Songklanakarin J. Sci. Technol.
35 (4), 437-442, Jul. - Aug. 2013

SJST SONGKLANAKARIN JOURNAL OF SCIENCE AND TECHNOLOGY
http://www.sjst.psu.ac.th

Original Article

Validation of standardized cranioplasty plates for thais

Khemajit Sena[1], Surasith Piyasin[1]*, and Kriskrai Sitthiseripratip[2]

[1] *Department of Mechanical Engineering, Faculty of Engineering, Khon Kaen University, Mueang, Khon Kaen, 40002 Thailand.*

[2] *National Metal and Materials Technology Centre (MTEC), Khlong Luang, Pathum Thani, 12120 Thailand.*

Received 21 October 2010; Accepted 15 May 2013

Abstract

This study presents the validation of the standardized design of skull implants for Thais. CT scanned data of 100 dry skulls from the native Thai cadavers were reconstructed into 3D models. The Computer Aided Design (CAD) program was then used to design three standard skull sizes: small (S), medium (M), and large (L), to fit the obtained 3D models. By using the statistical analysis method, these three standard sizes were clearly located and mapped with the most frequently injured area of the skulls. The results showed that 13 skulls matched size S, 77 skulls matched size M, and 10 skulls matched size L. The average gaps of each skull size to its matched dry skulls were 2.77±2.31 mm for size S, 2.69±1.93 mm for size M, and 2.82±2.02 mm for size L. The total average gap of all three skull sizes to their matched dry skulls (100 skulls) was 2.71±1.99 mm. The obtained results demonstrated the feasibility of using the standardized skull implants instead of designing implants individually for each operation. The standardized skull implants would also eliminate the use of CT scanning process in every implant preparation, leading to time and cost savings.

Keywords: cranioplasty, standardized implant, 3D medical imaging, computer aided design, implants validation

1. Introduction

Major cranial defects are caused by trauma, tumors, infected craniotomy bone and neurosurgical external decompression (Lee *et al.*, 2002; Chen *et al.*, 2006). Craniectomy for decompression is a process to increase the volume of the intercranial cavity to relieve intracranial hypertension resulting from methods of medical therapy (Gupta *et al.*, 2004). The success of the treatment is vital not only for the survival of the patients, but also for the improvement of the patients' functional results. In addition to protecting the underlying neural tissue, anatomical reconstruction and neurological improvement such as cerebral hemodynamics and metabolism, and the necessary aesthetics must be verified for the repair of cranial defects (Joffe *et al.*, 1999). One of the treatments is cranioplasty, which treats cranial defects, or holes in skulls, with implants. If the defects are large, complex, or located in the area of vital organs, for instance, the orbit of the eyes or thin bones, which makes intraoperative fabrication difficult, an implant can be designed and fabricated prior to a surgical operation (Lee *et al.*, 2002; Chen *et al.*, 2006). Currently, in order to repair skull defects, many surgeons still model implants by hand and often use Polymethylmethacrylate (PMMA) as a cranioplasty material. This method is rather conventional and the quality (shape and dimensional accuracy) of the implants is dependent on the individual skills and experience. In addition, PMMA setting time becomes an issue when implant preparation is performed intraoperatively.

Rapid development in medical image processing and simulation has contributed considerably to the design of

* Corresponding author.
Email address: surasith@kku.ac.th

implants. Computer-aided design (CAD) and computer-aided manufacturing (CAM) technology have been widely used to design and fabricate implants to repair complex cranial defects and to ensure the design accuracy. Since 1998, it has been reported that the designs of implants by using computer simulations and virtual insertions can reduce operation time, blood loss, and infection rate. By using medical graphics and imaging programs, distances, angles, thicknesses of cranial bones, and soft tissues can be measured easily. Cranial implants can be designed by the computer program using a mirror technique of the intact side to the defect side. Furthermore, surgical teams can see and diagnose the patient symptoms from a 3D reconstructed model, which is sent rapidly through a computer network before operation (Joffe *et al.*, 1999). Thus, CAD/CAM technology can greatly enhance the accuracy and aesthetics of the results.

In Thailand, the National Metal and Materials Technology Center (MTEC) also uses CAD/CAM to design and fabricate skull implants. The design and fabrication process carried out at MTEC can be summarized as follows. A defected skull is CT scanned and the scanned data is sent to a medical image processing software, which converts the data into a CAD format. A CAD software is then used to design an implant suitable to fit in the defected skull. Afterward, the CAD model of the implant is transferred to a rapid prototyping (RP) machine to fabricate a master part (implant model) for molding. Finally, the implant is fabricated from the mold and PMMA is used as the biocompatible material. It can be seen that the entire process requires much preparation time and skills from both the surgeons and the technicians. Moreover, this process requires expensive resources such as an efficient CT scanner, a 3D modeling program, and a CAD software, making the cost of fabricating skull implants considerably high. In general, personalized cranioplasty implants only show useful benefits for the treatment of complex skull defects caused by car accidents or bone tumors. In many cases, the skull defects caused by motorbike accidents are simple and located in the hair areas, thus, no cosmetic is needed. As a result, using personalized implants is not beneficial since the process is quite routine and not too complicated for neurosurgeons. Therefore, cheap implants are considered more suitable for the skull defects having simple shapes and small sizes. Since 1996, the use of standardized skull implants made of Carbon Fiber Reinforced Plastics (CFRP) with at least 150 patients has been reported. Operations using these implants for cranioplasty treatments have been successfully performed, taking approximately 1 to 2.5 hours to complete an operation (Hieu *et al.*, 2004).

As a result, an approach to improve the implants design and fabrication process by using standardized skull implants is presented in this paper. The main objective of this approach is to eliminate the costly and time-consuming process that always requires a new implant for every operation. If there are standardized skull implants, surgeons are able to select a suitable one that fits with the defected skull. This approach uses CAD/CAM technology only in the initial stage to design and fabricate standard parts. The statistical analysis is also used to select the standardized skull sizes. The results of this method will greatly reduce the time required to perform CT scanning and designing, particularly for cases having small or less complex skull defects. The operation time will also be minimized because standardized skull implants offer surgeons flexible options in preparing implants both pre- and intraoperatively. In addition, the skills required to prepare implants are not as critical (Hieu *et al.*, 2004).

2. Materials and Methods

One hundred donated dry skulls from Srinagarind Hospital, Department of Anatomy, Faculty of Medicine, Khon Kaen University, Thailand, were studied. These skulls were from the age range of 26 to 81 years old (54 skulls were males, 35 skulls were females, and 11 skulls were of unknown gender). These skulls were selected because they were in good conditions, undamaged, having no holes, and providing detailed records of age and gender.

2.1 CT scan and 3D modeling

Figure 1 shows the procedure to design the standardized skull implants. The obtained dry skulls were CT scanned with a Spiral CT scanner (SIEMENS). The commercial Medical Image Processing (MIP) software, MIMICS 10.0 (Materialise N.V., Belgium), was used to process the CT scanned data and perform STL (Stereo Lithography) model simulations. From MIMICS 10.0, 3D reconstructions of the skulls were obtained and anthropometrically measured by using Jorgensen's method (Jorgensen 1986), which identified significant landmarks in the skulls. These landmarks were also used later to classify the sizes of the standardized skull implants. A CAD technique was carried out to separate the outer wall contours of the skulls (only on the upper cranial vaults). Then, manual alignments were adjusted with respect to the reference plane passing through the landmark points: Glabella (GL), Left Porion (PorL), and Right Porion (PorR). The aligned contours were then converted into a Point Cloud format. These Point Cloud contours were then averaged by

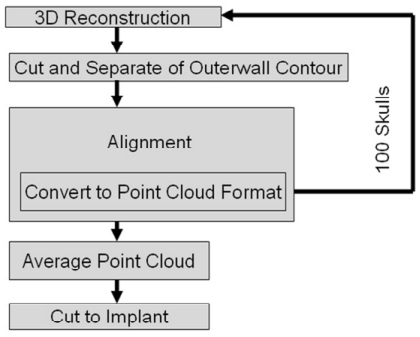

Figure 1. Design of the standardized skull implants

using a CAD technique, yielding the average surface contour of Thai skulls.

2.2 Statistical analysis

In this study, four main anatomical locations and their combinations were considered: Temporal (T), Parietal (P), Frontal (F), and Occipital (O). According to the statistics as shown in Figure 2, the area between Temporal, Frontal, and Parietal bones (T-P-F) was the most frequently injured area. Thus, the T-P-F area was focused in this study and the dimensions of the skull defects were then measured in this area. The average area (length and height) of the defects for both left and right sides was 115x94 ± (22x17) mm^2 (Sena *et al.*, 2006). The average surface contour was then incised in order to place suitable implants and this process was carried out under the supervision of surgeons. Usually, surgeons do not cut the bony contour directly on the sutures or midline, but leave approximately 1.5 cm distance from the Sagittal suture or other sutures. A freeform or shell-like shape of the final implant contour is illustrated in Figure 3, showing the left side of a skull that covers the temporal, frontal, and parietal bones. This type of shape can be made by titanium, PMMA, CFRP, or other alloplastic biocompatible materials.

The methodology to select standardized skull sizes was as follows: (1) an average surface contour must be known, and (2) by using the known average contour as a centroid, a multiplication factor was used to expand and reduce the average contour in order to obtain other sizes. In this study, the average surface contour from the previous steps was automatically named a medium size (M), which was the interval between -1σ and +1σ. By using the multiplication factors through the statistical analysis as shown in Table 1, two more sizes were derived as a large size (L) and a small size (S).

In order to determine which skull matched with any of the standardized size, the overall dimensions of the skull (maximum breadth (EuL-EuR), maximum height (Gl-Opc), and maximum length (Ba-Br) must be measured by CT scanning. In this study, the following terms were used instead: (1) maximum head breadth (mhb), (2) maximum head height (mhh), and (3) maximum head length (mhl). The standardized size which best matched two of three overall dimensions of the skull was then selected. If there was no match, size L would be chosen. For example, skull no.001 had the following dimensions: mhb = 146.6 mm, mhh = 118.8 mm, and mhl = 175.1 mm, thus, matching with the medium size (M) skull. In another example, skull no. 047 had the following dimensions: mhb = 149.9 mm, mhh = 125.0 mm, and mhl = 176.1 mm, which matched with all three sizes. As a result, the large size (L) skull was chosen.

2.3 3D comparison and error analysis

To validate the dimensional accuracy of the standardized sizes, a fitting technique using CAD was performed as follows. The CT scanned data of the 100 dry skulls were reconstructed as 3D models (Dicom format). Each model was measured to obtain mhb, mhh, and mhl values. Based on the statistical analysis from Table 1, one of the standardized skulls that best matched each dry skull model could be obtained as discussed previously. In each fitting, a dry skull model was compared to its standardized skull by measuring the gap between the outer wall contour of the dry skull and the surface of the standardized skull. Then, the result of the measured gap was analyzed and converted into color contours, showing the 3D gap. In this study, a total of 100 fitting tests was carried out to obtain the 3D gaps between the dry skulls and their standardized skulls. Afterwards, each standardized skull was virtually covered on top of its dry skull to determine if they were fitted and aesthetically accept-

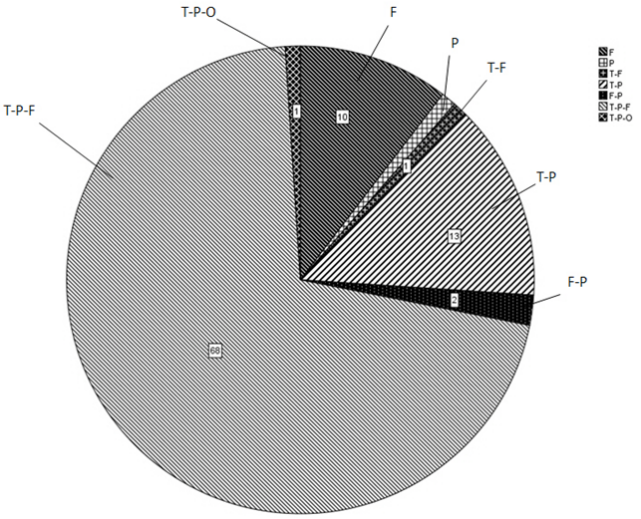

Figure 2. Frequently injured areas

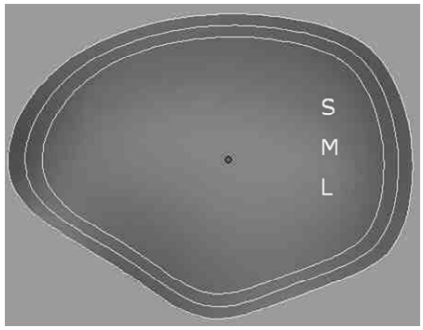

Figure 3. Implants with size S, M and L

Table 1. Size Classification

	S	M	L
Max Head Breadth	< 136.78	136.78 - 147.59	> 147.59
Max Head Height	< 129.38	129.38 - 140.87	> 140.87
Max Head Length	< 162.72	162.72 - 177.39	> 177.39

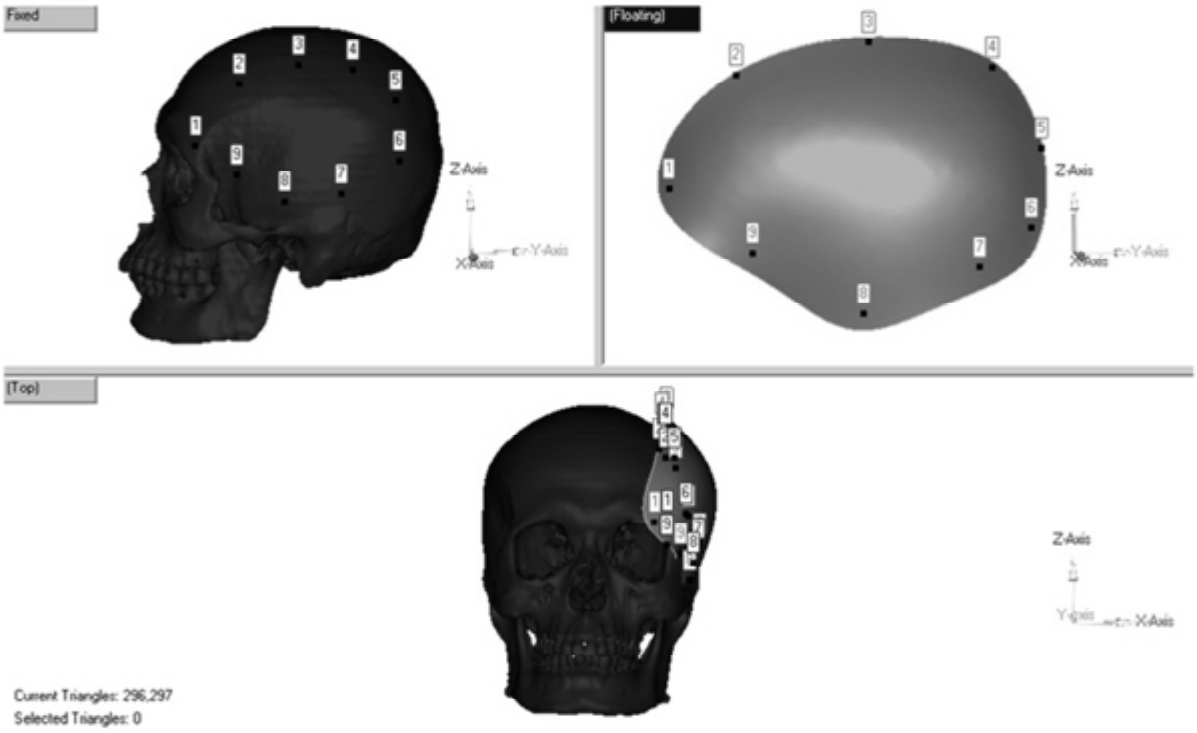

Figure 4. N - points registration

able. In order to adjust the positioning of each standardized skull to best fit its dry skull, the n-points registration method was used as demonstrated in Figure 4. From the figure, the dry skull was fixed and its standardized skull was floated. Finally, the 3D compare module in the CAD program (Figure 5) was utilized to observe the fit of the standardized skull to its dry skull. This validation method could also be used as a guideline for surgeons who would like to repair cranial defects by using standardized skull implants.

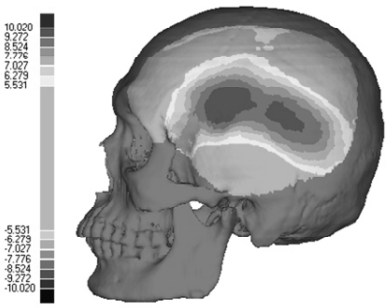

Figure 5. Contours of distance differences to test the fit of implants

2.4 Implant material selection

Regarding the material selection for implants, metal alloys were considered because they have been used to decrease trauma, e.g., total hip replacements, repair of knee or shoulder joints and spinal fixation devices, cardiovascular stents or even spinal discs replacement (Rack and Qazi, 2006). The biocompatibility of the materials must also be taken into account. Titanium is counted as the most biocompatible metal and is nonferrous with radiolucent properties, providing acceptable artifacts both in CT and MRI scanning (Chandler *et al.,* 1994). Recently, titanium implants have been applied to effectively cover cranial bone defects with good aesthetic results (Eufinger *et al.*, 1998; Eufinger *et al.*, 1999). The combination of titanium as a scaffold and hydroxyapatite in the load-bearing area is also possible (Ducic, 2002). Titanium also shows many advantages in its low elastic modulus, comparing more closely to *in vivo* bone than other metals. Titanium is lightweight when compared with other metals and has excellent corrosion resistance and enhanced biocompatibility. As a result, titanium should be selected as an implant material for repairing cranial defects and skull base reconstruction. In this paper, standardized skull implants made of titanium sheet metal (mesh) were considered because titanium has many biomedical advantages over other materials.

3. Results

Out of 100 dry skulls, 13 skulls matched size S, 77 skulls matched size M, and 10 skulls matched size L. The results of the 3D gaps obtained by calculating the difference between the outer wall of the dry skulls and the surfaces of their standardized surfaces are shown in Table 2. To determine the statistical values of all 100 3D gaps, the following

Table 2. 3D comparison between implants and skulls (in mm)

	Size S (n=13)	Size M (n=77)	Size L (n=10)
Maximum Distance Positive	15.54	16.51	14.57
Maximum Distance Negative	-7.96	-7.5	-6.79
Average Distance	2.77	2.69	2.82
Average Distance Positive	3.41	3.10	3.18
Average Distance Negative	-1.12	-0.85	-1.05
Standard Deviation	2.31	1.93	2.02

values were obtained: (1) maximum distance positive = 16.51 mm, (2) maximum distance negative = -7.96 mm, (3) average distance = 2.71 mm, (4) average distance positive = 3.15 mm, (5) average distance negative = -0.91 mm, and (6) standard deviation = 1.99 mm. The maximum, average, and minimum values represented the errors of the standardized skulls. Positive values indicated that the standardized skull surface protruded out of the dry skull. Negative values indicated that the standardized skull surface recessed into the dry skull. Figure 6 demonstrates the positive and negative areas of the skulls.

4. Discussion

Based on the average value of 2.71 mm with the standard deviation of 1.99 mm, these standardized skull sizes were considered feasible to be used as standard skull implants. According to the previous statistical analysis by Sena and Piyasin, it was found that the confidence intervals at 95% of the studied dry skulls were narrow (Sena and Piyasin, 2008). The same dry skulls were also used in this study, which implied that these dry skull samples could be representatives of the Thai population. In addition, the anthropometrical skull dimensions for the other races in ASEAN countries were compared as shown in Table 3 (Hung, 1995). Due to the similarity in the antropometrical skull dimensions, the standardized skulls could be potentially used in the ASEAN countries.

The standardized implants will help surgeons reduce the time required to prepare implants. Also, the CT scanning process will no longer be necessary, thus, decreasing the treatment costs considerably. Therefore, using standard implants will be a good option for cranioplasty when compared with conventional methods. Nevertheless, some of the following challenges must be overcome in order to implement the standardized implants method. Surgeons must be familiar with the medical imaging and 3D modeling techniques. Despite the fact that these techniques can remarkably shorten the product life cycle of the implants, the possibility of having unlimited designs is high because many trials have to be conducted until the satisfactory result is obtained. Also, bony reconstruction of cranial defects is a challenging technique and needs to be studied further. In this study, the bony reconstruction technique was only validated in the computer simulation. However, the in vivo test in a living bone tissue should be performed in order to evaluate the functional, aesthetic, and biocompatible aspects of the standardized implants prior to testing in clinical trials. Finally, the clinical outcomes need to be evaluated and validated for further development of the standardized cranial implants.

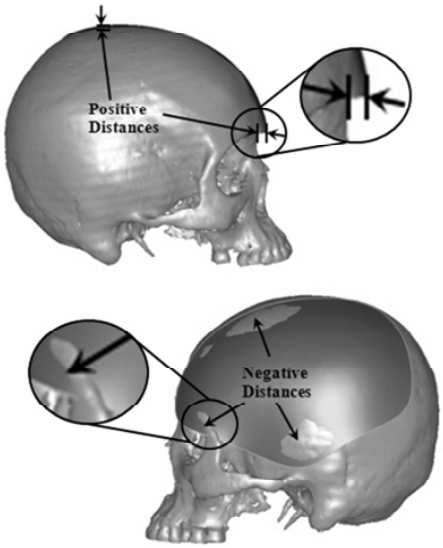

Figure 6. Positive and negative distances

Table 3. Anthropometrical dimensions between races (Hung, 1995)

Dimensions	Vietnamese	Lao	Thai	Cambodian
Head length[mm]	175.22±4.5	167.9±7.8	168.6±7.45	137.7±8.4
Head width[mm]	137.9±5.58	144.05±4.8	141.4±5.9	140.4±5.9
Head height[mm]	136.99±3.26	132.7±3.5	135.9±4.9	136.8±6.0

5. Conclusions

The standardized skull implants approach was presented by introducing three standardized skull sizes: small (S), medium (M), and large (L). The comparison between the standardized skulls with the dry skulls showed that the medium size skull (size M) provided the most matches, which agreed well with the statistical analysis. The average error of the gaps between the standardized skulls and the dry skulls was 2.71±1.99 mm and the statistical dimensions of the Thai skulls were very similar. The results showed that the standardized implants method was feasible for cranioplasty. This method can be applied in cases having major and minor defects where the areas are not too complex, e.g., forehead. By using the standardized skull implants, CT scanning, medical imaging, and RP processes are no longer required. Most importantly, the cost of implants preparation will be decreased because CT scanning is not conducted and one fabrication mold can be used multiple times. Surgeons only need to measure the overall sizes of a patient's skull and select one of the standard implants that best fits the skull. Standardized implants are suitable for patients with low income and practical in the regions where no costly aforementioned equipment is available.

Acknowledgement

The authors would like to thank the Department of Anatomy, Faculty of Medicine, Khon Kaen University, for supplying the cadaver heads and the Department of Radiology, Faculty of Medicine, Khon Kaen University, for the CT scanning support. In addition, the authors would like to acknowledge the National Metal and Materials Technology Centre (MTEC), Thailand, for their financial and facility supports.

References

Chandler, C.L., Uttley, D. and Archer, D.J., and MacVicar, D. 1994. Imaging after titanium cranioplasty. British Journal of Neurosurgery. 8, 409-14.

Chen, J.J., Liu, W., Li, M.Z. and Wang, C.T. 2006. Digital manufacture of titanium prosthesis for cranioplasty. International Journal of Advanced Manufacturing Technology. 27, 1148–1152.

Ducic, Y. 2002. Titanium Mesh and Hydroxyapatite Cement Cranioplasty: A Report of 20 Cases. Journal of Oral and Maxillofacial Surgery. 60, 272-76.

Eufinger, H. and Wehmoeller, M. 1998. Individual prefabricated titanium implants in reconstructive craniofacial surgery: Clinical and technical aspects of the first 22 cases. Plastic and Reconstructive Surgery. 192, 300-308.

Eufinger, H., Wehmoeller, M., Harders, A. and Machtens, E. 1999. Reconstruction of an extreme frontal and frontobasal defect by microvascular tissue transfer and a prefabricated titanium implant. Plastic and Reconstructive Surgery. 104, 198-203.

Gupta, R., Connolly, E.S. and Mayer, S. 2004. Hemicraniectomy for massive middle cerebral artery territory infarction, a systematic review. Stroke. 35, 539–543.

Hieu, L.C., Vander Sloten, J., Bohez, E., Phien, H.N., Vatcharaporn, E., An, P.V., To, N.C. and Binh, P.H. 2004. A Cheap Technical Solution for Cranioplasty Treatments. Technology and Health Care. 12, 281-292.

Hung, L.H. 1995. Anthropometric Characteristics of Modern Vietnamese Skulls. Doctoral dissertation, Hanoi University of Medicine, Hanoi, Vietnam 1995.

Joffe, J.M., Nicoll, S.R., Richards, R., Linney, A.D. and Harris, M. 1999. Validation of computer-assisted manufacture of titanium plates for cranioplasty. International Journal of Oral and Maxillofacial Surgery. 28, 309-313.

Jorgensen, J.B. 1968. Anthropometric and Anthroposcopic Technique. Publishing of Physical Anthropology Laboratory: Anatomik Institut. University of Copenhagen, Anatomical Institute: Denmark. Kobehavn, 10-15.

Lee, M.Y., Chang, C.C. and Lin, C.C. 2002. Custom implant design for patients with cranial defects. IEEE Engineering in Medicine and Biology Magazine. 21, 38-44.

Rack, H.J. and Qazi, J.I. 2006. Titanium alloys for biomedical applications. Material Sceince and Engineering C. 26, 1269-77.

Sena, K., Piyasin, S. and Sitthiseripratip, K. 2006. Craniometric Studies of Skulls for Design of Implants in Thailand. Proceedings of the 2nd International Symposium on Biomedical Engineering, Bangkok, Thailand, November 8-10, 2006, 103-106.

Sena, K. and Piyasin, S. 2008. Determination of Average Contour of Thais Skulls for Design of Implants. American Journal of Engineering and Applied Sciences. 1(3), 168-173.