



Three-dimensional printing versus freehand surgical techniques in the surgical management of adolescent idiopathic spinal deformity

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Background: Three-dimensional (3D) printed guides are finding increasing applications in the field of orthopaedic surgery and more recently spine surgery. This retrospective cohort study compares benefits and costs of 3D printed guides in surgical treatment of adolescent idiopathic scoliosis (AIS) compared to freehand techniques.

Methods: Intraoperative screw placement was conducted either with 3D printed guides (3D cohort) or traditional freehand technique (freehand cohort) for AIS patients undergoing spinal fusion at a single institution. Patient and perioperative data include: screw placement time, length of surgery, blood loss, hospital stay, spinal curvature correction, total implant costs and training level of surgical assist. Multivariate analysis assessed for confounding and effect modification. P-values <0.05 were considered significant.

Results: There were 29 patients included in analyses, 18 in the 3D and 11 in the freehand (FH) cohort, for a total of 263 3D and 307 freehand screws. Between cohorts, there were no significant differences in patient age (P=0.93), gender (P=0.15), height (P=0.18) or weight (P=0.40). The 3D cohort (mean \$26,215, SD =\$6,374) had significantly higher implant costs than FH (mean \$18,660, SD =\$5,587, P=0.003) with significantly reduced intraoperative blood loss (mean 559 mL, SD =273 FH; vs. mean 357 mL, SD =123 3D; P=0.01). On multivariate analysis, surgical residents had significantly faster screw placement times when using 3D guides (P<0.001) than when placing screws freehand. There were no significant differences between cohorts in length of postoperative hospitalization, spinal levels fused, or coronal or sagittal curve correction.

Conclusions: At significant cost, 3D printed guides reduce intraoperative blood loss compared to freehand pedicle screw placement and reduce screw placement time for surgical residents.

Keywords: Adolescent idiopathic scoliosis; 3D printing; scoliosis; screw guide; resident education

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Introduction

Three-dimensional (3D) printing technology was first developed in the 1980s (1,2). Through the printing of titanium hardware implants and in preoperative planning and patient education (3), 3D printing has found increasing application within the field of orthopaedic surgery. Patient-specific 3D-printed guides for pedicle screw (PS) insertion in spinal deformity surgery offer an alternative to image-guided, robotic, and freehand methods. The 3D guides are printed using advanced imaging, are customized to patients, and are placed directly onto posterior elements of the vertebral level to be instrumented intraoperatively with openings that mechanically guide drilling, tapping, and screw placement into each pedicle or vertebral body (Figures 1,2). Reported overall accuracy for pedicle screw misplacement ranges from 5–15% (4). Although these estimates are low, Sarwahi *et al.* (5) argued that this reported screw misplacement does not reflect the potential impact on patient morbidity; after evaluating PS placement on a per-patient basis, the authors found that misplaced screws are of greater concern than previously believed. Recently, Sugawara *et al.* conducted a prospective multicenter study and found that patient-specific 3D guides offered improved accuracy for PS insertion (6).

Customized surgical drill guides that can be sterilized and utilized intraoperatively constitute a relatively new application of 3D printing technology (1,7). As such, printing the models remains expensive and the benefits and costs of 3D printed guides in adolescent idiopathic scoliosis (AIS) instrumentation have yet to be characterized or documented in the extant literature (1,7). Our hypothesis asked, if we utilize 3D printing technology in AIS operative fixation, will it change perioperative patient outcomes? Therefore, the objective of this retrospective cohort study was to investigate the benefits and costs of AIS fusion conducted with and without 3D-printed guides at a single institution. We present the following article in accordance with the STROBE reporting checklist (available at <https://jss.amegroups.com/article/view/10.21037/jss-22-28/rc>).

Methods

This analysis was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was given Institutional Review Board (IRB) exemption status by the ethics review board of Yale University, with individual consent waived for this retrospective analysis.

3D guides

Pedicle screws were placed with the assistance of 3D printed guides (Figure 1) until the authors' institution acquired a 3D fluoroscopy unit, which enabled intraoperative verification of screw placement. Following this, all patients were managed with freehand surgical technique, which was followed by intraoperative 3-dimensional fluoroscopy verification of appropriate screw placement (8). The ZIEHM C-arm was utilized for intraoperative fluoroscopy. FIREFLY® Pedicle Screw Navigation Guides were obtained from Mighty Oak Medical®. Preoperative computed topography (CT) scans were conducted with slice thickness of 0.625 mm and pitch of 1.375. The material used to manufacture patient-specific components is an epoxy resin indicated for use in stereolithography systems. Patient-contacting materials used for non-patient-specific components are manufactured in accordance with ASTM F899 or F136 (9). In the pediatric population, surgery was to occur within six months of CT scanning for FIREFLY® compatibility.

Data collection

This retrospective cohort study included all patients with AIS who underwent spinal fusion at a single institution by a single surgeon from December 2019 through July 2021. Sample size was estimated via continuous outcome superiority trial with significance level (alpha) of 5%, and power (1-beta) of 90% (10). Patients with neuromuscular scoliosis were excluded. Patient data, training level of surgical assist, intraoperative measures including length of surgery, blood loss, and indication for pedicle screw intraoperative replacement were collected. Additionally, perioperative outcome measures including length of hospital stay and curve correction, and total implant and 3D printing costs were collected. Intraoperative blood loss was collected as cell saver volume x3 for consistency. The postgraduate training year (PGY) of the first surgical assistant, including fellows, was recorded. Residents ranged in experience from PGY2 through PGY5. Fellows were considered PGY6 for statistical analyses. To minimize bias, screw placement time was recorded in minutes per spinal level by the neuromonitoring team rather than surgical team. In cases where this data was not available, minutes per screw were calculated by recording the total surgical time for screw placement, again as measured by the neuromonitoring team, and dividing this time by the total



Figure 1 Three-dimensional printed anchor placement. Following exposure, the three-dimensional (3D) guide is placed onto the spinal model to determine how the docking points should sit on the inferior facets and transverse processes. In the above figure, the cephalad aspect of the spinal model is closest to the viewer, while the caudal aspect is hidden from view.

number of screws placed. The primary outcome evaluated was intraoperative blood loss. Secondary outcomes included time per screw placement, length of surgery, and length of hospitalization.

When the 3D guide could not be properly aligned intraoperatively on the bony spine, surgical instrumentation was completed with freehand techniques and the spinal level, side, and indicated reason were marked. This was most commonly encountered at the uppermost instrumented vertebra (UIV), where soft tissue constraints led to difficulty placing the guide on the posterior elements with appropriate fidelity of the bone to the 3D printed guide. There were no scenarios where a pedicle screw had to be removed following placement utilizing an appropriately-fitting 3D guide. Freehand pedicle screws were replaced and documented when a screw was found to be malpositioned on 3D fluoroscopic imaging, requiring



Figure 2 Three-dimensional printed guide placement on spine. The placement of three-dimensional (3D) guide on thoracic spinal level 7 (T7). The thoracic spinal level 6 (T6) screws are placed and the inferior facets of T6 are removed with a burr. The inferior facets of the transverse processes of T7 must be intact for the 3D guide to dock appropriately and appropriately guide drill hole placement.

intraoperative repositioning or removal. If the 3D guide did not fit appropriately intraoperatively, or spinal levels required fusion above or below the level planned by the 3D guide, screws were placed freehand.

Statistical analysis

Shapiro-Wilk test was used to determine data normality. Univariate analysis was conducted with Student's *t*-test and Pearson's chi-squared for normally distributed data. A Wilcoxon rank-sum (Mann-Whitney) test was used for nonparametric data. Multivariate analysis assessed for confounding and effect modification. Poisson modelling was used for multivariate analysis with heteroskedasticity. An interaction term was included to account for the observed relationship between time per screw placement and level of training (PGY year), which was treated as a categorical

variable: resident, fellow, or attending. A P value of 0.05 was established for statistical significance. All analyses were conducted with use of STATA MP version 16 (StataCorp).

Results

A total of 29 patients were included in the study, 18 in the 3D cohort and 11 in the freehand (FH) cohort (*Table 1*). Between cohorts, there were no significant differences in patient age ($P=0.93$), gender ($P=0.15$), height ($P=0.18$), weight ($P=0.40$), or preoperative curve magnitude ($P=0.42$) (*Table 1*). On average, 3D guides were used in cases assisted by surgical trainees of lower training levels, as the median training level for freehand screw placement was PGY6 (i.e., fellow), compared to the median training level of cases done using 3D guide (PGY5; $P=0.01$) (*Table 1*). The 3D cohort (mean \$26,215, SD = \$6,374) had significantly higher implant costs than those of the FH cohort (mean \$18,660; FH, SD = \$5,587, $P=0.003$) (*Table 1*). The 3D cohort also had significantly reduced intraoperative blood loss (mean 357 mL, SD = 123), compared to the FH cohort (mean 559 mL FH, SD = 273, $P=0.01$) (*Table 1*). On univariate analysis, there was no significant difference in screw placement time by screw type ($P=0.66$) (*Table 2*). There were no significant differences between cohorts with respect to the length of postoperative hospitalization, number of spinal levels fused, presence of postoperative kyphosis, presence of postoperative lordosis, or coronal curve correction.

Across 29 cases, 570 pedicle screws were placed, including 307 freehand and 263 with 3D guidance (*Table 2*).

On multivariate analysis, greater number of spinal levels fused was associated with significantly increased intraoperative blood loss ($P=0.01$), while 3D guided screw placement was associated with significantly decreased intraoperative blood loss ($P=0.04$) (*Table 3*). Patient age and training level of first assistant did not serve as statistically significant predictors of intraoperative blood loss (*Table 3*). Poisson modelling was used to account for data heteroskedasticity with an interaction term to account for a significant interaction between training level of first assist and 3D versus freehand techniques (*Table 4, Figure 3*). Screw placement time was significantly less for residents when 3D models were used compared to freehand ($P<0.001$) (*Table 4, Figure 3*). When the first assist was a fellow or attending level surgeon, freehand technique was significantly faster ($P<0.001$) (*Table 4, Figure 3*).

Discussion

This study is among the first (7,11,12) to examine the use of 3D printed technology in the surgical management of adolescent idiopathic scoliosis (AIS). This study suggests that the use of 3D printed guides decreases intraoperative blood loss when compared to the use of standard freehand pedicle screw placement. Additionally, for cases with a resident surgeon acting as first assist, the time per screw placement was significantly less when 3D guides were used compared to freehand technique. The use of 3D printed guides was associated with higher implant costs compared to cases done using traditional freehand technique for screw placement, with no significant difference between groups regarding other intraoperative performance measures or perioperative outcomes other than reduction in intraoperative blood loss.

In 2015, Yang *et al.* (7) conducted a retrospective study of 126 patients with Lenke 1 AIS who underwent posterior corrective surgery. Fifty of these patients had a preoperative 3D printed spine model made and had “simulated surgery” prior to their operation; the other patients had surgery using traditional freehand technique for screw placement without a preoperatively printed spine model. The patients who underwent posterior corrective surgery without a preoperatively printed 3D model had longer operative times, increased blood loss, greater transfusion volumes, and lower postoperative hemoglobin (7). The authors demonstrated the value of 3D printing in facilitating preoperative planning and enhancing a better preoperative understanding of the unique anatomical features of a malrotated spine. Their study, however, did not specifically examine the intraoperative use of 3D printed guides. Garg *et al.* (13) compared 10 patients treated with patient-specific-guides with 10 patients treated using freehand technique for screw placement and found greater accuracy and shorter operative times when using patient-specific guides.

Lopez *et al.* (11) recently conducted a systematic review of the use of 3D printed guides in spinal deformity surgery and found that cases performed with 3D printed guides reported greater accuracy of screw placement, shorter operative times, and no significant difference in estimated blood loss. A study by Talathi *et al.* (14) also showed that AIS cases first-assisted by a resident had higher blood loss than those assisted by fellows. Our analysis demonstrates that blood loss was significantly reduced when using 3D

Table 1 Comparative values of freehand vs. three-dimensional guided techniques per case

Factor	Freehand	3-D	P value	Test
N	11	18		
Age, years, mean (SD)	14 (1.8)	14.1 (1.4)	0.93	Two sample <i>t</i> -test
Gender			0.15	Pearson's chi-squared
Male	6 (55%)	5 (28%)		
Female	5 (45%)	13 (72%)		
Risser Score			0.74	Pearson's chi-squared
0	0 (0%)	2 (11%)		
1	2 (18%)	1 (5%)		
2	1 (9%)	1 (5%)		
3	1 (9%)	2 (11%)		
4	6 (55%)	9 (50%)		
5	1 (9%)	3 (17%)		
Height, mean (cm) (SD)	165 (7.7)	161 (7.2)	0.18	Two sample <i>t</i> -test
Weight, mean (kg) (SD)	56 (9.2)	60 (12.2)	0.40	Two sample <i>t</i> -test
Training year of surgical assistant			0.01	Pearson's chi-squared
Resident (PGY 2-5)	1 (9%)	13 (72%)		
Fellow	9 (82%)	3 (17%)		
Attending	1 (9%)	2 (11%)		
Implant cost, mean (\$) (SD)	18,660.4 (5,586.8)	26,214.9 (6,374.3)	0.003	Two sample <i>t</i> -test
Supply cost, mean (\$) (SD)	3,366.2 (1,174.5)	3,846.3 (1,453.9)	0.36	Two sample <i>t</i> -test
Length of surgery, mean (hours) (SD)	4.40 (1.1)	4.5 (0.8)	0.84	Two sample <i>t</i> -test
Intraoperative blood loss, mean (mL) (SD)	559 (273)	357 (123)	0.01	Two sample <i>t</i> -test
Cell saver repletion (mL) (SD)	179 (124)	116 (71)	0.14	Two sample <i>t</i> -test
Allogenic blood products used	1	1	0.72	Pearson's chi-squared
Length of hospitalization (days) (SD)	3.1 (0.5)	3.1 (0.8)	0.94	Two sample <i>t</i> -test
Levels fused, mean (SD)	11 (1.8)	9.7 (2.9)	0.20	Two sample <i>t</i> -test
Pre-op curve, mean (SD)	58 (9.7)	61 (11.5)	0.42	Two sample <i>t</i> -test
Post-op curve, mean (SD)	11 (5.1)	11.4 (4.9)	0.84	Two sample <i>t</i> -test
Curve change, mean (SD)	47 (11)	50 (9)	0.42	Two sample <i>t</i> -test
Postoperative kyphosis, mean (SD)	35.8 (6.4)	35.4 (6.2)	0.86	Two sample <i>t</i> -test
Postoperative lordosis, mean (SD)	59.3 (11.7)	56.3 (9.0)	0.44	Two sample <i>t</i> -test

3-D, three-dimensional; PGY, post-graduate year.

Table 2 Comparative time of screw placement using freehand vs. three-dimensional guided techniques

Factor	Freehand	3-D	P value	Test
N	307	263		
Time per screw, median (minutes) (IQR)	3.7 (1.7)	4.0 (1.9)	0.66	Wilcoxon rank-sum

3-D, three-dimensional.

Table 3 Multivariate regression of blood loss with respect to screw placement method and spinal levels fused

Characteristics	Impact on blood loss	95% CI	P value
Training level of first assistant	-13.9	-135.0, 107.2	0.82
Number of spinal levels fused	36.7	8.2, 65.1	0.01*
Patient age	1.2	-46.2, 48.5	0.96
Screw type (3D vs. freehand)	-164.1	-325.9, -2.3	0.04**

3D, three-dimensional.*Greater number of spinal levels fused had significantly more blood loss. **Screws placed with 3D models had significantly less blood loss than freehand.

Table 4 Time per screw placement by training level for freehand and three-dimensional guided screw placement

Input	Time (minutes)	SE	95% CI	P value
Freehand				
Resident	6.6	0.24	6.1, 7.1	<0.001
Fellow	3.6	0.05	3.5, 3.7	<0.001
Attending	3.9	0.13	3.6, 4.1	<0.001
3D				
Resident	3.9	0.09	3.7, 4.1	<0.001
Fellow	5.1	0.46	4.2, 6.0	<0.001
Attending	4.9	0.01	4.8, 4.9	<0.001

Poisson modelling was used to analyze the interaction term between screw type and training level of first assist when using freehand versus three-dimensional modelling techniques. 3D, three-dimensional.

guides, despite the majority of 3D printed cases being performed with a less experienced first assistant. Other perioperative outcomes were equivalent between groups. A larger cohort study is needed to clarify the mechanism

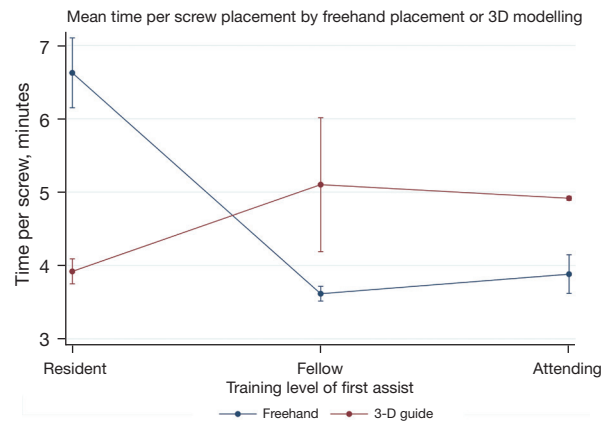


Figure 3 Poisson multivariate model for variables affecting screw placement time. A Poisson model was used to account for heteroskedasticity with respect to time per screw placement. Variables are expressed as means with standard 95% confidence intervals. A strong interaction term was observed between the training level of the first surgical assist and time per screw placement, with residents (PGY levels 2-5) benefitting the most from the use of three-dimensional (3-D) guides.

behind this decreased blood loss, as the total length of surgery was similar between groups and all other blood conservation measures (use of perioperative tranexamic acid, hypotensive anesthesia, etc.) were held constant in the present investigation. It is important to note that, in this study, the decreased blood loss in the 3D printed guides group did not translate to fewer blood transfusions between groups. Other perioperative characteristics were equivalent between the two groups. These findings suggest that the use of 3D printed guides may be a valuable training tool that can aid the education and proficiency of younger trainees without compromising patient safety and outcomes.

The total cost of spinal surgery completed with 3D printed guides was significantly more expensive than surgeries completed with freehand techniques, primarily due to implant costs. The increased average cost noted in this study of approximately \$7,500 in the 3D-printed group relative to the freehand group is similar to that reported in prior studies (7,11). Costs of 3D printed surgical planning models vary broadly from \$175 for a 3D printed template model to \$5400 for sophisticated 3D printed spinal phantom training (11) in addition to overall costs of pedicle screws and other permanent implant components. One potential solution to these costs could include the use of alternative materials to manufacture 3D printed guides, which may be less expensive than polymer-based 3D printed

models (11). Ultimately, further cost analyses, including cost-effectiveness analyses, may be warranted to determine if the increased cost of the 3D models is justified when similar perioperative outcomes have been demonstrated. It is possible that 3D guides may only be justified in academic training centers where surgical residents are regularly acting as first surgical assists.

It is possible that the true value of 3D printing is fully realized in more complex cases, where significant rotational deformity and dysplastic concave pedicles make safe pedicle screw placement particularly challenging. Pan *et al.* (15) demonstrated greater accuracy (96% *vs.* 89%) when using 3D printed mechanical guides in a comparison of spinal deformity cases done with 3D guidance versus those done freehand. Operative time was similar between groups. In contrast to this study, in which the average preoperative coronal curve magnitude of each cohort was 58° or 61° (Table 1), Pan *et al.* reported average curvatures in excess of 90°. Likewise Yang (7) found that preoperative 3D printing improved outcomes in curvatures in excess of 50°, but not in curvatures below this threshold. Selective utilization of 3D printing for more complex cases may serve as the optimal solution to ensure safety and accuracy while minimizing costs.

Limitations to this study include its relatively small sample size and lack of follow-up. In addition, pedicle screws placed freehand were assessed for accuracy with intraoperative 3D fluoroscopy, whereas the screws placed using 3D printed guides were not, precluding a true comparison between the two groups in terms of accuracy. Moreover, it was found that use of the 3D printed guide was often precluded due to body wall issues, preventing the guide from docking securely on the upper instrumented level. This resulted in the surgeon resorting to the FH method of screw placement or the placement of alternative anchors (hooks) at the top of the construct.

Conclusions

3D printed guides constitute an emerging tool in aiding safe and efficient placement of pedicle screws in pediatric spinal deformity surgery. This study shows that they may decrease intraoperative blood loss and time per screw placement for surgeons in training, but total operative time, curve correction, and other perioperative outcomes appear to be the same when compared to cases done with freehand technique. The associated cost of 3D guides, compared to freehand surgical techniques, are significantly greater due

to the cost of product manufacturing. Future research to further evaluate the utility of 3D printed guides in spinal deformity surgery may include cost-effectiveness analyses, large, retrospective randomized studies, and larger cases series with longer patient follow-up. The findings described herein add credence to some of the known benefits associated with the use of 3D printed guides in pediatric spinal deformity correction surgery, which merit further investigation and innovation to refine their utility.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jss.amegroups.com/article/view/10.21037/jss-22-28/rc>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This analysis was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was given Institutional Review Board (IRB) exemption status by the ethics review board of Yale University, with individual consent waived for this retrospective analysis.

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