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Exploring the Impact of Using Patient-Specific 3D Prints during Consent for Skull Base Neurosurgery

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Abstract

Objectives Informed consent is fundamental to good practice. We hypothesized that a personalized three-dimensional (3D)-printed model of skull base pathology would enhance informed consent and reduce patient anxiety.

Design Digital images and communication in medicine (DICOM) files were 3D printed. After a standard pre-surgery consent clinic, patients completed part one of a two-part structured questionnaire. They then interacted with their personalized 3D printed model and completed part two. This explored their perceived involvement in decision-making, anxiety, concerns and also their understanding of lesion location and surgical risks. Descriptive statistics were used to report responses and text classification tools were used to analyze free text responses.

Setting and Participants In total,14 patients undergoing elective skull base surgery (with pathologies including skull base meningioma, craniopharyngioma, pituitary adenoma, Rathke cleft cyst, and olfactory neuroblastoma) were prospectively identified at a single unit.

Results After 3D model exposure, there was a net trend toward reduced patient-reported anxiety and enhanced patient-perceived involvement in treatment. Thirteen of 14 patients (93%) felt better about their operation and 13/14 patients (93%) thought all patients should have access to personalized 3D models. After exposure, there was a net trend toward improved patient-reported understanding of surgical risks, lesion location, and extent of feeling informed. Thirteen of 14 patients (93%) felt the model helped them understand the surgical anatomy better. Analysis of free text responses to the model found mixed sentiment: 47% positive, 35% neutral, and 18% negative.

Conclusion In the context of skull base neurosurgery, personalized 3D-printed models of skull base pathology can inform the surgical consent process, impacting the levels of patient understanding and anxiety.

Keywords
- 3D printing
- consent
- skull base

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Introduction

Three-dimensional (3D) printing, the manufacture of a physical object based on a three-dimensional digital model, is now accessible and affordable.[1] The routine generation of volumetric CT and MRI imaging provides data that can, with *post hoc* processing, be used to print 3D models of anatomy and pathology.[2–4] 3D printing has already been used in various surgical contexts including teaching,[5–8] surgical planning, and patient information delivery.[9–12]

Informed consent for a surgical procedure is fundamental to good medical practice. It can be defined as "when a person with capacity and *understanding* of the attendant risks and benefits consents to the proposed intervention."[13] Skull base surgery poses a particular threat to critical neurovascular structures, damage to which may lead to lifelong disability or death.[14] How adequately and appropriately consented a patient becomes, prior to surgery, is very hard to quantify and record. What constitutes informed consent for surgery is ever changing, being informed by individual and societal expectations[15,16] and (lagging behind) case law.

The surgical literature suggests that patients may in fact have a very limited understanding of their operation.[13,17–19] Different people vary in their outlook, curiosity, and capacity to understand and retain information.[20,21] The psychological impact and *stress* of facing a neurosurgical procedure modulate the process further. Consent for anything other than the simplest of procedures takes time and consideration. All of these factors demand a degree of professional discretion, empathy, and adaptability on part of the clinician leading the consent process.

It is incumbent on the profession to constantly seek ways to improve information giving and consent. Tools that allow a patient to better understand where their tumor is, and how it relates to nearby neurovascular structures, are a means of highlighting why a given surgical risk exists. Showing patients their CT or MRI may help, though fully processing these images is an acquired skill (and a medical subspecialty in itself). Using generic models of similar pathology may also help, particularly for more prosaic disease processes such a herniated lumbar disk.

We hypothesized that providing a 3D-printed model of a patient's individual pathology –that they could see and touch – would enhance the consenting process. Specifically, we sought to answer the following questions:

- Can 3D printed models of patient-specific pathology be used to improve consent in skull base surgery?
- Does the use of patient-specific 3D printed models affect patients' anxiety and fears regarding their operation?

Methods

In total, 14 patients undergoing elective skull base surgery at a single neurosurgical unit were identified prospectively. Caldicott approval was obtained for permission to handle anonymized patient data using an encrypted USB. Prior to surgery, patient images (a combination of volumetric CT and MRI scans) were anonymized and exported as digital images and communication in medicine (DICOM) files[22] and then converted to neuroimaging informatics technology initiative (Nifti) files using the MRICRON processing toolbox.[23]

Nifti files were segmented using the open-source Slicer 3D software and errors were repaired using Meshmixer prototype software (Autodesk, United States).[24] Stereolithography files were generated, cropped, and used to produce the final G-code (the standard language for 3D printing, ►**Fig. 1**).

A fused deposition modelling printer was used (Prusa Ultimaker Mark 3 with a multi-material upgrade, Prusa Research, Prague, Czech Republic). Polylactic acid was used as the main build filament with polyvinyl alcohol supports. Models were washed in warm tap water to dissolve the support structures (►**Fig. 2**).

All patients attended a pre-assessment clinic 7 to 10 days prior to surgery during which preoperative investigations are performed, anesthetic review occurs, and a consent for surgery form is completed. During this attendance, consent was confirmed in the usual way by the primary operating surgeon. Next, after giving verbal consent for involvement in the study, patients completed part 1 of a two-part questionnaire. They were then shown, and could handle and manipulate, their personalized 3D printed model. Afterward, they completed part 2 of the questionnaire. The questionnaire was a combination of Likert type questions,[6] binary response questions, and free text open questions. Questions sought to explore patients' *factual understanding* of the disease process and operation (anatomical location and surgical risks) and also *emotional* aspects (perceived involvement in decision-making, anxiety, and concerns).

Patient demographics and underlying clinical diagnoses were extracted manually from electronic patient records. Descriptive statistics were used to report patient responses

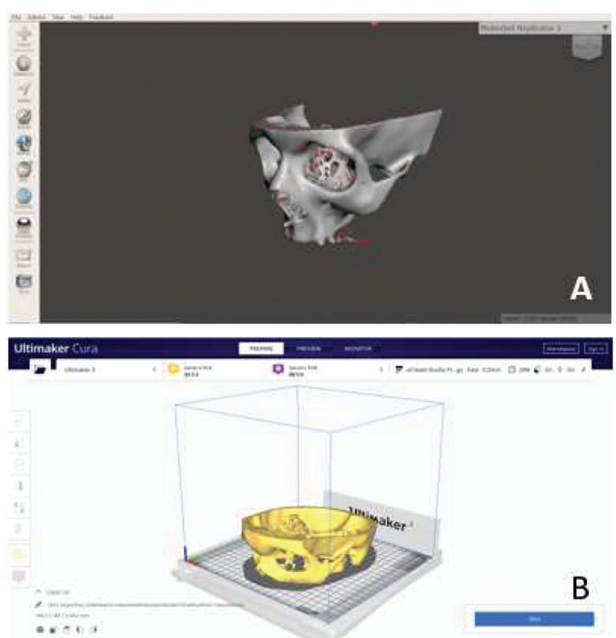

Fig. 1 Screenshots of the software workflow for 3D model production. (**A**) Meshmixer auto-repair is used to identify the flaws within a model. (**B**) Ultimaker slicer software places the model into the build plate prior to production of G-code.

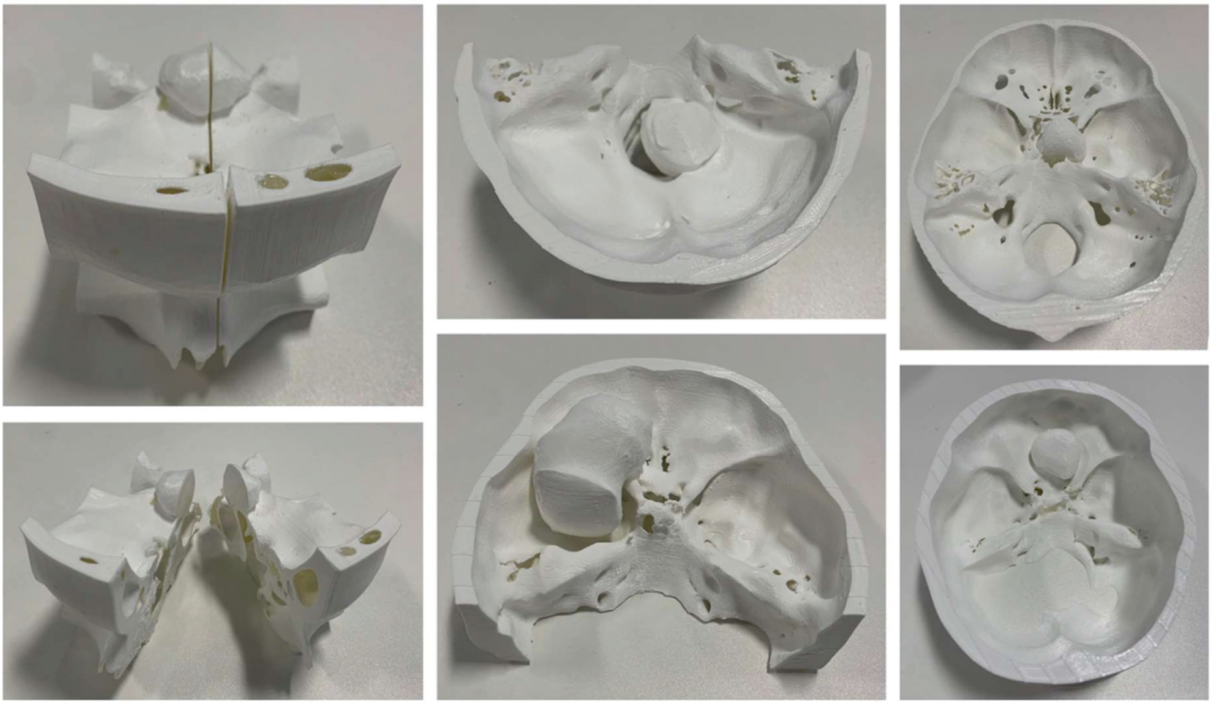

Fig. 2 Examples of completed 3D printed models.

to Likert and binary response questions. An AI driven text classification machine learning tool[25] was used to analyze sentiment expressed in the free text responses.

Results

Fourteen patients were included in the final study. ►Fig. 3 shows their underlying neuropathology. Ten patients were male, four were female, and participant age ranged from 28 to 83 years (mean age of 60).

Emotional Aspects Pre and Post Model

►Fig. 4A illustrates patient reported anxiety levels regarding their operation before and after viewing and manipulating their model. Six of 14 (43%) felt less anxious after seeing their personalized model, 7/14 (50%) were unchanged, and one (7%) felt more anxious. There was a net trend toward decreased anxiety after being exposed to the 3D printed model.

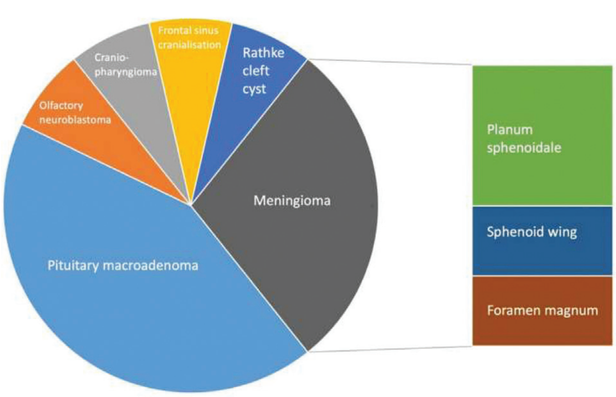

Fig. 3 Chart illustrating the skull base pathologies affecting the study participants.

►Fig. 4B illustrates patient scores for their perceived degree of involvement in the treatment process, before and after exposure to their 3D model. Seven of 14 (50%) patients felt more involved as a consequence of seeing the model, 4/14 (29%) unchanged, and 3/14 (21%) felt less involved. There was a small net trend toward feeling more involved.

After seeing the 3D model, 13/14 patients (93%) reported feeling better about their operation. Thirteen of 14 patients (93%) thought all patients should have the opportunity to view 3D models as part of their consent, given the relatively low cost of production. Six of 14 (38%) patients would have valued the opportunity to take the model home to study it more, prior to making a decision about surgery, but the majority did not feel this was necessary (62%).

Most patients disagreed that production of a personalized 3D model raised additional concerns about privacy (mean 3.7, mode 5; where 1 = strongly agree and 5 = strongly disagree). Nine of 14 (64%) did not regret having seen the 3D model, while 5/14 (36%) people did. There was a clear consensus amongst patients that the benefits of personalized 3D models outweighed any concerns (mean 1.4, mode 1; where 1 = strongly agree and 5 = strongly disagree).

Free text ideas, concerns and expectations prior to seeing personalized model:

"I just want to make it through the surgery"

"Worried about the risk of anaesthesia and not waking up"

"Do not want to know too much"

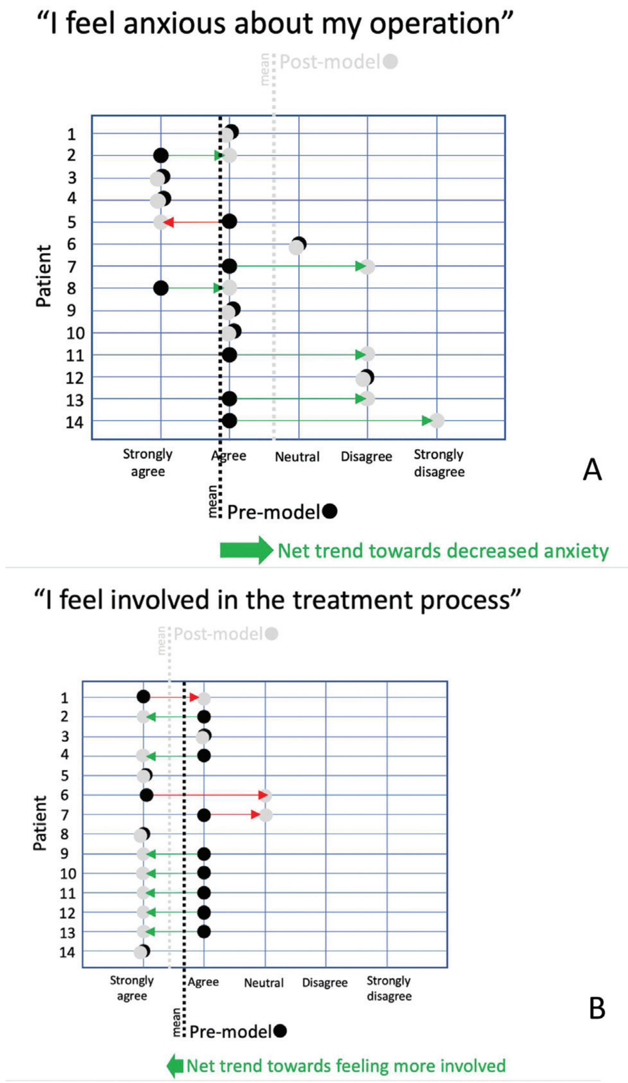

Fig. 4 (A) Patient reported anxiety scores before and after 3D model interaction. (B) Patient reported scores of perceived involvement in the treatment process, before and after 3D model interaction.

"Concerned about preserving vision"

" Not much understanding… but trust the team anyway"

"Keen to finish surgery"

Free text responses after initial exposure to the 3D model:

"It was so different to the images I saw with the surgeon"

"Thought the tumor was actually outside the skull, not at the base. Very surprised about where the tumor actually was"

"Informative, Brilliant, Good idea"

"Interesting"

"Excellent visual aid"

"Helps a lot"

"Did not understand much before"

"Did not expect tumor to be so large"

"Makes it much clearer, can't understand the scans"

"Interesting"

"Feel better informed"

"More aware"

"Feel I have better understanding, feels a bit better"

"Found it quite reassuring to visualize it properly"

"Still nervous"

"Feel very much the same about the operation"

"More informed"

"Makes me more certain about wanting surgery"

"Understand the reason for doing it much better"

"Made you think about the surgery"

"Ideal way to explain to patients"

A machine learning text classification tool was used to analyze sentiment expressed in the free text responses articulated by patients after seeing and manipulating the 3D model. This tool found 47% positive sentiment, 35% neutral, and only 18% negative.

Factual Understanding Pre and Post Model

►**Fig. 5A** shows patient reported scores of their perceived understanding of the nature of the operation, before and after exposure to the 3D model. Five of 14 (36%) felt they understood better, 5/14 (36%) felt they understood less, and four (28%) were unchanged. There was a net trend toward a small reduction in degree of understanding after seeing the 3D model.

►**Fig. 5B** shows patient reported scores for their understanding of the surgical risks associated with the procedure, before and after seeing the 3D model. Six of 14 (42%) felt the risks were clearer after seeing the model, 5/14 (36%) were unchanged, and three (22%) felt the risks were less clear. Overall, there was a small net trend toward a better understanding of the risks across the cohort.

►**Fig. 6A** shows patient reported scores of their perceived understanding of the anatomical region being targeted by surgery. Eight of 14 (57%) felt they understood better after seeing/handling the 3D model, 4/14 (29%) were unchanged, and two (14%) felt they understood less. Overall, there was a clear net trend toward increased understanding of lesion location as a result of exposure to the 3D model.

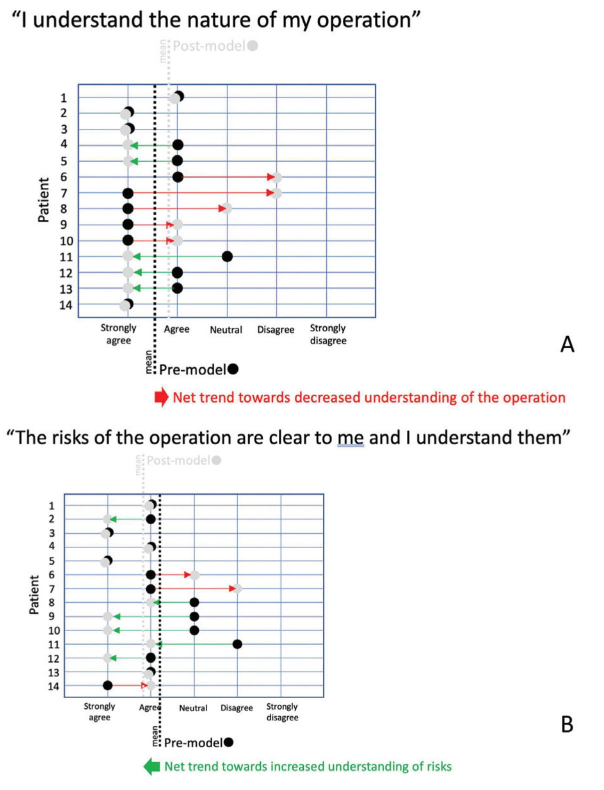

Fig. 5 (**A**) Patient reported understanding of the nature of their operation before and after 3D model exposure. (**B**) Patient reported understanding of perceived risks of operation, before and after 3D model exposure.

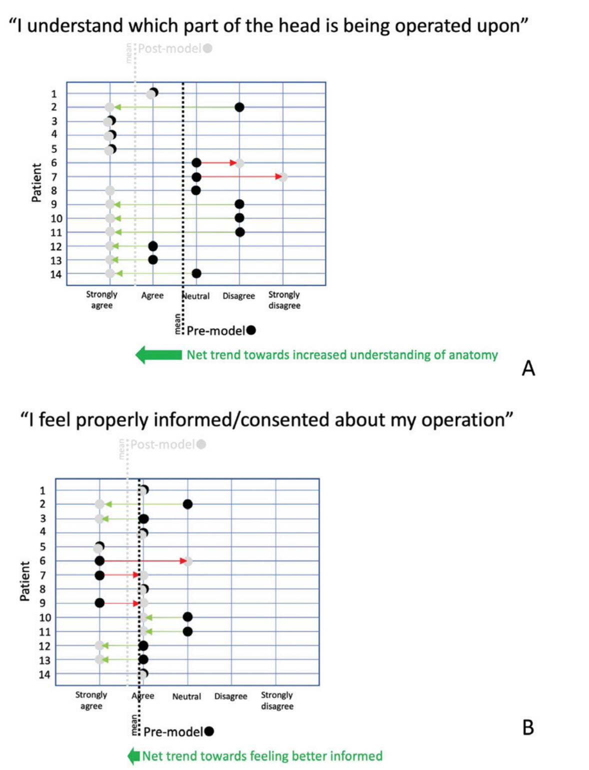

Fig. 6 (**A**) Patient reported understanding of the region of anatomy being targeted by surgery, before and after 3D model exposure. (**B**) Patient reported scores regarding the extent to which they felt well informed, before and after 3D model exposure.

►**Fig. 6B** illustrates patient reported scores for the degree to which they felt informed. Six of 14 (43%) felt better informed after the model, 5/14 (36%) unchanged, and three (21%) less well informed. Overall, there was a small net trend toward feeling better informed after seeing and handling their 3D model.

Thirteen of 14 patients (93%) felt the model helped their understanding of the part of the body being operated on and the method of doing so. Most patients felt the 3D model was more helpful than on-screen images in helping to understand their operation (mean score 1.8, mode 1; where 1 = strongly agree and 5 = strongly disagree). Fourteen of 14 (100%) patients would be happy for their models to be used in surgical education.

Discussion

Regarding the consent for surgery, the law provides a framework for practice. In United Kingdom, prior to the Montgomery *versus* Lanarkshire[26] ruling, the consenting process was more paternalistic. The Montgomery case established a duty of care to warn of any *material* risks, with materiality being when "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it." As such, ambiguity persists. Even with all the material risks of a procedure fastidiously articulated by a clinician, and with written evidence of having done so, the "informed-ness" of consent from the perspective of the patient remains unknown to all bar the patient themselves. Braddock et al[27,28] found that 71% of clinicians felt that patients blame poor outcomes on them because of a lack of understanding of risks.

Emotional Impacts of Personalized 3D Model Use

The emotional impact of using the bespoke 3D models, across several patient-reported domains, was largely positive. There was a net trend toward decreased anxiety and toward feeling more involved in treatment. All except one patient reported feeling better about their operation after seeing their model and all except one felt that the opportunity to view personalized 3D models ought to be universal. There were no additional concerns regarding privacy, likely highlighting the fact that such models merely augment existing imaging data.[29,30] The sentiment expressed in free text responses was largely classed as positive, with 18% of responses considered negative.

Impact of Personalized 3D Model on Patient-reported Understanding of Pathology

There was a marked trend toward increased understanding of lesion location after exposure to 3D model. This likely reflects the impact of appropriately representing pathology that manifests in our three-dimensional Cartesian world in three-dimensional model form, rather than either describing it with words or showing two-dimensional scan slices.[31] There was a small trend toward better patient-perceived understanding of surgical risks. This may reflect the fact that tumor location became better understood in relation to adjacent at-risk structures.

Notably, there was a small reduction in patient-reported understanding of the nature of operation, after seeing the 3D model. Potentially, their previous conceptual framework of the problem may have been undermined by the new three-dimensional appreciation granted by the model. That said, there was an overall trend toward feeling better informed after seeing and handling their 3D model. The small degree of increased uncertainty did not apparently have an obvious negative impact. These findings echo the consent predicament of just how much information is too much information.

While the overall impact of 3D model use was positive, two patients (numbers 6 and 7) were notable outliers in several domains. For these two patients (one craniopharyngioma and one sphenoid wing meningioma), the model made them feel less involved, reduced their understanding of the operative anatomy and risks, and left them feeling less well informed. It is not clear why they responded differently but this highlights heterogeneity in patient understanding and opinion—and the fundamental need to personalize consent discussions.

Technical and Resource Considerations

We produced models illustrating only the tumor bulk in the context of surrounding normal skull base *bone* anatomy. 3D printers that use multiple filaments and allow vascular and neural structures to be included are available[32] and may add desirable additional detail. However, they come with greater demands on processing time and higher costs. The models we produced for this study cost approximately US$20 per patient.

Limitations and Future Work

Importantly, the extra clinician time that came with providing and discussing the 3D models may confound our findings. Isolated exposure to the model, without added discussion, might well be less beneficial and – vice versa – longer consent without a model might be more beneficial.[5,11,33] Future work would be strengthened by standardizing the amount of time spent across comparative groups and also by increasing the sample size. Attempting to collect patient educational level or socio-economic background would also provide additional insight into the utility of this idea. Furthermore, this is a single surgeon series. Just as patients vary, so too do surgeons in their approach to consent and their own strategies for explaining pathology and treatments.

These limitations noted, no study of this sort can ever fully disentangle the complex interactions that occur between surgeon and patient (with their varied and dynamic understanding, outlook, risk appetite, and cognitive capacity) when discussing the nuanced management of high risk, anxiety-inducing pathologies. Almost never will the patient have the same degree of information and understanding as the treating team, and there is an innate element of trust in the interaction.[19,34]

Trust is established by faith in both the health care system and the immediate team treating the patient. Without a satisfactory therapeutic alliance, it is unlikely that information delivered will be retained or understood. As such, a humane approach which details all material risks but which is tailored to the individual and avoids any unnecessary increase in stress and anxiety, is the goal. The use of 3D printed patient-specific models may aid in this goal.

Conclusion

In the context of skull base neurosurgery, we have shown that personalized 3D printed models of skull base pathology can inform patient understanding and anxiety during consent. The impact is complex and varies according to patient but this tool may add value. The requisite software and hardware are affordable and accessible.

Previous Presentations
Early work was presented as a poster at the Congress of the European Association of Neurological Surgeons in Hamburg, in October, 2021.

Ethical Approval
The NHS Lothian Caldicott Guardian (ref 20173) issued approval of handling of patient data. Given no identifiable data was used, and that this was an observational study of outcomes with no treatments offered, no further ethical committees were consulted.

Authors' Contribution
S.M., S.J., A.Q., and M.H. all contributed to and partook in the execution of the study and collection of data, with S.M. and M.H. writing the report. M.H. acted as a supervisor and guarantor for the study.

Data Sharing
As this study was conducted by a postgraduate student, any published data will be held in its repository. As such, the data within has not been deposited or shared elsewhere, or prior to this submission, with the exception of the abstract referred to on the first page.

Conflict of Interest
None declared.

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