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Feasibility of customizing titanium implant with three-dimensional CT imaging of low dose in skull

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Abstract

Object: To explore the feasibility and practicability of making virtual three-dimensional model of skull defect and customizing titanium implant by skull three-dimensional CT examination of low dose.

Methods: Sixty patients with skull defects who underwent skull three-dimensional CT before cranioplasty were randomly divided into 4 groups: group A (conventional dose 120 peak Kilovoltage (kVp), 150 tube current time product (mAs)), low dose group B (120 kVp, 50 mAs), low dose group C (100 kVp, 50 mAs), low dose group D (100 kVp, 30 mAs). After the scanning, we compared radiation doses and image quality among the groups. The CT data were sent to the reconstruction company to produce accurate titanium implants, and neurosurgeons performed cranioplasty. After the operation, patients immediately underwent head CT scans to confirm the accuracy of the implantation position, and a series of clinical functions were evaluated.

Results: There were significant differences in dose length product (DLP) and effective dose (ED) among the 4 groups ($P < .001$). The volume CT dose index (CDTIvol), DLP, and ED in group D were, respectively, 87.1%, 86.9%, and 87.3% lower than those in group A ($P < .001$). All images quality were at or above the general level, and there was no statistical difference ($P > .05$). Titanium implants were successfully manufactured, every cranioplasty was carried out smoothly, and the clinical function of patients recovered well.

Conclusion: Customizing titanium implant with three-dimensional CT imaging of low dose in skull not only met the clinical requirements, but also significantly reduced the radiation dose and hazard.

Abbreviations: 3D = three dimensional, ALARA = as low as reasonably achievable, CAD = computer-assisted design, CAM = computer-assisted model, CPR = curved planar reformation, CTDIvol = volume CT dose index, DLP = dose length product, ED = effective dose, kVp = peak Kilovoltage, mAs = tube current time product, mGy = milligray, MIP = maximum intensity projection, MPR = multiple plane reconstruction, PACS = picture archiving and communication system, VR = volume rendering.

Keywords: skull, three-dimensional, titanium

1. Introduction

In neurosurgery, with the increasing number of patients with skull defects, it is always necessary to do cranioplasty, that is, a

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reconstruction operation to repair skull defects. In recent years, computer aided design (computer-assisted design, CAD)/computer aided manufacturing (computer-assisted model, CAM) customizing titanium mesh implants have been widely used in cranioplasty all over the world, and considerable experience and achievements have been obtained.[1–5] All patients undergo thin slice computerized tomography (CT) and three dimensional (3D) reconstruction before operation, and the scanning data are sent to the implant reconstruction company. Then the company make the titanium mesh in accordance with characteristics of the patient by using CAD/CAM technology according to the CT data.[1–7] Therefore, the three-dimensional model based on CT data becomes particularly important, and CT images are set as the gold standard for evaluating skull defects.

Subsequently, the additional radiation dose of CT examination has been the focus of debate. Some researchers opposed to CT scanning just for collecting data to make 3D models which can increase the incidence of mutations.[6–7] Therefore, the feasibility and practicability of making virtual three-dimensional model based on the skull three-dimensional CT examination of low dose are on the schedule. There is no relating report in literature.

2. Materials and methods

2.1. General information

From March 2014 to December 2017, 60 patients with skull defects who needed skull 3D CT examination before cranioplasty were randomly assigned into 4 groups according to CT tube voltage and current. In group A (conventional group), 15 patients

were examined at 120 kVp and 150 mAs. In low dose group B, 15 patients were examined at 120 kVp and 50 mAs. In low dose group C, 15 patients were scanned at 100 kVp and 50 mAs. In low dose group D, 15 patients were scanned at 100 kVp and 30 mAs. After scan CT data were sent to Reconstruction Corporation (Kunshan, Suzhou, China) to make accurate titanium implants (Johnson). Before cranioplasty, neurosurgeons verified the skull defect area, flap outline and marked edge, and finally confirmed the patient's clinical condition. After general anesthesia, the bone defect area was exposed and a custom titanium implant was implanted. Thin slice CT scan was performed within 1 and 3 days after operation to confirm the accurate position of the implant and to evaluate a series of clinical functions at the same time. This study was approved by the Hospital Ethics Committee, and all patients filled in informed consent form.

2.2. CT technique and acquisition protocol

When using 16-slice spiral CT machine (GE Brightspeed) scan, the patient was in the routine supine position, the head was placed in the head frame, the jaw was adducted, and the nose tip plane of the skull base was scanned upward to the top of the head for axial images. The following imaging parameters were used: rotation time 1 second/rot, pitch 1.375, slice thickness 1.25 mm, interval 1.25 mm, matrix 512×512, FOV 250 mm, window width 2000 Hu, window position 700 Hu. All images were transferred to the GE ADW 4.6 workstation and the 3D reconstruction techniques such as multiple plane reconstruction (MPR), curved planar reformation (CPR), maximum intensity projection (MIP), and volume rendering (VR) were used for image post-processing and establishing the 3D model of skull. Finally, the original images and 3D images were transferred to PACS for evaluating the images quality.

2.3. Radiation dose assessment

The volume CT dose index (CTDIvol) and dose-length product (DLP) displayed on the CT system were recorded and used to calculate the radiation dose. The effective dose (ED) was calculated by multiplying the DLP with the conversion factor recommended by the International Commission on Radiological Protection.[11,12]

2.4. Image quality assessment

Two senior radiologists with more than 10 years experience in CT diagnosis who were blinded to the scanning protocols and patients information worked together to diagnose and evaluate the image quality. If there were differences, agreement can be reached after negotiation. The CT image quality was rated on a grading system as follows: excellent image quality, diagnostic without limitations, fine graininess, very sharp skull borders, minimal artifacts; good image quality, diagnostic without significant limitations, less fine graininess, relatively sharp skull borders, minor artifacts; moderate image quality, diagnostic with minimal limitations, slightly thick graininess, slightly blurred skull borders, some artifacts; poor image quality, non-diagnostic, thick graininess, notably blurred skull borders, prominent artifacts.[9] The quality above the moderate grade can meet the requirements of diagnosis, that is, it does not affect the radiologists diagnosis of skull defect, and can reconstruct the virtual three-dimensional model of skull at the same time.

2.5. Statistical analysis

SPSS 21.0 software was used for statistical analysis. K-S test was used to test whether the data conformed to the normal distribution. If the data accorded with the normal distribution and the variance was uniform, the mean ± standard deviation was used for statistical description, and the differences between groups were compared by t test or analysis of variance. If the data didn't conform to the normal distribution or uneven variance, the median ± quartile spacing was used for statistical description, and the K-W rank sum test was used to compare the differences between the groups. When the differences between multiple groups were statistically significant, pairwise comparison was carried out. The counting data were statistically described by frequency (N) and percentage (%), and the differences between groups were compared by chi-square test or KW rank sum test, and the difference was statistically significant when $P < .05$.

3. Results

In the group A, there were 10 males and 5 females, ranging in age from 8 to 66 years old, with a median age of 45 years. In the low dose group B, there were 12 males and 3 females, ranging in age from 17 to 62 years old, with a median age of 50 years. In the low dose group C, there were 14 males and 1 female, ranging in age from 5 to 64 years old, with a median age of 47 years. In the low dose group D, there were 12 males and 3 females, ranging in age from 23 to 71 years, with a median age of 51 years. No significant differences in patient characteristics, including age and sex were observed among the 4 groups($P > .05$).

Of the 60 patients, 56 were postoperative patients with intracranial hematomas, 2 were after resection of intracranial tumors, and 2 were after clamping of intracranial aneurysms. Fourteen patients had mild complications, such as wound pain, fever, dizziness, and headache, 1 patient had subcutaneous effusion and 1 patient had epidural hematoma, which had been absorbed in a short time. After follow-up for 1 to 34 months, the scalp wounds of all patients healed well. Postoperative CT showed that titanium implants were fixed well, skull morphology was symmetrical, aesthetic effect was significant, clinical function recovered well, and patients were satisfied.

The results of CTDIvol, DLP and ED of 4 groups were shown in Table 1. The CDTIvol, DLP, and ED in group C were, respectively, 78.5%, 77.5%, and 78.0% lower than those in group A ($P < .001$). The CDTIvol, DLP, and ED in group D were, respectively, 87.1%, 86.9%, and 87.3% lower than those in group A ($P < .001$).

There was no significant difference in image quality evaluation among 4 groups ($P > .05$). All images quality assessments were at or above the general level (Table 2). Comparison showed that the graininess of conventional dose images was delicate, and the particles of low dose images at 100 kVp and 30 mAs settings were slightly rough, but they can clearly show the location and scope of skull defect, which was still sufficient for successful diagnosis, and making virtual three-dimensional skull model to customize accurate CAD/CAM titanium Implant (Figs. 1–4).

4. Discuss and conclusions

Skull defects can be caused by trauma, infection, tumor, dysplasia and decompression of bone flap, resulting in scalp depression, disturbing brain self-regulation, and damaging hemodynamic state. Patients may develop circular saw syndrome such as

Table 1

Radiation dose between groups under different scanning conditions.

	Group A	Group B	Group C	Group D	Z (ABCD)	P (ABCD)	P (CD)	P (BD)	P (AD)	P (BC)	P (AC)	P (AB)
CTDIvol (mGy)	20.26	6.75	4.35	2.61								
DLP (mGy.cm)	368.39±20.27	130.4±10.98	82.28±2.18	49.37±3.26	55.402	<0.0001	0.112	0.000	0.000	0.112	0.000	0.112
ED (mSv)	1.17±0.09	0.4±0.04	0.26±0.00	0.15±0.02	55.72	<0.0001	0.110	0.000	0.000	0.110	0.000	0.110

Table 2

Image quality assessment of the 4 groups.

Groups	Excellent	Good	Moderate	Poor	K-W value	P
Group A (n=15)	14 (94%)	1 (6%)	0 (0%)	0 (0%)	4.889	.180
Group B (n=15)	13 (88%)	1 (6%)	1 (6%)	0 (0%)		
Group C (n=15)	10 (67%)	4 (27%)	1 (6%)	0 (0%)		
Group D (n=15)	10 (67%)	3 (20%)	2 (13%)	0 (0%)		

dizziness, irritability, anxiety, irritability, etc.[3] These situations can be avoided by cranioplasty. Its ideal material is autologous bone, but it may not be used because of autologous bone infection, fragmentation, bone resorption, insufficient quantity, storage difficulty and so on.[1–2] Therefore, the development of satisfactory materials and techniques for cranioplasty has been a medical and bioengineering challenge in recent years. Polymethyl methacrylate (PMMA), polyether ether ketone (PEEK), hydroxy-apatite (HA), and porous polyethylene are the most widely used in non-metallic heterograft.[15–18] Each material has its own advantages, such as PEEK which has been reported to have other numerous advantages over other alloplastic materials in terms of strength, stiffness, durability, biocompatibility, thermal conductivity, and radiographic translucency.[16–17] Titanium in metal implants is still the only metal used for cranioplasty.[1–6] Titanium has the advantages of light weight, high strength, low thermal conductivity, good stability, low infection rate, easy shaping, similar bone elasticity, and can be sterilized at high
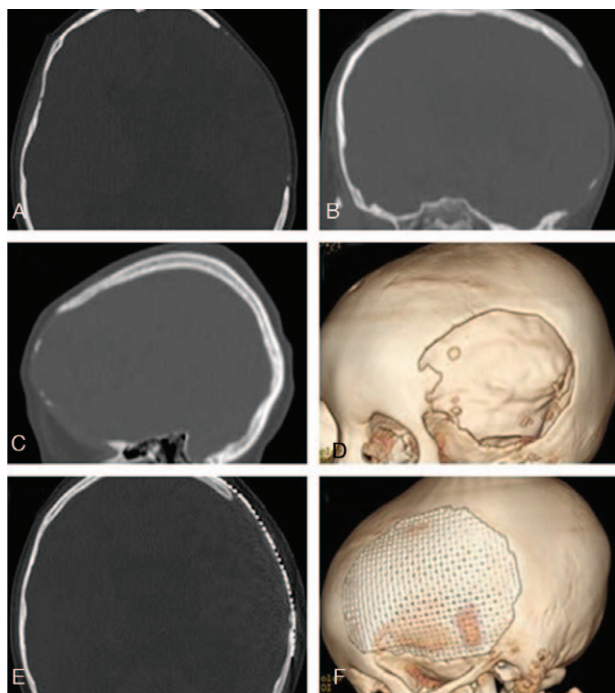

Figure 1. A-1F. The patient was a male, 8-year-old, with the scanning parameter of 120 peak Kilovoltage (kVp), 150 tube current time product (mAs) in the group A (conventional dose). 1A-1D were the skull three-dimensional CT scan before operation: 1A was a high-resolution thin-layer CT plain scan axial map, 1B was a multiple plane reconstruction (MPR) coronal map, 1C was a MPR sagittal map, and 1D was a volume rendering (VR) map, showing a partial defect of the frontotemporal bone on the left side. 1E-1F were the skull three-dimensional CT scan after cranioplasty: 1E was a high resolution thin-layer CT plain scan axial map, and 1F was a VR map, illustrating that the titanium implant was well fixed and the cranial shape was symmetrical.
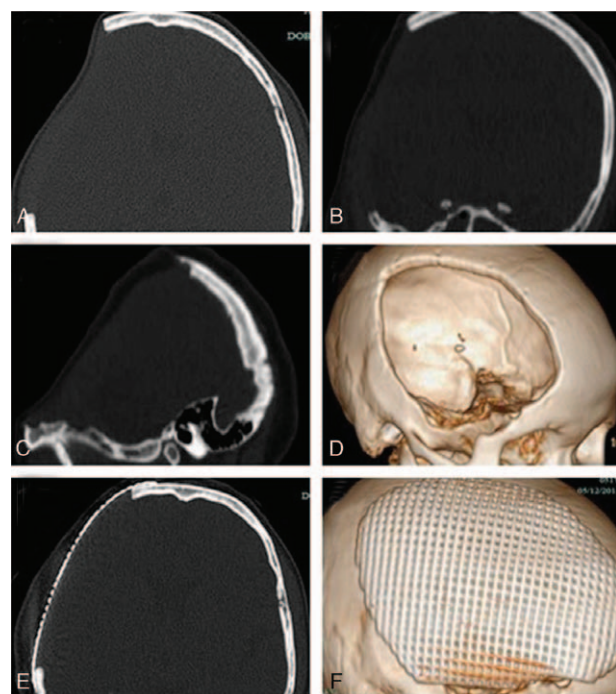

Figure 2. A-2F. The patient was a female, 51-year-old, with the scanning parameter of 120 kVp,50 mAs in the low dose group B. 2A-2D were the skull three-dimensional CT scan before operation: 2A was a high-resolution thin-layer CT plain scan axial map, 2B was a MPR coronal map, 2C was a MPR sagittal map, and 2D was a VR map, showing a partial defect of the frontotemporal parietal bone on the right side. 2E-2F were the skull three-dimensional CT scan after cranioplasty: 2E was a high resolution thin-layer CT plain scan axial map, and 2F was a VR map, illustrating that the titanium implant was well fixed and the cranial shape was symmetrical.
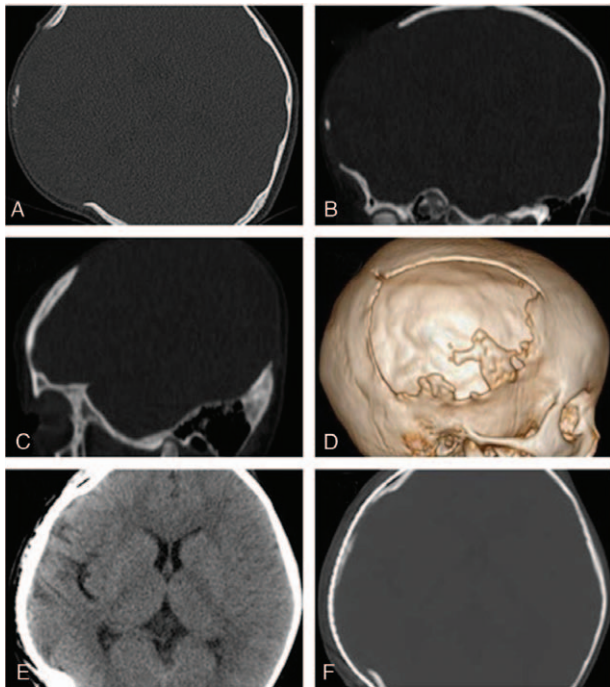
Figure 3. A-3F. The patient was a male, 5-year-old, with the scanning parameter of 100 kVp, 50 mAs in the low dose group C. 3A-3D were the skull three-dimensional CT scan before operation: 3A was a high-resolution thin-layer CT plain scan axial map, 3B was a MPR coronal map, 3C was a MPR sagittal map, and 3D was a VR map, showing a partial defect of the frontotemporal parietal bone on the right side. 3E-3F were the high-resolution thin-layer CT plain scan axial map of the brain with parenchyma and bone window after cranioplasty, illustrating that the titanium implant was well fixed and the cranial shape was symmetrical.
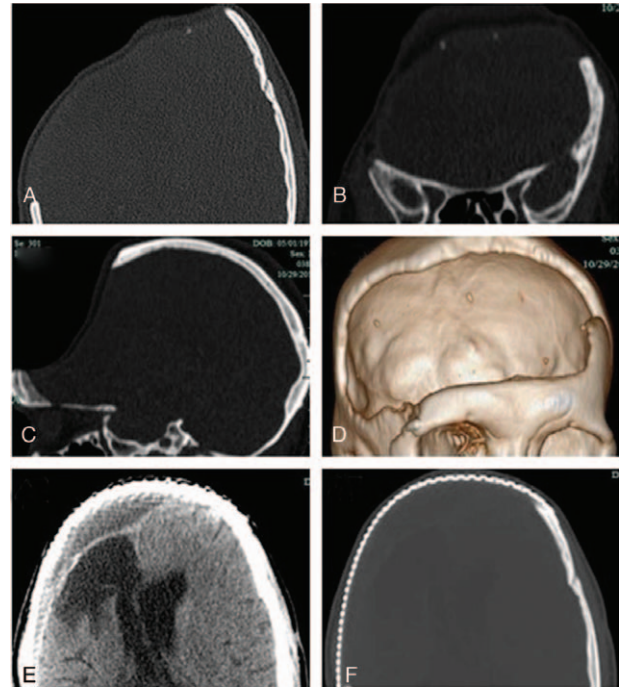
Figure 4. A-4F. The patient was a male, 38-year-old, with the scanning parameter of 100 kVp, 30 mAs in the low dose group D. 4A-4D were the skull three-dimensional CT scan before operation: 4A was a high-resolution thin-layer CT plain scan axial map, 4B was a MPR coronal map, 4C was a MPR sagittal map, and 4D was a VR map, showing a partial defect of the right temporal and bilateral frontal bone. 4E-4F were the high-resolution thin-layer CT plain scan axial map of the brain with parenchyma and bone window after cranioplasty, illustrating that the titanium implant was well fixed and the cranial shape was symmetrical.

temperature. Furthermore, titanium is a metal with good biocompatibility, which is inertial, non-toxic and non-allergic, and it is easy to obtain and prepare before operation. It costs cheap, and can be permanently integrated with the skull, good cosmetic effect, without affecting CT and MRI imaging. These characteristics make it one of the most widely used implant materials in craniofacial osteoplasty in the world.[1–6]

With the development of medical imaging technology and computer software, it provides a new idea and method for the repair of skull defect. The effectiveness of CAD/CAM titanium implant in craniofacial repair have been reported in more and more literatures. Compared with traditional autotransplantation or allotransplantation, it can customize prefabricated titanium implant before operation, omit intraoperative design, shape and adjustment, finally has shorter operation time, less complications, less screw dosage and better cosmetic effect, faster postoperative recovery and higher patient satisfaction.[1–5] Therefore, CAD/CAM titanium implants have been widely used in craniofacial reconstruction, such as orbital floor, paranasal sinus, jaw bone, zygomatic bone, and skull.[1–7] The technique of CAD/CAM titanium implant begins with the creation of a defect model based on CT data. In short, each patient undergoes a high-resolution thin-layer CT scan of the whole skull, from the skull base to the convex surface, including the skull defect area. After post-processing editing and three-dimensional reconstruction, the virtual three-dimensional model of the skull is obtained, and then all the CT data are transmitted to the manufacturer. The manufacturer uses a variety of image editing softwares to extract

digital information from the CT scan and reconstruct the CAD model of the skull. The symmetry of the reconstructed outline and its relationship with the existing skull are observed at the axial, coronal and sagittal position, and then tested from appearance and symmetry. Finally, the CAD data are transmitted to the CAM system for the manufacture of the final titanium implant.[1–4]

Computer tomography (CT) scan is considered as the most preferred imaging modality for clinical diagnosis due to its ability to produce sectional images and affluence the observer to identify the accurate location of lesions and ensure that prefabricated implants can be accurately fabricated using any dissimilar material.[1–7] It is a common practice for patients with skull defects to receive multiple times of CT head examinations, regardless of symptoms in order to evaluate progression of the basic disease because head CT procedure is able to provide detailed images of the head region including the skull, brain, paranasal sinus, ventricles, and eye sockets. So the cumulative radiation dose of these patients was significant, and a three-dimensional CT scan of the skull, which was just to collect data, no doubt, increased the amount of radiation. Many scholars have studied the relationship between scanning dose and radiation hazard, and found that lens, gonad, thyroid and bone marrow are more sensitive to the radiation. With the increase of dose, there will be varying degrees of damage, such as cataract, sterilization, malignant tumor or leukemia. Especially in children during the period of growth, the sensitivity of radiation is more than 10 times that of adults, and the risk of children is much higher when

they receive the same dose.[6–7] Therefore, any factors that may contribute increment in radiation dose must be taken seriously to avoid the patient from receiving unnecessary radiation dose.

Now low dose scanning is realized mainly by optimizing scanning parameters, adjusting tube current or tube voltage under the condition of the human factors and the machines are relatively fixed in clinical research. Because the radiation dose is proportional to the square of the tube voltage and to the first power of the tube current, reduction of tube voltage and current is an effective means of decreasing the radiation dose.[8–10] Therefore, our study reduced the amount of radiation by reducing tube current and voltage while keeping the other scanning conditions unchanged. The comparison of radiation doses of different scanning schemes is mainly through comparing volume CT dose index (CTDIvol), dose length product (DLP) and effective dose (ED).[8–13] CTDIvol is automatically calculated and recorded by equipment according to scanning technology (tube voltage, tube current and pitch, etc.). Generally the higher the dose, the more serious the biological effect and the greater the damage to the body. CTDIvol is the output value of the device, which does not take into account the size of the subject, and DLP has overcome this defect, DLP= CTDIvol × scan length. The radiation effective dose (ED) is obtained by using the DLP method recommended by ICRP report in 2007 using following equation: $E = k \times DLP$, and k is a conversion factor from DLP to ED as function of tube voltage, body region, and age recommended by ICRP Publication 103.[11–12] ED is an indicator that commonly understood as the amount of radiation received by patients undergoing a numerous type of radiological examinations which is significantly practical and provides meaningful information to many respective researchers.[13]

In our study, we observed decreases in CTDIvol of 66.7%, 78.5%, and 87.1% at groups B, C, and D, respectively, which significantly reduced the total radiation dose and hazard. Moreover, there was a significant difference in DLP and ED among 4 groups. At the same time, there were no unqualified images in the 3 groups of low dose scanning groups. Compared with the conventional dose images, the image noise increased and the particles thickened when the tube voltage and current were reduced, but because of the natural high contrast of the skull itself, the reconstruction of the skull model was carried out on the CT bone window, and there was no need to look at the details such as the pathological changes of the brain parenchyma and skull bone fractures. Therefore, although the image quality was slightly reduced, it can still clearly show the location and extent of the skull defect, meet the needs of diagnosis and make virtual three-dimensional model of skull defect to customize accurate titanium implants. It can be seen that low dose three dimensional CT scan of skull can be used in clinical application. However, our study had some limitations of note. The sample of this study was small, and the scanning technical parameters were relatively conservative. It is necessary to need more people and do further study whether the tube voltage can be further reduced.

With the urgent need of the world and the public to reduce radiation, the world is working to reduce radiation exposure, especially in children with craniofacial patients. Some researchers used MR examination to make 3D models to reduce radiation, but MR is not suitable for some attention to bone anatomical details, and CT scanning is still used as the gold standard for image evaluation.[6–7] The three-dimensional CT scan of low dose in skull is suitable for patients with craniofacial bone repair,

whether using titanium or other heterogeneic materials, and CAD/CAM technology or 3D printing technology. Moreover, it is in line with the principles of justification and optimization and follows the "as low as reasonably achievable" (ALARA) proposed by the International Commission on Radiological Protection.[14] In conclusion, among the above 4 protocols, it is of great practical value to make virtual 3D model of skull defect and customize titanium implant by using skull 3D CT examination of the low dose protocols (100 kV tube voltage and 30 mA tube current).

Author contributions

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Critically revising the article: all authors.
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Reviewed submitted version of manuscript: all authors.
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