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Original Research

# A Patient-Specific Three-Dimensional-Printed Surgical Guide for Dorsal Scaphoid Fracture Fixation: A Comparative Cadaver Study



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#### ARTICLE INFO

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Key words: 3D printing Custom surgical guide Patient-specific Scaphoid fixation Scaphoid fracture *Purpose*: This study proposes a patient-specific three-dimensional (3D)-printed surgical guide designed for scaphoid fracture fixation through a limited dorsal approach.

Methods: Computed tomography scans of five cadaveric wrists were modeled in 3D segmentation software and cannulated screw guidewire trajectory was planned. Custom 3D-printed surgical guides for guidewire insertion were designed for each scaphoid. Guidewire placement was performed with and without the surgical guide through a dorsal approach. Postoperative scans were overlaid with the planned trajectory and compared. Five variables were measured: angular deviation, distance between entry points, distance between exit points, embedded guidewire length, and number of attempts.

Results: Mean angular deviation from the planned trajectory was  $10.80 \pm 6.72^{\circ}$  for the guided and  $14.08 \pm 4.65^{\circ}$  for the freehand group. The offset between entry and exit for the guided group was  $2.22 \pm 1.04$  and  $3.52 \pm 2.80$  mm and for the freehand group  $2.95 \pm 1.31$  and  $4.91 \pm 2.37$  mm, respectively. The mean length for the guided group was  $23.25 \pm 3.33$  mm and  $23.31 \pm 3.07$  mm for the freehand group. All guided cases took one attempt and the freehanded cases  $2.0 \pm 1.0$  attempts. A significant positive correlation was found between trajectory and exit. No significance between groups was found between any of the measured variables. A minimum sample size of 28 was determined for follow-up studies.

Conclusions: The use of a custom surgical guide improved guidewire placement in four of five specimens when compared with a freehand approach. Specifically, the trajectory was closer to the planned trajectory. All guidewire placements were clinically acceptable. Therefore, we consider the use of this surgical guide for the dorsal approach feasible to be used in clinical practice.

Clinical relevance: This device could be used to treat nondisplaced scaphoid fractures. The use of a custom surgical guide could allow for accurate and efficient screw placement as well as reduced operating time and fluoroscopy exposure.

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A scaphoid fracture is the most common type of carpal fracture, making up 10% of all hand fractures with an annual incidence rate of 29 per 100,000.<sup>1–3</sup> Scaphoid fractures can be treated nonsurgically or surgically depending on the fracture and patient needs<sup>4</sup> but surgical approaches are often recommended.<sup>4–6</sup>

Corresponding author: Johannes Sieberer, MS, Department of Orthopaedics and Rehabilitation, Yale School of Medicine, 47 College Place, New Haven, CT 06510. E-mail address: johannes.sieberer@yale.edu (J.M. Sieberer). The standard surgical intervention is a single cannulated headless compression screw inserted over a guidewire.<sup>7</sup> Precise screw placement through the center of the scaphoid and long screw length provides optimal fixation.<sup>8–10</sup> Inadequate screw placement could result in a longer time to union<sup>11</sup> or nonunion, which, in turn, can lead to arthritis over time and scaphoid nonunion advanced collapse.<sup>2</sup> Placing a scaphoid screw centrally can be challenging because of the bone's small size and unique shape.<sup>10,12</sup> Intraoperatively, the surgeon must position the guidewire as close as possible to the longest and most central scaphoid axis in both the anteroposterior and lateral planes.<sup>13</sup> Achieving this perfect

**Table 1**Five Cadaveric Arms Used in this Study Labeled C1—C5 With Relevant Characteristics

Case No.	Age (y)	Weight (kg)	Sex Assigned at Birth	Surgical Side
C1	61	144	F	L
C2	63	126.1	M	R
C3	62	124.3	M	L
C4	48	131.5	F	R
C5	37	84.4	M	L

"center—center" may require several attempts, which prolongs fluoroscopy exposure and operating time. The ability to efficiently insert the guidewire at center—center is critical for optimizing the surgical outcome. Advanced three-dimensional (3D) navigation methods can help surgeons not only achieve a better freehand trajectory but also allow for positional error.<sup>13</sup>

Three-dimensional-printed patient-specific surgical guides can and have been used to successfully force a predetermined guidewire trajectory. 14–21 However, the current scaphoid surgical guides in the literature are limited to large sleeve-like designs that rely on fully encasing the patient's wrist and partially the forearm. Although this does allow for a percutaneous approach, patient swelling or excessive soft tissue (eg, fat tissue) may lead to reduced accuracy, as these guides rely on the wrist's or forearm's outer shape to maintain positioning. Additionally, the manufacturing of large designs needs more preoperative time and printer capacity limiting their large-scale use.

Furthermore, these studies demonstrate the use of a surgical guide in a volar approach instead of dorsal. Although the procedure can be performed from either approach, central placement might be more reliably achieved dorsally.<sup>2,8,22</sup> Additionally, depending on the fracture location and patient anatomy, a dorsal approach may be required.<sup>2,23</sup> For example, engaging a small bone fragment in the proximal scaphoid can be difficult to achieve through a volar approach.

This study proposes a dorsal scaphoid surgical guide design, relying solely on the proximal pole of the scaphoid to direct the guidewire to the central, long axis of the scaphoid. Guidewire placement on five cadaveric wrists using the guide was compared with the standard freehand technique. We hypothesize that with the guide, a surgeon will consistently achieve central guidewire placement from a miniopen dorsal approach with improved guidewire placement compared with the freehand approach.

#### **Methods and Materials**

Surgical guide design

### 3D model preparation

Five cadaveric arms were procured from United Tissue Network for this study and labeled C1—C5 as outlined in Table 1. Preoperative computed tomography (CT) scans were acquired of each arm in two positions, one with the wrist secured in maximum flexion and another in a neutral pronated position (0.625 mm slice thickness with contiguous slices,  $512\times512$  matrix and 0.72 mm pixel size, Spectrum Dynamics). These were used for designing the surgical guide and to validate initial guide designs. The flexed CT scans were acquired to better understand bone movement during surgery and were not needed for guide design.

## Guidewire trajectory planning

Computed tomography scans were segmented in Materialise Mimics 26.0, and planning was performed in 3-matic 18.0 (Mimics Innovation Suite, Materialise NV). All scans were segmented with a

threshold >250 Hounsfield units and manually corrected to produce a 3D model to be used in 3-matic. The guidewire and cannulated screw were modeled after a commonly used scaphoid fixation system (Acutrak 2 Mini Headless Compression Screw; Acumed Ltd). Guidewire insertion was planned at the tip of the proximal pole, and the trajectory was centered in the anteroposterior and lateral planes to determine center—center placement (Fig. 1). All trajectories were planned to provide the most central screw placement possible as well as maximize screw length for optimal fixation. Guidewire trajectory for C1—C5 was validated by the senior author, an experienced fellowship-trained hand surgeon.

## Guide base design

The surgical guide base was designed to cover the proximal pole of the scaphoid that is exposed during traditional scaphoid fracture fixation without increasing the standard 1-1.5cm transverse incision.<sup>23</sup> A curvature analysis was conducted for each cadaveric scaphoid to optimize the guide base by including areas of high curvature while avoiding anatomical attachment points and critical vasculature such as distal to the dorsoradial ridge (Fig. 2A, B).<sup>2</sup> The guide base was then generated from the footprint to be 3 mm thick at the proximal pole to provide maximum stability for the guiding tubes with a 0.15 mm offset from the bone model. The proximal volar extension shown in Figure 2D was 1 mm thick to avoid interference with the distal radius. A primary guiding tube was added based on the preplanned center-center guidewire trajectory. A second guiding tube was added parallel to the first to be used if needed (Fig. 2E). In a clinical setting, this second parallel guidewire would serve to stabilize the scaphoid fragment during screw insertion and is recommended for unstable fractures according to the Acutrak 2 Headless Compression Screw System surgical technique guide.<sup>24</sup> The guidewires used were Kirschner wires (K-wires) with a 1.14 mm diameter, and the guiding tubes were designed with a 1.44 mm diameter to allow a glide fit and account for printing tolerances. All surgical guides were appropriately labeled with edges smoothed. The guide surfaces were marked as proximal "P," radial "R," and dorsal "D" (Fig. 2C-E) to ease placement. All surgical guides were then printed on a FormLabs SLA printer with BioMed Amber V1 resin and postprocessed according to the manufacturer's guidelines. Guides were then autoclaved according to our institution's sterilization procedure.

## C1-C5 comparison of guided and freehand placement

#### Guided group

The surgical guide design was tested on all five cadaveric wrists, C1–C5, each with unique scaphoid morphologies and customized corresponding surgical guides. A standard transverse dorsal approach for guidewire insertion was followed.<sup>23</sup> For each wrist, the corresponding custom surgical guide was placed on the scaphoid proximal pole with the wrist in maximum flexion. A supplementary guidewire was placed through the off-center secondary guiding tube to stabilize the surgical guide placement (Kirschner wires, 1.14 mm [0.045 in] diameter). Once proper positioning of the surgical guide was confirmed by the surgeon, the primary guidewire was directed through the guiding tube into the center of the scaphoid (Fig. 3). Only one attempt was allowed to ensure that the resulting images would demonstrate how well the guide succeeded in directing the guidewire trajectory. Clinically acceptable guide wire placement was evaluated after placement. In this study, no screw was placed to compare the planned and achieved guidewire trajectories for both groups. A cone beam CT scan of each cadaveric wrist was then acquired with the wrist in a

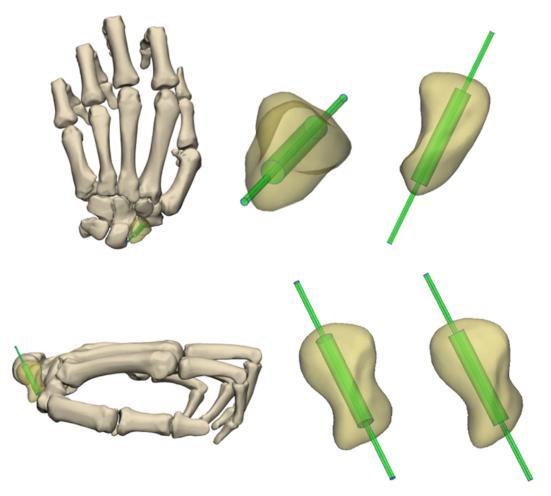


Figure 1. Visualization of the planned guidewire trajectory of C5 centered in the anteroposterior (top row) and lateral (bottom row) planes.

neutral position. The guidewire and surgical guide were removed for testing the freehand placement.

## Freehand group

To assess the validity of our surgical guide design, guidewire insertion was repeated without the surgical guide in all five wrists. Using the conventional freehand dorsal approach, the guidewire was inserted through the scaphoid proximal pole. Because of the small-sized K-wire used, the surgeon could not see the guided attempt for initial placement of the guidewire. The trajectory was assessed intraoperatively using fluoroscopic imaging. The surgeon was allowed as many attempts as needed until the guidewire placement was deemed clinically acceptable per fluoroscopy imaging according to their experience. The number of attempts was recorded. Cone beam CT scans were taken afterward with each wrist in a neutral position.

Comparison of planned versus postoperative guidewire trajectory

Postoperative cone beam CT scans of C1–C5 were segmented and modeled in Mimics and 3-matic following the protocol described above. For both groups, the postoperative scaphoid bone and guidewire model were overlaid with the planned trajectory in 3-matic. In order to evaluate the accuracy of the guidewire placement, five variables were measured for each scan: angular deviation ( $\alpha$ ), distance between entry points (e1), distance between exit points (e2), the length of the guidewire inserted from entry to exit point (1) (Fig. 4), and the number of attempts per group (n). The

angle between the planned and postoperative trajectory was calculated as  $\alpha$  in degrees, and all distances (e1, e2, and l) were recorded in mm.

#### Statistical analysis

The mean and SD were calculated for all five variables in both the guided and freehand groups: Angular deviation  $(\alpha)$ , distance between entry points (e1), distance between exit points (e2), the length of the guidewire from entry to exit point (l), and the number of attempts (n). Box plots were created to visualize the results.

Statistical differences between angular deviation and distance between entry points and exit points were calculated with Mann-Whitney U tests, as the expected distribution is unknown. Significance was assumed at *P* values <.05. For nonsignificant results, an a priori sample size calculation was conducted to inform future studies.

Additionally, correlation between the variables determining accuracy,  $\alpha$ , e1, and e2, was evaluated with a bivariate Pearson correlation test.

## Results

All recorded measurements are shown in Table 2. The mean angular deviation was  $10.80 \pm 6.72^{\circ}$  in the guided group and  $14.08 \pm 4.65^{\circ}$  in the freehand group. The difference between planned and achieved entry and exit was  $2.22 \pm 1.04$  mm and  $3.52 \pm 2.80$  mm, respectively, for the guided group. For the freehand group, e1 was

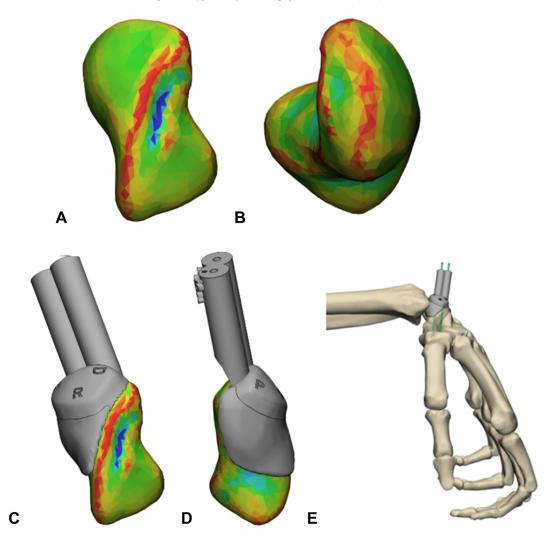


Figure 2. Scaphoid curvature analysis to identify key features including the dorsoradial ridge (A) and proximal pole (B). Final guide base design with orientation markers (C lateral view, D volar view) and planned K-wire trajectories (E).

 $2.95 \pm 1.31$  mm, and e2 was  $4.91 \pm 2.37$  mm. Figure 5 shows box plots of the guided and freehand groups for  $\alpha$ , e1, and e2. The mean embedded length for the guided group was  $23.25 \pm 3.33$  mm and for the freehand group was  $23.31 \pm 3.07$  mm. All guided cases were deemed clinically acceptable and took only one attempt (n=1), as mandated by the study methodology. The average number of attempts for the freehand group was  $2.0 \pm 1.0$ .

No significant results were found between any of the variables measured in this study (Table 2). A bivariate Pearson correlation test was performed to determine the correlation between the three measured variables that determine accuracy:  $\alpha$ , e1, and e2 (Table 3). A significant positive correlation was found between angular deviation and exit point deviation with a correlation value of 0.769.

The guided attempts of C1 and C4 did not adhere to the planned trajectory, with angular deviations of 19.05 and 16.79°, respectively. C1 is pictured below in Figure 6A—C. However, C2, C3, and C5 in the guided group did show low angular deviation and alignment with the planned trajectory. The most accurate guided trajectory was found to be C5, pictured in Figure 6 D—F. The entry point deviation in C5 was 0.84 mm, with a 4.15° angular deviation, resulting in an exit point deviation of 1.65 mm (Fig. 6D—F). Further comparison of the freehand with the guided trajectory demonstrated more central placement for C5 when the guide was used (Fig. 7). Similar observations of improved placement were found for C1, C2, C3, and C5;

however, C4 had a more central placement when freehanded as opposed to guided.

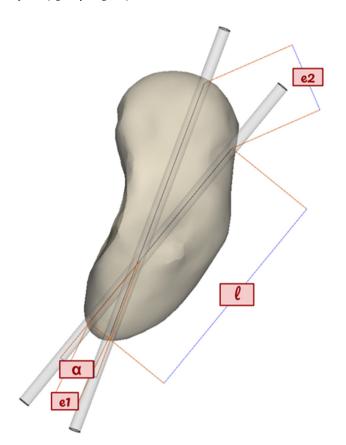
## Discussion

In this study, we developed a surgical guide for dorsal scaphoid fracture fixation. We evaluated our design by measuring the accuracy of the guided guidewire placements and comparing the use of a surgical guide with a freehand approach. We found that four of five guidewire placements were superior to the freehand method used as control because of a more central placement. Three of five placements were deemed highly accurate as a result of a small angular deviation from the planned trajectory and minimal offset from the desired entry and exit points. Statistical significance of differences was not shown due to the limited sample size of five cadavers. A minimum sample size of 28 was determined for further studies or clinical trials.

The high accuracy of the guided guidewire trajectory in C2, C3, and C5 suggests acceptable screw placements that would be embedded through the center—center of the scaphoids. However, the guided placements of C1 and C4 were less accurate. As verified by the significant correlation between  $\alpha$  and e2, even with adequate starting points for C1 and C4, the high angular deviation above  $10^\circ$ 



Figure 3. Guidewire placement through the custom surgical guide from a miniopen dorsal approach. Some cadaver arms (left top image, C1) had more soft tissue and smaller scaphoids (right top image, C1) than others.



**Figure 4.** Measurements pictured include angular deviation ( $\alpha$ , degrees), distance between entry points (e1, mm), distance between exit points (e2, mm), and the length of the guidewire from entry to exit point (I).

resulted in an inaccurate exit point. However, the guided C1 attempt still improved placement compared with the freehand because of a closer exit point and longer length. C4 is the only case in which the freehanded attempt was more accurate than the guided attempt. Contrary to the trajectory, the average embedded length was not significantly different between the groups. Although center—center placement may lead to the best mechanical properties, because of the shape of the scaphoid, it does not necessarily lead to the longest embedded length, which might explain why embedded length was not different between the two groups.

Prior to this cadaveric experiment, multiple guide base designs were considered. The goal of the current design was to allow for optimal stability without increasing the surgical window. The final design was pulled back from the scapholunate joint as far as possible while maintaining the desired guidewire entry point. To avoid harming critical vasculature, the radial surface of the guide base follows the proximal part of the dorsoradial ridge. We observed during the cadaveric study that the most important component of the guide was the proximal volar extension. This extension cups around the volar edge of the scaphoid, signifying to the surgeon when the guide is properly placed. However, it is important to note that because of these anatomic restrictions, the surgical guide is not fully constrained. The primary point of stability is the volar edge, but there is still a possibility of the guide deviating if not placed correctly as seen in C1 and C4. Both guided trajectories deviate radially at the exit point, indicating that the radial surface of the surgical guide was not flush with the bone as intended. This could potentially be because of unseen soft tissue caught underneath the guide surface or movement of the guide during guidewire insertion. During the guide development, both flexed and unflexed CT scans were acquired to better understand bone movement during surgery, which proved to be unnecessary for

**Table 2**Measurements Recorded for Angular Deviation ( $\alpha$ ), Distance Between Entry Points (e1), and Distance Between Exit Points (e2), the Length of the Guidewire From Entry to Exit Point (I), and the Number of Attempts to Achieve Satisfactory Placement (I) for Both the Freehand Group and the Guided Group

Group	Case	α (deg)	e1 (mm)	e2 (mm)	l (mm)	n
Guided	C1	19.05	2.78	6.69	21.35	1
	C2	5.66	1.42	2.18	27.98	1
	C3	8.34	3.32	0.71	21.89	1
	C4	16.79	2.72	6.38	20.50	1
	C5	4.15	0.84	1.65	24.81	1
	Mean	10.80	2.22	3.52	23.31	1
	SD	6.72	1.04	2.80	3.07	0
Freehand	C1	18.91	1.75	8.47	19.97	3
	C2	12.31	3.44	6.25	27.62	2
	C3	18.94	5.00	3.26	20.03	3
	C4	11.73	2.50	3.43	23.38	1
	C5	8.52	2.07	3.13	25.26	1
	Mean	14.08	2.95	4.91	23.25	2
	SD	4.65	1.31	2.37	3.33	1
Guided versus Freehand	MWU test	0.42	0.55	0.42	N/A	N/A
	P value					
	Minimal Sample size	24	22	28	N/A	N/A

MWU, Mann-Whitney-U test.

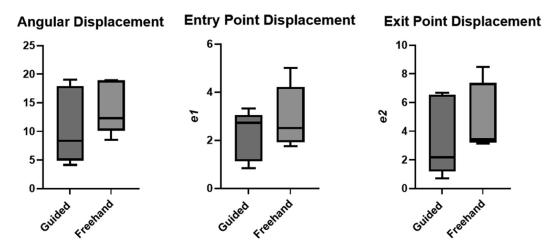


Figure 5. Box plots for the three variables that directly influence accuracy: angular deviation (α), distance between entry points (e1), and distance between exit points (e2).

creation of the final guide design. CT scans in either flexed or unflexed wrist position are adequate to create the personalized guide.

Because of the small size of the scaphoid and surrounding soft tissue structures, it is difficult to securely place the surgical guide and confirm a perfect fit on both the volar and radial scaphoid surfaces. During the cadaveric study, we noted a need for careful exposure of the scaphoid proximal pole with retraction of dorsal tendons and the use of a Freer to elevate the proximal pole for surgical guide placement. Although this technique maintains a small surgical window, the surgeon is not able to view the entirety of the bone that the guide is interfacing with. As a result, it is difficult for the surgeon to feel confident that the guide is correctly placed. Although it may feel as though the guide is correctly seated around the volar edge, it may be deviating in a place the surgeon is unable to see. For this surgical guide design to be reliable for clinical use, future studies must examine if any additions can be made to the design to ensure a secure fit without having to increase the surgical exposure.

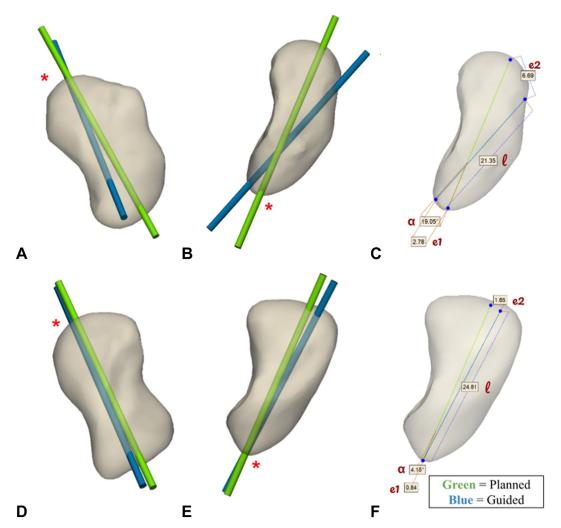
The scope of this pilot study was limited to five cadaveric wrists. The relative inaccuracy of C1 and C4 could also be influenced by demographics. C1 and C4 were both female specimens with scaphoids of a lower average volume, as well as the two specimens

**Table 3** Bivariate Pearson Correlation for the Three Variables That Directly Influence Accuracy: Angular Deviation  $(\alpha)$ , Distance Between Entry Points (e1), and Distance Between Exit Points (e2)

Correla	Correlations						
		a	e1	e2			
а	Pearson correlation	1	0.552	0.769*			
	Sig. (two-tailed)		0.098	0.009			
	N	10	10	10			
e1	Pearson correlation	0.552	1	0.057			
	Sig. (two-tailed)	0.098		0.875			
	N	10	10	10			
e2	Pearson correlation	0.769*	0.057	1			
	Sig. (2-tailed)	0.009	0.875				
	N	10	10	10			

<sup>\*</sup> Correlation is significant at the 0.01 level (two-tailed).

with the highest body weight (Fig. 3). This suggests that our surgical guide design may be less compatible with smaller scaphoids or patients with greater amounts of soft tissue. Future studies should include several more unique scaphoid morphologies to better assess if the surgical guide design can achieve high accuracy across all demographic variables. Additionally, all guidewires were



**Figure 6.** The results for the guided trajectories of C1 (**A–C**) and C5 (**D–F**) in blue compared with the planned trajectory in green. Measurements are pictured in **C** and **E**. For C1 (**C**),  $\alpha = 19.05^{\circ}$ , e1 = 2.78 mm, e2 = 6.69 mm, and l = 21.35 mm. For C5 (**F**),  $\alpha = 4.15^{\circ}$  and e1 = 0.84 mm, e2 = 1.65 mm, and l = 24.81 mm.

placed by a clinical fellow and a fellowship-trained hand surgeon with extensive experience with dorsal scaphoid fracture fixation. Even with allowing only one attempt, the trajectory with the surgical guide was better than in the freehand group, indicating that guide usage might lead to fewer attempts and is user-friendly. Next steps should not only test more morphologies but also assess how user-friendly the surgical guide is depending on the user's level of familiarity with the surgical procedure.

Current literature has validated the use of surgical guides in scaphoid fracture fixation for achieving central guidewire placement.<sup>14–21</sup> However, these studies do not attempt to design a surgical guide that sits on the scaphoid itself as opposed to wrapping around the wrist like a cast. Although these devices have shown high accuracy, they raise concerns for practicality in terms of manufacturing and limiting the surgeon to a volar approach. The proposed surgical guide in this study is only 3 mm thick with an average volume of just 1.3 cm², leading to approximately 3 mL of required material and 2.5 hours of print time on the 3D printer used (Form 3BL, Formlabs). This design does not require a more extensive incision and is compatible with the standard miniopen dorsal procedure.

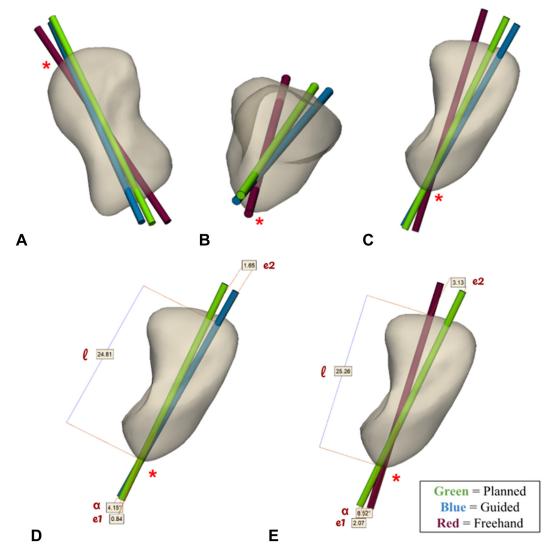
Overall, the average start and exit point was closer to the planned trajectory when using the surgical guide as hypothesized. The angular deviation from the predetermined center—center was, on average, lower for the guided group than the freehand group. This suggests that the use of a surgical guide helps ensure that the guidewire is placed closer to center—center and potentially minimizes the number of attempts needed. This pilot study has demonstrated the feasibility of our surgical guide to achieve accuracy with just one guidewire insertion attempt and without additional fluoroscopic imaging. Further experiments with a larger sample size must be conducted to achieve reproducibility across a wider range of scaphoid morphologies.

## **Conflicts of Interest**

No benefits in any form have been received or will be received related directly to this article.

## Acknowledgments

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**Figure 7.** The results for C5, guided and freehand. Overlay of postoperative guidewire placement for the guided group (blue) and the freehand group (red) with the preplanned placement (green) (**A–C**). Part figure (**D**) shows the measurements for the guided group and (**E**) shows the freehand group measurements. For C5 guided (**D**),  $\alpha = 4.15^{\circ}$ , e1 = 0.84 mm, e2 = 1.65 mm, and l = 24.81 mm. For C5 freehand (**E**),  $\alpha = 8.52^{\circ}$ , e1 = 2.07 mm, e2 = 3.13 mm, and l = 25.26 mm.

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