Technical Strategies

Development of a New Three-Dimensional Cranial Imaging System

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The development of a new three-dimensional (3D) imaging system designed to obtain a digital image of an infant's cranium is described. This system is intended to replace the manual plaster-casting technique currently used during the process of fabricating cranial remodeling bands. The system uses 18 triangulated digital cameras and the projection of random infrared patterns to capture a 360° image of an infant's cranium instantaneously, including the face and top of the head. Accuracy was calculated by comparing models digitized with this system with the same models digitized with high-precision inspection equipment. Safety was documented under guidelines established by the American Council of Governmental Industrial Hygienists. Images were acquired in 0.008 seconds and processed for viewing in software within 2.5 minutes. Accuracy was calculated to be ±0.236 mm. Hazard analysis confirmed the system to be safe for direct continuous exposure. The data acquired may be viewed as a point cloud, wire frame, or surface on which a digital photograph (ie, texture) is automatically overlaid. Physical models are created by exporting the digital data to a multiaxis milling machine or stereolithography machine. Quantitative data (linear and surface measurements, curvature, and volumes) can be obtained directly from the digital data. The cranial imaging system is a safe and accurate method of obtaining digital 3D images of an infant's cranium. Along with the obvious clinical and manufacturing benefits, it also has significant potential as a research tool for documenting the natural history and evaluating the treatment of plagiocephaly.

Key Words: Imaging, three-dimensional, deformational plagiocephaly

The use of cranial remodeling bands in the treatment of deformational plagiocephaly has become a standard of care in the United States.[1–10] The process by which a cranial band is fabricated requires the clinician to obtain a negative or "cast" impression of the child's head. This is accomplished by first pulling a cotton stockinette over the child's head and then casting with quick-setting and low-temperature plaster splints (Fig 1).[5]

The casting process takes approximately 7 to 10 minutes; when performed by a skilled clinician, it results in an accurate three-dimensional (3D) model of an infant's cranium. Unfortunately, the current technique does not allow for casting of the infant's face, which is often desirable considering the significant amount of facial asymmetry that may be present. Additionally, because the casting process is messy, many parents are reluctant to repeat it at the end of treatment, limiting the amount of quantifiable data regarding treatment outcome. For these reasons, we have developed a new 3D imaging system intended not only to replace the plaster-casting technique but, more importantly, to allow us to 1) obtain more detailed information about the infant's initial deformity; 2) monitor progress throughout treatment; and 3) perform more sophisticated outcome studies, including a more detailed analysis of

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Fig 1 Obtaining a cast impression of an infant's head.

changes in facial and skull base asymmetry. Designed as a safe and noninvasive method of obtaining a 3D model of an infant's cranium, the system had to overcome numerous technological challenges that were not immediately evident during the initial stages of development.

To be useful in a clinical setting, the system had to be fast (<1 second), safe, accurate, repeatable, quiet, and impervious to motion; the system also needed to capture all skin tones and could not require the child to be restrained in a specific orientation. Additionally, the system needed to capture a 360° image, including the face, top of the head, and lower occiput/neck region. It was also determined that a photographic image of the child should be acquired and seamlessly overlaid on the model to guarantee patient identification. The digital models needed to be processed and visualized within minutes to ensure that no data were missing before allowing the patient to leave the office. Calibration and operation of the system had to be simple, fast, and robust enough to handle normal clinical operation.

In this article, we discuss the development of this imaging system, describing the unique challenges faced in digitization of young infants. We present this work because we believe that it is important to demonstrate how safety and accuracy were established before introducing this technology to market and as a baseline for future studies. We also discuss the potential clinical benefits and research opportunities that are now becoming available as a result of this work.

MATERIALS AND METHODS

To begin the development process, we undertook an exhaustive search to identify and evaluate different digitization techniques. Numerous laser scanning, structured light, moiré, and triangulated charge couple device (CCD) camera systems were evaluated and rejected for reasons to be discussed later.[11–26] Therefore, we designed a new system using off-the-shelf components from 3dMD (Atlanta, GA).

The system comprises 18 triangulated digital cameras (6 located in each module) arranged in an equilateral triangle with each module located at a vertex (Fig 2). Twelve of the triangulated cameras are used to obtain information regarding the 3D shape of the infant's head (ie, shape data), whereas the remaining 6 capture black and white digital photographs (ie, texture data) of the child. A single projector is located in each of the three modules and projects a random infrared pattern onto the child at the moment the image is taken (Fig 3). This pattern cannot be seen by the operator or the child but is visible to the 12 cameras that obtain the shape information.

Calibration is accomplished by placing a calibration standard into the center of the system and simultaneously capturing 12 images of the standard. Using the 12 images and information about the calibration standard, the precise location and orientation of each digital camera with respect to one another are determined. This information, along with data regarding each of the camera's focal lengths and lens aberrations, is recorded in the computer as part of the calibration file. This calibration file is used later to reconstruct a 3D image of a child from 12 separate digital images.

To acquire an infant's image, the child and parent are positioned in the center of the equilateral triangle, with the infant sitting on an adjustable rotating stool. The infant is supported by the parent, who

Fig 2 Mother and child in three-dimensional cranial imaging system.

Fig 3 Random infrared pattern projected onto the surface.

may remain in the system while the child is digitized. Once the parent and infant are in position, the system operator presses a shutter and 18 images of the child are simultaneously recorded. Within 2.5 minutes, images from the 12 shape cameras are reconstructed into a 360° digital model using the previously recorded calibration data. Texture data (ie, digital photographs) are automatically overlaid on the model, although the data may be viewed with or without this information (Figs 4–7). Processing the 12 images into a single model can be done immediately after the acquisition, or several images can be acquired and processed at a later time.

Validation of Accuracy

System accuracy was validated by comparing the results of models digitized with the new imaging system (NIS) against the same models digitized with a high-precision coordinate measuring machine (CMM). The data obtained from the CMM machine were used as control data.

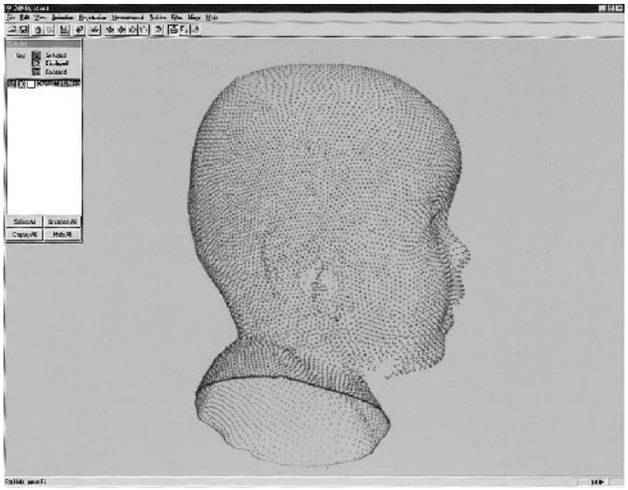

Fig 4 Point cloud representation of digital data.

A series of five 3D plaster head models (A-E) were digitized using the NIS, and the digital data were saved to compact disk (Fig 8). The models and data were then immediately delivered to an inspection service (Datum Inspection Services, Phoenix, AZ) for independent analysis. The plaster models were digitized a second time by the inspection service, this time using a Mitutoyo Bright A910 CMM calibrated and traced to National Institutes of Standards and Technology standards. The plaster models were set up on the CMM, and a coordinate system was established with the origin centered in the neck region and the z-axis protruding through the top of the head. Progressive scans were then taken along the x-axis from the top of the model to the bottom as the model was incrementally rotated about its origin.

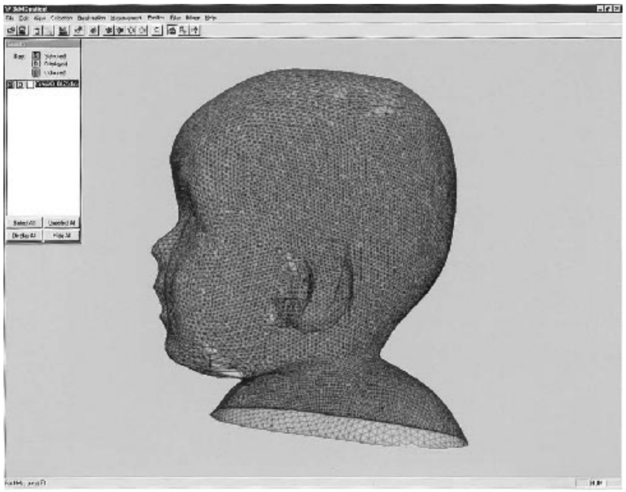

Fig 5 Polygon or triangulated representation of digital data.

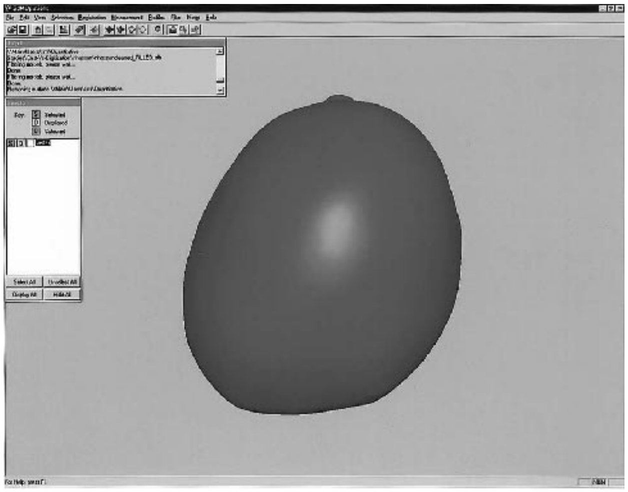

Fig 6 Surface representation of digital data.

The inspection service then imported the CMM data into a nonuniform rational B-spline modeling program (Rhino3D; Robert McNeel and Associates, Seattle, WA), which created a nonuniform rational B-spline surface from the point data, and the surface was offset to accommodate for the probe radius of the stylus. The original data obtained from the NIS system were also imported into Rhino3D and positioned approximately over the nonuniform rational B-spline model. Both models were then imported into dimensional analysis software (IQ-FormFit; Integrated Quality, Columbus, OH), and a best-fit analysis was performed to determine the accuracy of the new digital data (NIS).

Fig 7 Texture (photograph) overlaid on digital data.

Fig 8 Image of plaster model on screen as model is being digitized.

Safety (Hazard Analysis)

To ensure the safety of this system, an optical hazard analysis was performed by an independent product safety testing laboratory (Lasermet LTD, Dorset, UK) using standards established by the American Council of Governmental Industrial Hygienists.[27,28] This analysis examines the potential hazard to the human eye based on three specific mechanisms of injury: 1) retinal thermal injury; 2) retinal blue-light injury; and 3) infrared damage to the cornea, lens, and retina.

RESULTS

Accuracy

The best-fit analysis determines the amount of variation between a surface created with the new digitizer (NIS) and a reference surface created by the CMM machine. Accuracy is often reported as a "mean" or "average" difference between the surfaces; however, in this situation, reporting an average is inaccurate, because the surface created from the new data set may have components that lay above (+) and below (−) the reference surface. These positive and negative values offset each other, resulting in a mean value around zero. In situations where this cancellation can occur, it is necessary to report the mean difference as a root mean square. The root mean square statistic reflects the magnitudes of deviation without regard for positive or negative values.[29]

From the best-fit analysis, the root mean square mean deviation between the surfaces was calculated to be ±0.236 mm, with greater than 95% of the data clearly falling within ±0.5 mm. This is similar to results previously reported in a study using a phantom skull model and computed tomography scanner.[30] Results are presented in Table 1.

Safety

Results of the hazard analysis (Table 2) demonstrate that when used as designed, the system is safe. The system does not cause retinal blue-light and infrared eye injuries. Retinal thermal injury may only be caused if the infant is in the system 150,000 times longer than needed to capture the 3D image.

Capture Speed/Processing Speed

One of the fundamental requirements of this system was that the image acquisition had to be fast enough that movement of the infant would not present a problem for image capture or affect the accuracy of the data acquired. If the image could not be captured "instantaneously," it would be necessary to fix or restrain the child in one position to ensure there would be no motion artifact in the data.

The capturing of all 18 images (12 shape, 6 texture) is accomplished through utilization of a single frame grabber circuit board. At the time the shutter is depressed, a signal is sent out to all cameras to record the digital images for processing simultaneously, with all images being recorded within 1⁄125 of a second (0.008 second). This nearly instantaneous capture has allowed us to digitize infants in motion. The symmetrical placement of the cameras around the periphery also ensures that a child's specific orientation and position within the system are not factors.

A second requirement was that the postprocessing of the images into a single digital model had to be done quickly so that the image could be reviewed before allowing the patient to leave the office. Initially, integration of the 18 images into a single model required approximately 5 to 7 minutes, which was considered to be too long for efficient clinical operation. Recent improvements, including upgrading random access memory, processing speeds, and optimization of software algorithms, have now reduced this time to 2 to 3 minutes.

Table 1. Accuracy of New Imaging System

Model	*Mean Deviation Individual Models (mm)*	*Standard Deviation*	*Root Mean Square Deviation Individual Models (mm)*
A	0.109	0.191	0.219
B	−0.163	0.210	0.266
C	−0.104	0.206	0.231
D	−0.075	0.207	0.220
E	−0.095	0.226	0.244
Average values	−0.066	0.208	±0.236

Table 2. Exposure Limits

Injury Mechanism	*Exposure*
Retinal thermal	20 minutes per 8-hour period
Retinal blue-light	No limit (continuous exposure)
Infrared	No limit (continuous exposure)

Viewing of Data

Once processed, the data may be viewed in a variety of formats, including point cloud, wire frame, surface, and texture. As the name implies, the image presented as a point cloud consists of thousands of independent single points of data (see Fig 4). A wire frame, sometimes referred to as a polygon or triangulated mesh, connects three individual data points into a single polygon, with each data point being referred to as a vertex. A wire frame is the first step in viewing the individual data points as one continuous connected "surface" (see Fig 5). Once connected as a series of polygons, sophisticated mathematical algorithms are applied to convert the faceted and polygonized surface into a smooth continuous surface on which more complex measurements and mathematical analyses can be performed (see Fig 6). Although point clouds, wire frames, and surface renderings are the most common formats for viewing digital data, it is also possible to obtain texture information that is seamlessly overlaid on the model. Inclusion of "texture" data is critical to ensure proper patient identification (see Fig 7).

DISCUSSION

Significant advances in the field of 3D digitization in medicine have been achieved over the past 20 years based primarily on the efforts of numerous authors.[12-24,31–37] These investigators have demonstrated the utility of 3D imaging systems for numerous applications in the field of plastic and reconstructive surgery while overcoming many of the inherent challenges. The challenges we faced were unique to the specific limitations of digitizing infants. The patients to be digitized range in age from 3 to 18 months, with the younger patients often unable to demonstrate head control and the older patients being difficult to control for any extended period. A wide variety of head configurations, skin tones, and hair configurations also needed to be captured. The system had to acquire the image in a fraction of a second so that a child would not need to be restrained during image capture and any movement during image acquisition would not affect the data. The system had to be repeatable, accurate, and safe for regular repeated use. To be used in a clinical setting, the system had to be robust, simple to use, and easy to calibrate and maintain without the need for specialized staff to run the equipment. Image acquisition, processing, and viewing of the data had to be performed in real time to ensure that no data were missing before allowing the patient to leave the office.

To meet these stringent requirements, numerous digitization techniques were evaluated. Laser scanning methods were initially rejected because of the long time (typically 14-20 seconds) they took to scan an object, which would have required restraining an infant in a specific orientation. Recent advances have increased scan speeds to within 1 to 2 seconds; however, we have still found this to be unacceptably slow for the digitization of infants. The use of lasers also raised concerns regarding their appropriateness and safety for use with an infant population. Although many of the systems we evaluated did use "eye safe" lasers, fitting the patient with protective goggles was still frequently recommended. Structured-light moiré and phase-shifted moiré systems were also reviewed, but issues related to difficulty of calibration, cost, and speed removed these technologies from consideration. Computed tomography and magnetic resonance imaging were not considered simply because of size, expense, and concerns regarding radiation as well as the need to anesthetize the infant. At the time of initial evaluation, methods that relied solely on the triangulation of digital cameras proved to have insufficient accuracies, although recent improvements in digital camera technology may have resolved these issues. Structured light systems that combined triangulated digital cameras with a projected grid or line pattern were more successful; however, only one surface could be captured at a time, because the patterns projected by multiple projectors interfered with each other, resulting in a loss of data. In addition, the images captured by this system would need to be fitted together like a 3D jigsaw puzzle and required that markers be placed on the subject to facilitate this registration process.

The projection of a random infrared pattern overcame the problems with interference and enabled the digital capture of an entire infant head in a single shot. This comprises a 360° image, including the face, top of the head, and neck/occipital region, all acquired within 0.008 seconds. As designed, the system has been demonstrated to be accurate to within ±0.236 mm (root mean square), with greater than 95% of the data falling within ±0.5 mm. The system is safe and impervious to motion, it does not require the infant to be sedated or restrained, and images can be viewed within 2 to 3 minutes of acquisition. The data can be viewed in a wide variety of formats, including point cloud, wire frame, surface, and texture (photo), and can be exported to create physical models using stereolithography or carved on a multiaxis milling machine. Quantitative data (linear and surface measurements, curvature, and volume) can also be obtained directly from the digital data.

This system does have its' limitations, however. Despite the fact that this 3D imaging system yields much better data on the position of the ears than the casting technique, the current system cannot capture the intricate detail of the ears. This will likely be remedied through the addition of a few more camera pairs and/or by increasing the resolution of the existing cameras. Another limitation is that a stockinette must still be placed on the infant's head during digitization to eliminate problems associated with hair. This limitation is not critical, because stockinettes have been traditionally used in the casting process, do not bother the infants, and conform beautifully to the shape of the child's head. The prototype shown in Figure 1 is also much larger than originally envisioned, primarily because it was constructed with "off the shelf" components. Future systems will be much smaller and may even be hung from the ceiling.

The conclusion that will undoubtedly be drawn from this work is that a system now exists to replace the manual plaster-casting technique. If this were all the system was designed to accomplish, however, it would not be cost-effective to replace the low-cost manual casting technique with high-cost digital imaging. What makes this system valuable, and worth the expense in our opinion, is the potential improvement in clinical care that can be achieved. By digitizing our patients on a regular basis, we hope to be able to evaluate treatment outcomes more precisely and provide feedback and continuing education to our clinicians in the field.

As stated previously, the opportunity will exist to perform more sophisticated outcome and control studies. Nevertheless, it must be recognized that before these studies can be performed, many other issues that are outside of the scope of this paper must be addressed. For example, if one wishes to study changes during treatment with a cranial headband, issues arise with respect to registration and landmark identification as a result of the fact that the head will have changed not only in size but in shape. As appropriately pointed out by one of the reviewers of this report, how this analysis is performed is as important, possibly even more so, than the accuracy of the system itself. Any system that presents "before and after" results should be viewed with skepticism if the method of registration, method of measurement, and method of analysis are not specifically identified.

With these issues addressed, we hope to be able to investigate the success or failure of conservative interventions used in the treatment of plagiocephaly, such as repositioning, changes in the home environment, and neck-stretching exercises. In this scenario, the infant's head shape will be digitized before advising the parents to reposition the child and then digitized a second time when the child returns in 4 to 6 weeks. Comparison of these two images will demonstrate whether the child's deformity has improved, worsened, or remained the same. The natural history of plagiocephaly can thus be documented and normative data acquired for comparative purposes.

Broader application of this technology will eventually allow evaluation of the full spectrum of craniofacial deformities, monitoring of craniofacial growth patterns and processes that disrupt them, and evaluation of surgical outcomes. With more detailed quantifiable information, investigations can be performed to understand these disease processes better as well as the procedures designed to treat them.

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