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Semi-Automatic Computer-Aided System for Scoliosis Brace Design

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Abstract

With the emergence of Three-Dimensional (3D) printing technology, there has been a significant advancement in the design of corrective scoliosis braces. These braces can now incorporate multi-planar corrections, resulting in reduced manufacturing time and improved precision compared to conventional manual procedures. However, despite its potential, widespread adoption of 3D printing in this field is hindered by several factors. These include the lengthy design process; the limited availability of user-friendly scoliosis bracing design software for surgeons/orthoptists, and the additional resources required for technology development. In this study, a software system for personalized bracing design was developed using Blender. The system encompasses various features such as bi-planar X-ray/3D scan matching, machine-learning-based automatic spine segmentation, semi-automatic progressive scoliosis correction prediction based on free-form deformation, 3D bracing construction, and 3D model output function for 3D printing. The system was utilized by an orthopedic surgeon to design braces for 10 patients. All the 3D braces were printed using Nylon-12 material in a three-dimensional space. The findings of this study demonstrate several advantages of the developed system. Firstly, it significantly reduces the time required for designing 3D-printed scoliosis braces. Secondly, it decreases the learning curve associated with the software and minimizes the communication time necessary for treatment planning. Lastly, it provides accurate and comprehensive planning for scoliosis correction. Overall, the system facilitates the widespread adoption of 3D printing technology, benefiting a larger number of patients in need of scoliosis braces.

Keywords: Scoliosis; Scoliosis brace; 3D-printing technology

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Introduction

Scoliosis is a medical condition characterized by a minimum of 10° deviation from the normal vertical line of the spine (*i.e.* lateral curvature). The causes of scoliosis are heterogenous and can be categorized into congenital, neuromuscular, syndrome-related or idiopathic forms. The progression of the lateral curvature depends on the initial degree of curvature and the underlying cause. In several cases where patients suffered from idiopathic scoliosis after their skeletal development reached maturity, progression was observed if the curvature was above 50° but no progression if it was below 30°. To prevent such progression, orthotic management such as bracing is highly advised for patients who are not skeletally mature and with the curvature range between 25° and 50° [1-3].

The manufacturing of patient-specific scoliosis brace can be undergone by traditional manual processes. At first, a layer of plaster will be placed onto the patient's body to create a mould. The mould will be used to construct the negative casting of physical 3D body model in the factory. It is followed by modifications of the mould such as cutting or smoothening according to the clinical requirements. A plaster will be placed into an oven where it will be heated at the temperature of 160°C to 180°C until it becomes transparent. It will be wrapped around the body contour of the 3D model until their ends are fused together. It is essential to allow it to cool down before moving to next step where further editing was undergone to achieve the desirable shape. Lastly, all the jigsaw points will be manually smoothened. However, the conventional manual way of body moulding has become less popular and used considering its labor-intensiveness and inability of generating a customized scoliosis brace that meets the needs of the user. Therefore, the integration of novel

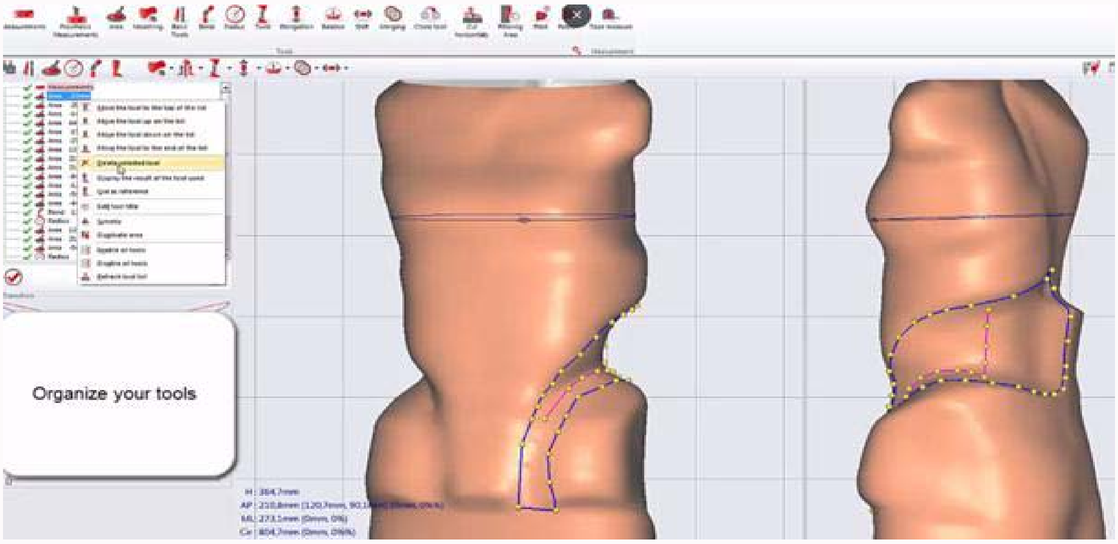

Figure 1: Tool library in Rodin4D.

brace-designing software with 3D printing technology was proposed as an alternative method of body moulding considering the benefits offered using 3D printing in different fields [4-6].

In medical aspect, 3D printing has advantages in the operating time, blood loss, fluoroscopy times, bone union time, pain, accuracy, and function [7-9]. It helps to plan the surgery more effectively and transfer to a better outcome from computer to operation room. 3D printing allows the surgeon to try various approaches before the operation in a riskless environment. It saves lots of time and minimizes the malpractice by comparing with the conventional approach as the best tool already determined during the planning. By implementing the 3D printing, the scoliosis brace is personalized for different patients and have immediate treatment effectiveness [10,11]. Besides, the 3D scoliosis brace is more comfortable to wear because it is thinner, lighter, more flexible and breathable, also with less labor time to manufacture by comparing with the standard polypropylene brace [12]. Furthermore, 3D printing can easily create complex shapes and make the precise adjustment to the stiffness of the brace to fit in the patients.

Nevertheless, the application of 3D printing has been hindered by the following factors: 1) long designing time, 2) deficiency of commercially available user-friendly brace designing software and 3) extra resources needed for developing the technology [13,14]. This study aimed to investigate the modelling time (*i.e.* the time for software learning and brace designing) needed for the use of conventional 3D system and the novel 3D system & also the structural similarities of the 3D brace models created by the two systems.

Materials and Methodology

Subject recruitment

In this study, 10 scoliosis patients were recruited according to a set of clinical requirements (*i.e.* inclusion criteria) which were as follows: 1) patients who were 10 years of age or greater, 2) Risser sign 0-II, 3) Cobb angle within the range of 20° and 40°, 4) pre-menarche or less than 1-year post-menarche for female and 5) did not receive prior treatment [15-17]. Other than the acquisition of X-ray images, patients also undergone scanning (EOS scan imaging system) to make up the 3D brace models prior to brace making.

Conventional 3D design software

Rodin4D software is one of the most used conventional 3D design software. With the Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) technology, Rodin4D software allows the orthopedic technicians to manufacture all kinds of 3D devices; including scoliosis brace models. Rodin4D also provides a wide range of high-performance tools (Figure 1), which makes 3D model design easy and fast. The finished 3D model can be exported as STL files for 3D printing. However, a two-day training course is needed for an orthotist to attend and learn to use the software.

Software structure and features

The novel system was built using Blender and with the use of Visualization Toolkit (Kitware, U.S.). The graphical user interface was built based on C programming language. To create a user-friendly software platform, the function keys were linked to 7 distinct functionalities: The import of X-ray/3D model, the matching of X-ray/3D model, extraction of spine curve, correction of 3D model, brace design, output of model and save scene functions (Figure 2).

Workflow of brace design and production

At first, the 3D human model was imported by clicking “Import STL” in “File Menu”. By clicking “Import X-ray” in “File Menu”, an X-ray image was also imported into the software. It was followed

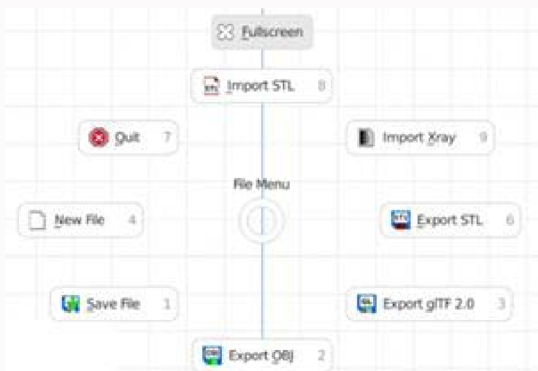

Figure 2: The function keys.

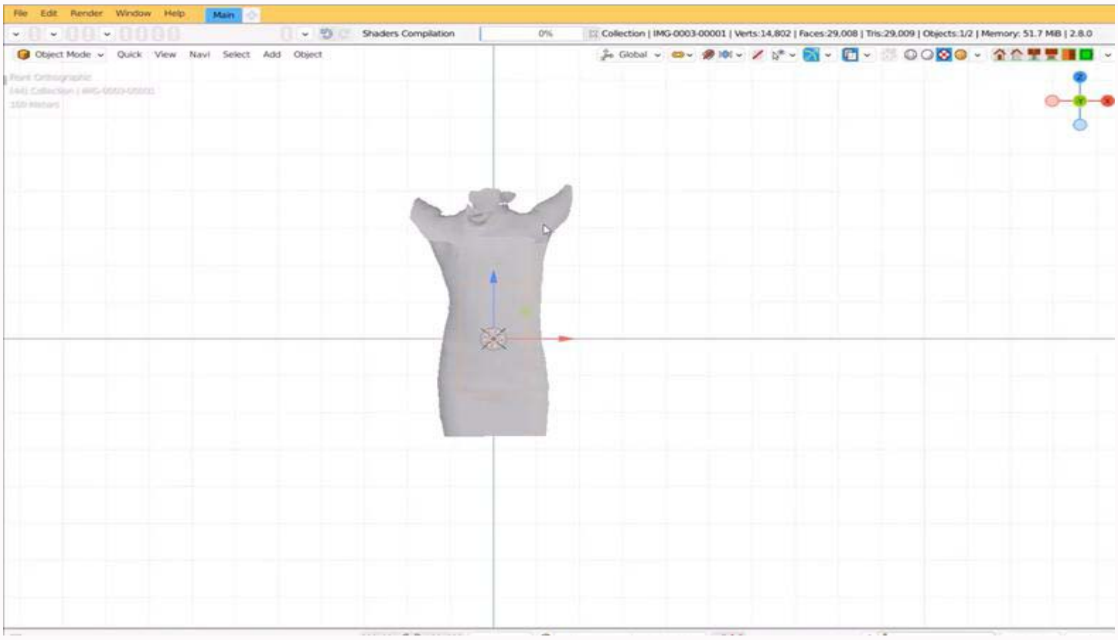

Figure 3: Matching between a pair of X-ray images and 3D model.

Figure 4: Extraction of spine curve with the use of drawing tool.

by positional matching between the X-ray image and the 3D model (Figure 3). During the matching, manual alignment of the image and model was conducted. The scale and the rotation angle of the X-ray image could be adjusted. The transparency of the 3D model could also be changed for viewing the alignment of the image and the model. The spinal curve was then extracted with the aid of drawing tools (Figure 4). In the center of each vertebra, joints were added with the drawing tool. The curvature of the spine was then extracted and visualized. After that, 3D correction and adjustment of the spinal curve was undergone. As the spinal curve was adjusted and straightened, all the joints were lined up. Hence, the appearance and the shape of the scoliosis brace were modified (Figure 5). At last, the repairment and cleaning up of the model were carried out in the "Edit Mode". The 3D model was selected by clicking "Select All Toggle". To remove the unnecessary parts, the "Bisect" function was used (Figure 6). After removal, "Object Mode" was selected. The "Flatten" function was used in the final step to flatten the minor protrusions of the scoliosis brace model and create a smooth brace surface. Finally, a lightweight, patient-specific brace design was ready for 3D printing (Figure 7).

Clinical assessment

It is important to conduct part-comparison analysis upon the structures of the "traditional" model (*i.e.* the brace model that was manually constructed by experienced orthoptists) and "novel" model (*i.e.* the brace model that was constructed based on the functionalities offered by the brace design software) in order to assess the degree of structural similarities between the 3D brace models made by two different systems.

At first, it started with N-points registration/part-comparison which consists of two phases-where the "fixed entity" and "moving entity" were initially selected. Fixed entity is the object that does not move whereas the moving entity moves to overlay onto the

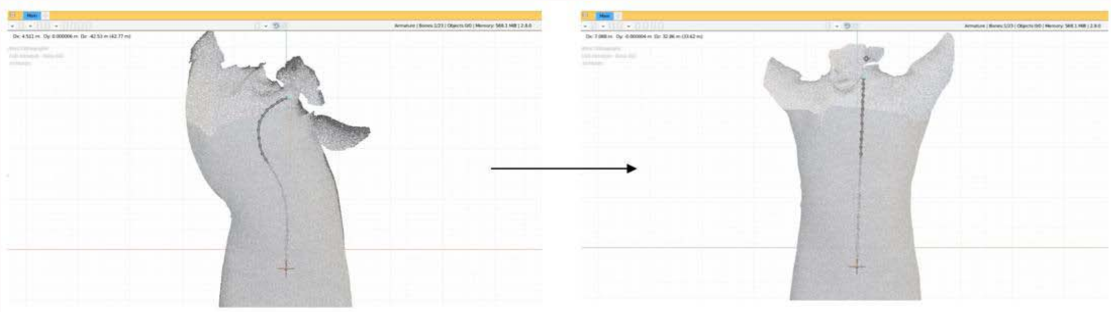

Figure 5: Adjustment of the spinal curve.

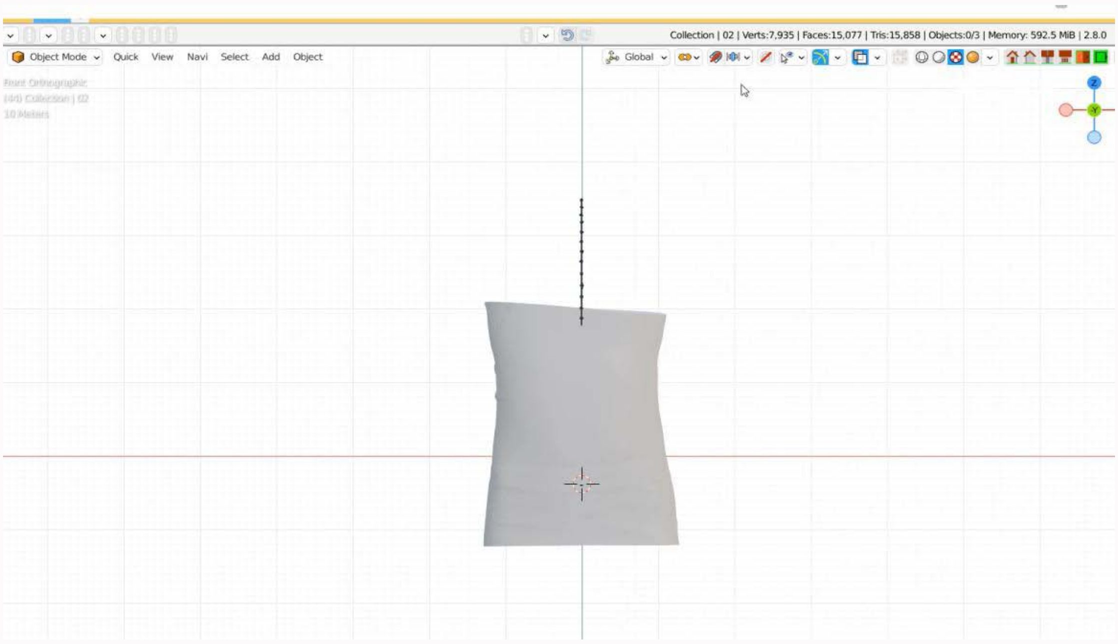

Figure 6: Removal of unnecessary part.

fixed entity. Then, it moved on to the second phase where several points were registered onto the two entities at the same coordinates which was to inform the points on the moving entity to coincide with the corresponding points on the fixed entity. Secondly, Global Registration which acted as the final registration of the two entities or models was undergone. The “traditional” model and “novel” model were chosen for “Selected entity” and “Target entity” respectively and then the overlaying processes were carried out for 10 iterations.

In this context, selected entity was the one moving to overlay upon the target entity. After the overlaying process was undergone, it came to the last step (part-comparison analysis) which results in a visible color gradient and a table of results in the processed 3D image (Figure 8). The range of colors displayed on the gradient implicates different degrees of spatial distance between the selected entity and the target entity. When the target entity is inside the selected entity, the values are more negative and tend to move towards the blue color of the gradient. Conversely, when the target entity is outside of the selected entity, the values are more positive and tend to move towards the red color of the gradient. Within the table of results, it consists of a list of statistical data such as RMS distance, mean, standard deviation and also analysis type- “signed” or “unsigned” where the former indicates that there is difference between the two models whereas no difference is found if the latter is shown.

Results

When the novel method was applied in brace making, it was observed that the designing and learning time were approximately 20.8 min and 31.2 min respectively. As an estimate of structural similarity between the braces made by the novel method and the conventional method, the Root Mean Square (RMS) distance between them was shown to be 2.51 ± 0.808 mm.

Discussion

According to the findings, as the scoliosis brace is designed personally based on the physique and spine curvature status of the patient, the structure similarity between the conventional plaster moulding method and the novel method is relatively high. Moreover, with the reduction in the complexity the executional framework of the software, the novel approach demonstrated a dramatic reduction in the time of designing and learning which is essential to facilitate the production and delivery of customized scoliosis brace to the hands of the patients.

Other than that, Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) technology which is in essence the

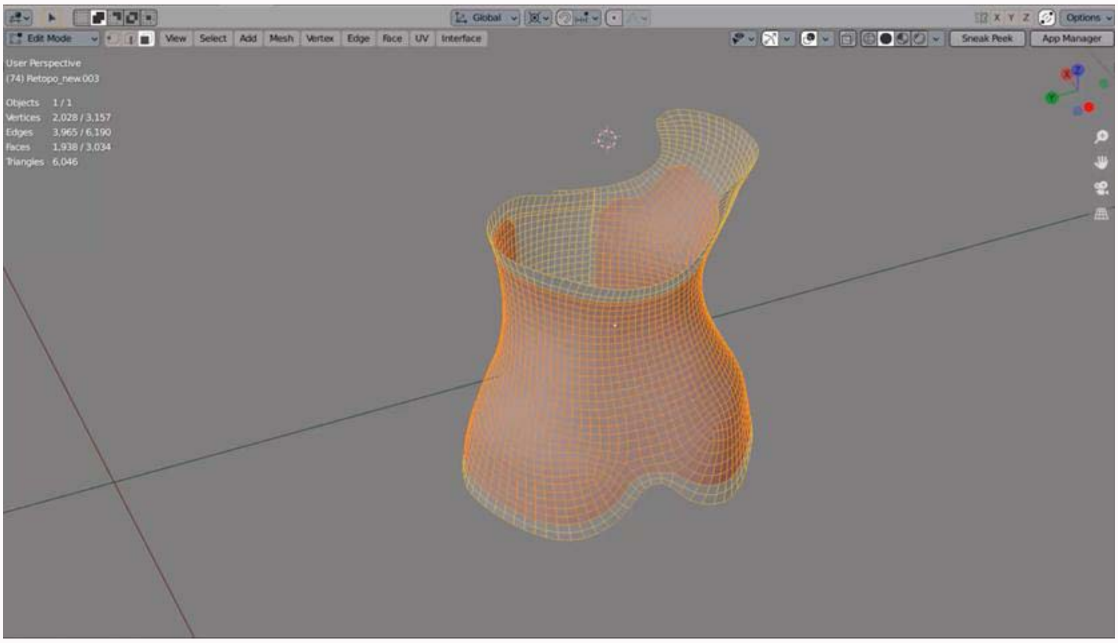

Figure 7: It showed a patient-specific scoliosis brace model that was ready for 3D printing after final modifications were undergone.

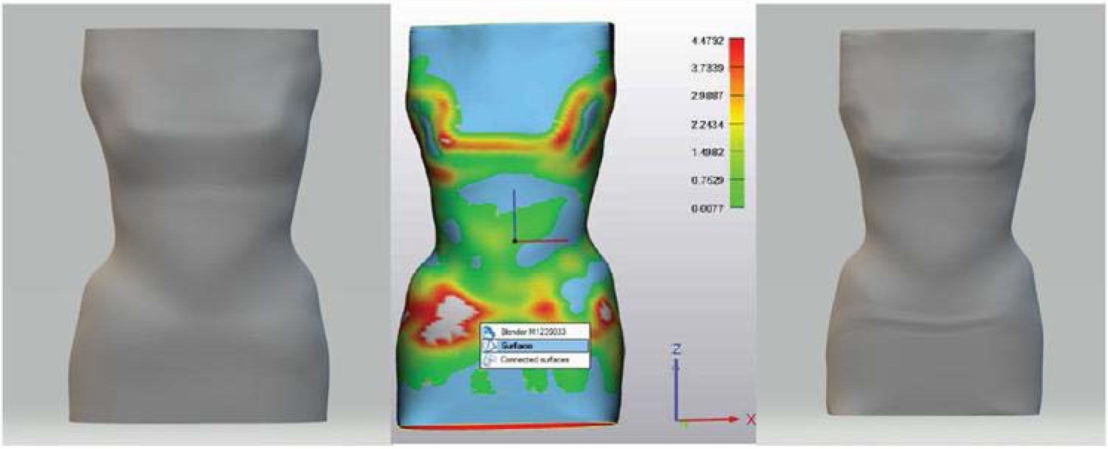

Figure 8: Part comparison analysis showing the RMS distance of product between new system and conventional 3D system.

foundation of the software is more effective and accurate than the conventional plaster-casting method in production of correction brace allowing more braces to be manufactured daily [8]. This novel approach has also shown to be superior to the traditional method in terms of clinical outcomes and users' preference [9]. Despite the average curve correction percentage caused by the novel method (51%) was not significantly different from the traditional one (44%) in patients with average Cobb angle of 30.8°, majority of patients were in favor of the novel brace than the traditional brace. The observed phenomenon could potentially be explained by the surface unevenness of the traditional brace which was caused during manual processes thus caused discomfort and unease of the patients. To which, the involved development suspected an improvement in the finalizing step of the traditional method might contribute a similar result between the two methods. Furthermore, the novel approach allows the storage of digital information of patient-specific brace whereas a new mould will need to be fabricated from scratch in the case of loss or damage of brace [9].

When a part-comparison analysis between models made by "traditional" and "novel" methods was conducted, the RMS distance was shown to be 2.51 ± 0.808 mm which was comparable with RMS distance between 20 distal femur models (*i.e.* 2.34 ± 0.82 mm) extracted from one literature [10]. Traditionally, RMSd is an indicator of structural similarities between two molecular structures in the field of biology. In this context, the RMSd value were able to obtain through part-comparison analysis and it was used to understand the degree of similarities between the structure of two corrective braces since there were same number of points placed on each structure for their alignments [18].

Other software's for designing scoliosis brace

Other than the mere use of CAD/CAM technology in brace production, additional elements can be introduced to further improve the effectiveness in scoliosis correction and enhance user experience. For instance, a group of researchers had employed the CAD/CAM software (Rodin4D) and simulation platform to construct NewBrace which is not only user-specific but also provides more comfort compared to traditional brace which is made by plaster/cast method. Despite a number of shortcomings with its clinical effectiveness such as relatively poorer reduction in Cobb angle, mean kyphosis and lordosis angles, it was reported to be more comfortable than the traditional brace by the majority of the recruited subjects [19].

Similar approaches could be observed in another study where they compared between their novel method (*i.e.* combination of CAD/CAM technology and numerical simulation in brace design in three planes which produced FEMBrace) and control method (*i.e.* rely solely on CAD/CAM in brace design in three planes to produce CtrlBrace) in terms of their impacts upon correction of scoliosis curve by using Randomized Controlled Trials (RCT). The three planes were coronal, transverse and sagittal planes. It was shown that the correction rendered by FEMBrace was significantly greater than the CtrlBrace in all three planes except sagittal plane- for instance, greater reduction in both Thoracic (T) and Lumbar (L) Cobb angles in the coronal plane, greater reduction in apical axial rotation but less reduction in kyphosis and no changes of lordosis [12]. Although the above two studies both used CAD/CAM and simulation in brace designing, the underlying mechanisms of simulation platform & CAD/CAM technology and other factor such as ways of conducting clinical trials might differ in each study which explained the different clinical outcomes brought about by each of them. To summarize upon their findings, the incorporation of simulation platform could potentially be an important element in designing corrective braces that render better clinical outcomes such as reduction of Cobb angles, apical axial rotation, kyphosis, and lordosis [20-23].

By comparing the novel approach with the methods of the two studies, the framework of the software is simpler which makes it easier to use. With the advantage, even an unexperienced orthoptist can learn to use the software in a short period of time to design and develop a high quality, patient-specific brace.

Limitations and Improvement

There are several limitations in this study including small sample size and lack of randomization during patient allocation. Firstly, there was a small sample size as only 3 subjects were recruited. Inadequate samples can result in the following problems: 1) data interpretation, 2) over-estimation of the existing relationship between variables and 3) unreliable findings [19]. When it comes to the interpretation of the findings, small sample size will generally result in a broader confidence interval and lower statistical significance (*i.e.* $p>0.05$) thus it will be hard to deduct any sensible or reliable meanings from small studies. Secondly, although the findings might assume potential benefit provided by the novel software, it might suggest otherwise in a larger sample size. Lastly, statistical analysis that aims to investigate the relationship between two variables will include other statistical models such as multivariate linear regression model to account for potential confounding factors. However, unreliable findings might result since numerous adjustments are made for a few confounders included to reduce the effects of the small sample size [24,25].

Last but not least, lack of randomization during subject allocation to respective groups. The Randomized Controlled Trial (RCT) has been deemed the gold standard to investigate the effectiveness of certain interventions (in this context, scoliosis brace) [26-28]. Randomization is defined as the allocation of subjects to control or experimental group in such manner that the subject has equal chance of being assigned to either group [29,30]. It renders numerous benefits including the elimination of selection bias and weighing between known and unknown confounding elements to ensure there is high degree of similarities between the control and experimental groups [31-33].

Future Investigations

There are various subjects that can be investigated in the near future. For instance, the user-experience of the brace designed by the novel design software can be investigated. A well-rounded questionnaire could be formed where questions about numerous aspects of the brace-aesthetics, weight and compliance which will provide valuable input for further modification of the system. A pressure sensor could also be incorporated into the scoliosis brace to monitor parameters (*e.g.* wearing time, body pressure) that are important for fine-tuning the features of the brace and also providing feedback for the design system in order to meet the requirements of the users [34,35].

Conclusion

As one of the methodologies in treating adolescent idiopathic scoliosis, corrective braces have been commonly used for correction of the spinal curvature at the range of 25° to 50°. The designing process of the braces can be conducted either by the conventional method (*i.e.* plaster cast) or more recently developed method (CAD/CAM technology). The latter was what this study used. It was clearly demonstrated that CAD/CAM braces were associated with improved clinical outcomes such as greater reduction in Cobb angles and kyphosis. Moreover, CAD/CAM technology also allowed orthoptists to design corrective braces in shorter period of time and with better quality which will significantly increase the manufacturing speed and user-experience thus more scoliosis patients will receive braces that are customized to their needs (*e.g.* comfort and compliance).

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