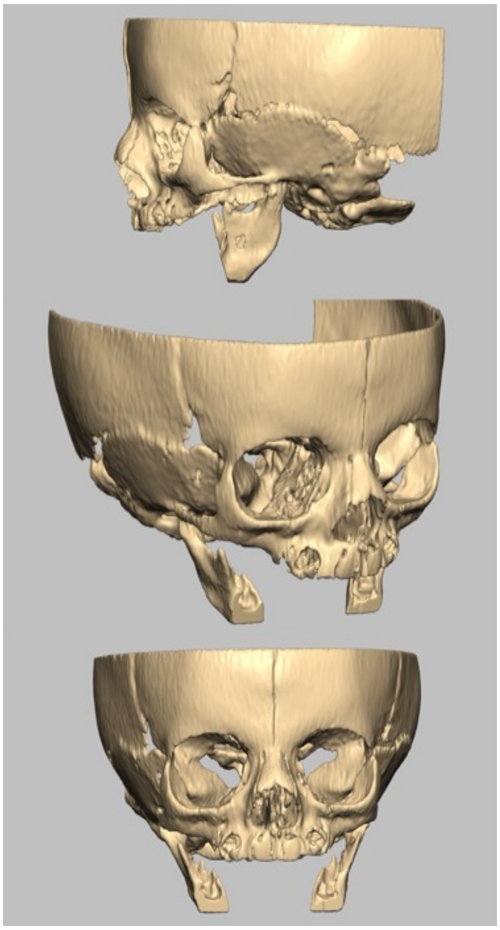
Term baby boy with bilateral dacrocystocele, failing conservative management and presenting with nasal airway obstruction and dacrocystitis. Underwent sinoscopy, turbinoplasty and marsupialization of cyst bilaterally at 2 months of age (*Figure 1*).

Patient 2

A 37^{+1}-week-old girl who required intubation at birth for bilateral high grade choanal atresia, CHD7 negative. Underwent multiple procedures in first month of life including repair of choanal atresia, stent replacements and revision surgery/dilatation (*Figure 2*).

Patient 3

A 6-week-old boy with nasal pyriform aperture stenosis. No genetic condition or other abnormalities identified. Underwent sub-labial approach to repair of pyriform



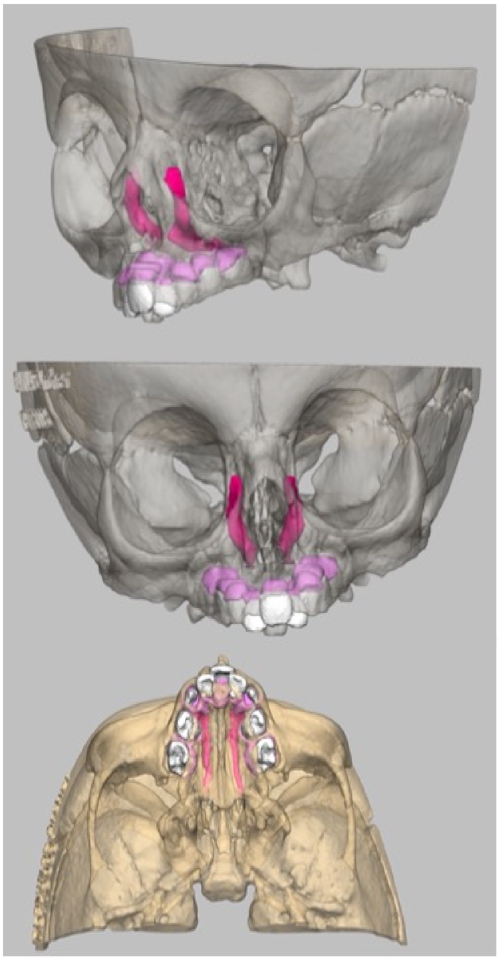
Background	SVD at $37^{+1}/40$, stridor, poor APGAR requiring intubation followed by CPAP
Dx	Bilateral high-grade choanal stenosis
Rx	Initially, open repair of choanal atresia, followed by EUA nasopharynx & stent replacement, and then a revision/dilatation
3D model	Fused deposition modelling as per patient 1. This model was suitable for explaining the procedure to the parents, and also allowed the surgeon to test which instruments would enable access to perform the require procedure

Figure 2 Case 2. Computer design of the 3D model and patient clinical information. 3D, three-dimensional; SVD, spontaneous vaginal delivery; APGAR, appearance, pulse, grimace, activity, respiration; CPAP, continuous positive airway pressure; EUA, examination under anaesthesia; Dx, diagnosis; Rx, treatment.

aperture stenosis and bilateral turbinoplasty and balloon dilatation of nasal cavity. He had a prolonged hospital stay post operatively due to parental concern regarding discharge home with the nasal stent *in situ* (*Figure 3*).

Questionnaire outcomes

In all cases, the use of 3D models was associated with the highest ratings in the questionnaires for satisfaction of the information provided and value of the 3D models. The high rating of satisfaction did not change between the pre-operative and post-operative results. There were high to highest rating of the surgeon's explanation, information and parental comprehension of disease and anatomy. All parents or guardians also reported an improvement in parental anxiety when comparing counselling before and after with



Background	Elective C/S, 38/40, inpatient desaturations, referred to ENT at 6-week-old with 'snuffly' breathing
Dx	Piriform aperture stenosis
Rx	Sinuscopy, inferior turbino-plasties, marsupialization of nasolacrimal duct cysts
3D model	A more advanced 3D printer (PolyJet printer—prints in multiple materials) was used for this case. The model consisted of the skull/ facial bones, ducts, teeth and tooth buds in different colours. This enabled visualisation of the relevant anatomical structures

Figure 3 Case 3. Computer design of the 3D model and patient clinical information. 3D, three-dimensional; C/S, caesarean section; ENT, ear, nose and throat; Dx, diagnosis; Rx, treatment.

the 3D model. *Figure 4* shows the tabulated results of the survey. Further statistical analysis was not performed due to limited case numbers.

Discussion

Industrial 3D printing, also known as additive manufacturing, has existed for over four decades (9). There have been significant advances since its introduction, and there are now various materials and applications for its use within and outside of the field of medicine (9). In the field of surgery, the main applications of additive manufacturing are rapidly expanding and a number of applications have been successfully validated (9,10). Indications include pre-

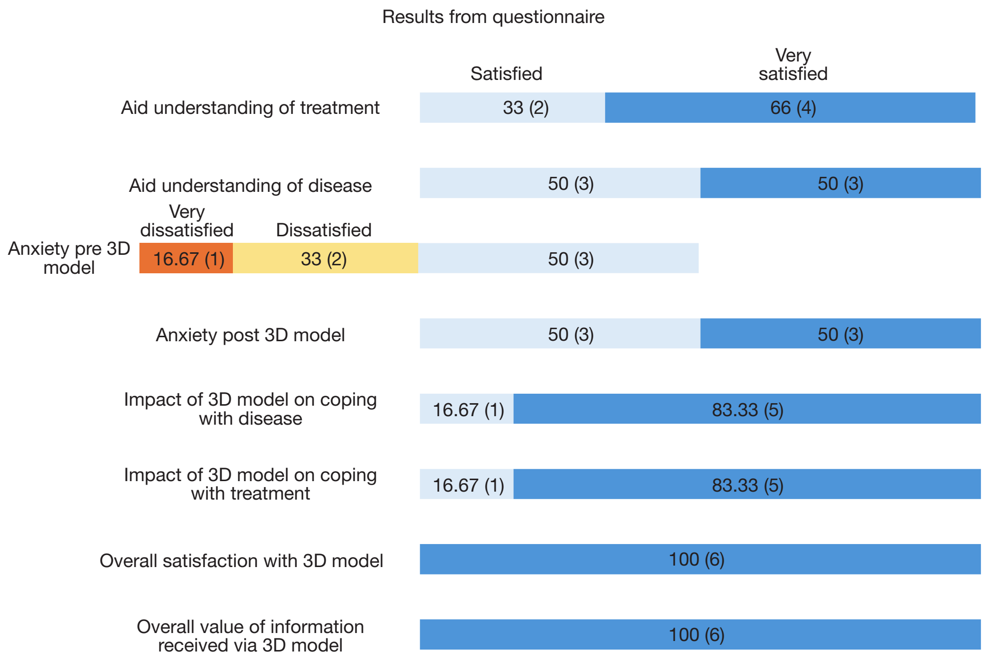


Figure 4 Patient reported outcomes on the impact of the 3D model on different aspects of their care. Data are presented as % (raw number). 3D, three-dimensional.

operative planning, patient communication, training, and intraoperative navigation (10). Furthermore, since its development, 3D printing has become significantly more accessible and affordable for use in healthcare (11).

The use of 3D printing in otolaryngology is gaining popularity. A recent systematic review identified 121 papers that focused on the implications of 3D printing in otolaryngology and head and neck surgery (12). The vast majority of studies focused on surgical planning and pre-operative education (12). In paediatric otolaryngology, 3D printing was historically first used as a training tool for placement of tracheobronchial stents (13,14). Since then, the uptake of 3D models is now used across all subspecialties of otolaryngology. However, the use of these models as a communication aid during the consent process has not been formally investigated in otolaryngology, hence the purpose of this study.

The nature of paediatric surgery makes informed consent more challenging and thus the use of an effective aid will improve understanding and reenforce the trust between parents and otolaryngologist. 3D models have been shown in other surgical specialties to aid patient care. In paediatric cardiology, Karsenty *et al.* found a significant reduction in parental anxiety with the use of cardiac printed models (14,15). In our series, the 3D models were also well received by patients and their families. All patients consent-givers gave the highest score for satisfaction with the use of 3D models. This high score was maintained on the repeat questionnaire post operatively in all patient surveys, indicating that the benefits persisted with time. This suggests the overwhelming positive feedback patients give on the 3D models is not due to novelty but rather a true benefit to their care. With regards to the domain of anxiety, all patients responded favourably to the use of models alleviating their worry when comparing their scores before and after the use of the model. Anxiety can play a significant role in paediatric surgery, particularly operations of the head and neck. Parents are commonly worried about how surgery to this area will impact growth, appearance and function of their child. Not understanding the function and development of these complex anatomical areas may further add to the stress they feel. These models allow the surgeon to explain the operation in great detail, including the approach, anatomy of growth plates and vital structures. They also are simple tools that quickly allow parents to visualize and better understand the disease, treatment plan and even the post operative care.

In addition to the benefits enjoyed by the patients, there were several benefits noted by the surgical team when using the models. Traditionally, surgeons may have utilized medical imaging or diagrams to guide patients through the surgery. This can be difficult for patients to visualise. The ability to separate the 3D model into multiple pieces to reveal the inner anatomy is of particular relevance to otolaryngologist. Operating on areas that are not remotely familiar to the lay person is well exemplified in our 3 cases. We found that by doing so, we were able to better explain the rationale behind not only the surgery, but also the surgical approach and disease manifestations. Overall, this reduces consultation time and facilitates the trust patients have in their surgeon and care. While the option of using 3D computer animation exists without physically printing the models, there are several reasons to explain why animations may be inferior to models. Animations do not allow a clinician to handle and physically interact with the model. Equally, from a patient's perspective, interaction with a tangible object greatly enhances communication and understanding of complex surgical discussions. Furthermore, it is worth noting that the cost of the initial design step in the production of a 3D printed model is actually comparable to generating a computer animation. Future studies comparing animations to models may assist with our understanding of this technology and its efficacies.

Finally, it is important to consider potential drawbacks of 3D printed models. Cost may influence the adoption and uptake of this technology. Cheaper models may have limitations including only producing single-colour and not being sterilisable. Despite this, these limitations might not impact their utility as pure aids for patient informed consent. Once the 3D model is produced, it can be used for clinician-to-clinician communication, surgical practice and visual reference in-theatre. Often, a model is required for one or more of these other purposes, and using it for patient informed consent is an additional use that comes at no extra expense as the model has already been created.

Additionally, delays to patient care may occur if the development of the 3D model takes a significant time. However, many hospitals are increasingly providing these models at the point-of-care, which has the benefit of facilitating rapid production and delivery. Our facility has even produced a model that was requested while surgery was underway.

Limitations

The main limitation of our study is the small sample size. The primary reason for this was that, in our institution, 3D modeling for informed consent purposes has not yet been widely utilised or accepted. Nevertheless, this pilot study aids confirmation that this application of 3D models is a feasible and beneficial one for all involved.

Conclusions

3D-printed anatomical models are a valuable tool for preoperative communication and consent. We have demonstrated that it is a valuable tool in paediatric otolaryngology in helping parents visualize their children's disease, improving comprehension, and reducing anxiety. This all contributes to better patient outcomes and satisfaction and, in an appropriate setting, should be considered as a tool for paediatric otolaryngologist in providing excellent holistic care.

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Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at https://www.theajo.com/article/view/10.21037/10.21037/ajo-24-38/rc

Data Sharing Statement: Available at https://www.theajo.com/article/view/10.21037/ajo-24-38/dss

Peer Review File: Available at https://www.theajo.com/article/view/10.21037/ajo-24-38/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://www.theajo.com/article/view/10.21037/ajo-24-38/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and approved by institutional ethics board of the Governance Evidence Knowledge and Outcomes (approval number 39832). Written informed consent was obtained respectively from the patients' parents for publication of this article and accompanying images.

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