


Short-term results and complications of the operative treatment of the distal radius fracture AO2R3 C type, planned by using 3D-printed models. Prospective randomized control study

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Aleksandr Grinčuk , Giedrius Petryla, Povilas Masionis, Tomas Sveikata, Valentinas Uvarovas and Aleksas Makulavičius

Abstract

Purpose: 3D-printed models rapidly evolving in orthopaedic. Studies show that 3D-printed models used for preoperative planning improve a better understanding of fracture morphology and reduce operative time, blood loss and frequency of fluoroscopy, but there are no studies that investigated possible advantages in the outcomes and complications for the treatment of distal radius fracture (DRF). Our study aims to evaluate short-term functional results and complications between two groups treated DRF using 3D-printed models for preoperative planning and without. We hypothesize that the addition of 3D-printed models would improve functional outcomes and reduce complication rates.

Methods: 66 randomized cases of DRF AO/OTA C type were enrolled and divided into “Control group” ($n = 33$) and “3D-printed model group” ($n = 33$). Personalized 3D-printed models were created. The primary outcomes were: Patient-Rated Wrist Evaluation questionnaire, Quick Disabilities of the Arm, Shoulder and Hand Score questionnaire, and complications. The secondary outcomes were: measurement of the range of motions, grip strength, radiological evaluation, and the visual analogue scale. Assessments were measured at 6 weeks, 3 months, and 6 months intervals.

Results: We found that the integration of the 3D-printed model in preoperative planning decreased complication incidence significantly – from 30.3% in the “Control group” to 6.1% in the “3D-printed model group”, $p = .022$. But we did not find a difference in functional and radiological outcomes.

Conclusion: The 3D-printed models for preoperative planning surgically treating DRF AO/OTA C type can help minimize the complication rate, however, they can't improve functional outcomes in the short-term results.

Level of evidence: Level I randomized controlled study.

Keywords

3D-printed model, distal radius fracture, functional outcomes, complications

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Clinic of Rheumatology, Orthopaedics Traumatology, and Reconstructive Surgery, Faculty of Medicine, Vilnius University, Vilnius, Lithuania

Corresponding author:

Aleksandr Grinčuk, Republican Vilnius University Hospital, Šiltnamių Str. 29, Vilnius LT-04130, Lithuania.
Email: agrincuk@gmail.com



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Data Availability Statement included at the end of the article

Introduction

Distal radius fracture (DRF) became a more common injury in the population because young and older individuals promote an active lifestyle.¹ DRF in young individuals is mostly related to high-energy trauma, while for older patients prevails low-energy trauma.² Because trauma incidence increases, medical costs of DRF treatment are rising each year.³

In the past decade, the overall rate of open reduction and internal fixation (ORIF) has increased.^{4,5} According to the AO Foundation (AO/OTA) classification, 25%–35% of distal radius fractures are complex intra-articular fractures and surgical management remains a challenge.⁶

The overall complication rate following DRF internal plate fixation in the literature varies from 4% to 36%.⁷ Management of the complex distal radius fracture AO/OTA C type has a higher incidence of complications such as loss of reduction, implant problems, infection, tendon irritation, carpal tunnel syndrome, malunion and traumatic osteoarthritis.^{8,9}

3D-printed models rapidly evolving in orthopaedic for preoperative planning.¹⁰ Recently published studies show that 3D-printed models used for surgical planning reduce operative time, blood loss and frequency of fluoroscopy.^{11,12} In addition, 3D-printed models improve a better understanding of fracture morphology and communication between doctors and patients.^{13,14} Chen et al.¹⁴ randomised-controlled study show that 3D-printed models did not improve functional outcomes after 1-year follow-up. To our knowledge, there are no randomized-controlled clinical studies that investigated possible advantages in the short-term outcomes and complications of using 3D-printed models for the treatment of complex DRF. The main question for surgical planning remains determining - which fragments can be fixed and how they should be technically fixed with implants because there is a correlation between joint reduction and functional outcomes, especially in higher demand cases.^{15,16}

Our study aims to evaluate short-term functional results and complication rates between two groups surgically treated intra-articular distal radius fracture AO/OTA C type using 3D-printed models for preoperative planning and without. We hypothesize that the addition of 3D-printed models for preoperative planning would improve functional outcomes and reduce complication rates in the short-term.

Materials and methods

Study design and preparations

The prospective randomized controlled study was approved by ***** Regional Biomedical Research Ethics Committee. From January 2021 to February 2022 70 randomized cases of unstable distal radius fracture AO/OTA C type surgically treated in the level I Trauma Centre were enrolled

in this study according to the inclusion and exclusion criteria. Flowchart of the study (Figure 1).

Study population

Patients selected were from 18 to 75 years of age who met inclusion criteria: isolated acute displaced distal radius intra-articular fracture AO/OTA C type with/or without ulnar styloid fracture diagnosed clinically and radiologically with no previous history of significant wrist pathology, agreed to participate in the study and gave written consent. The main exclusion criteria were: patients who disagree to participate in a clinical study, fractures beyond 3 weeks, open fractures, polytrauma, bilateral fractures, neurovascular injury, prior fractures of the wrists, hands or arms, other diseases: oncology, rheumatological diseases, neurologic deficiency, or mental disorders.

Randomisation

Participants ($n = 70$) were randomly divided with a 50/50 ratio into two groups: the “Control group” ($n = 35$) and the “3D-printed models group” ($n = 35$) by sealed envelope assistance. The envelope was taken randomly before each surgery by a third person who is not an author of this study. “Control group” –participants were surgically treated using preoperative planning pre-reduction and post-reduction X-rays and CT scans with 3D CT reconstructions. “3D-printed model group”- participants were surgically treated using preoperative planning same as the “Control group”, but with the addition of the 3D-printed model. All patients underwent ORIF with the same operative technique with volar or dorsal approach or combined approach^{9,17} and the same postoperative care algorithm was applied with wrist immobilization for 2 weeks and starting early motions exercises.¹⁸

3D-printed models were created by a single surgeon, who neither evaluated nor had any influence on this study. Three orthopaedic surgeons performed the ORIF of the patients included in this study. All surgeons have more than 10 years (>35 cases in a year) of experience in the surgical management of DRF.

3D-printed models for preoperative planning

3D-printed models of the distal radius fracture were created using CT scan files in Digital Imaging and Communication in Medicine (DICOM) format obtained from the hospital's MedDream software, version 7.6.0. Using *3D Slicer*, version 4.10.2 software. DICOM files were processed and a 3D digital model of the distal radius fractures was created in *Standard Triangle Language (STL)* format. With *Z-suite*, version 2.16.2 software for the *Fused Deposition Modeling (FDM)* 3D printer *Zortrax M200Plus (Olsztyn, Poland)* 3D-printed model of

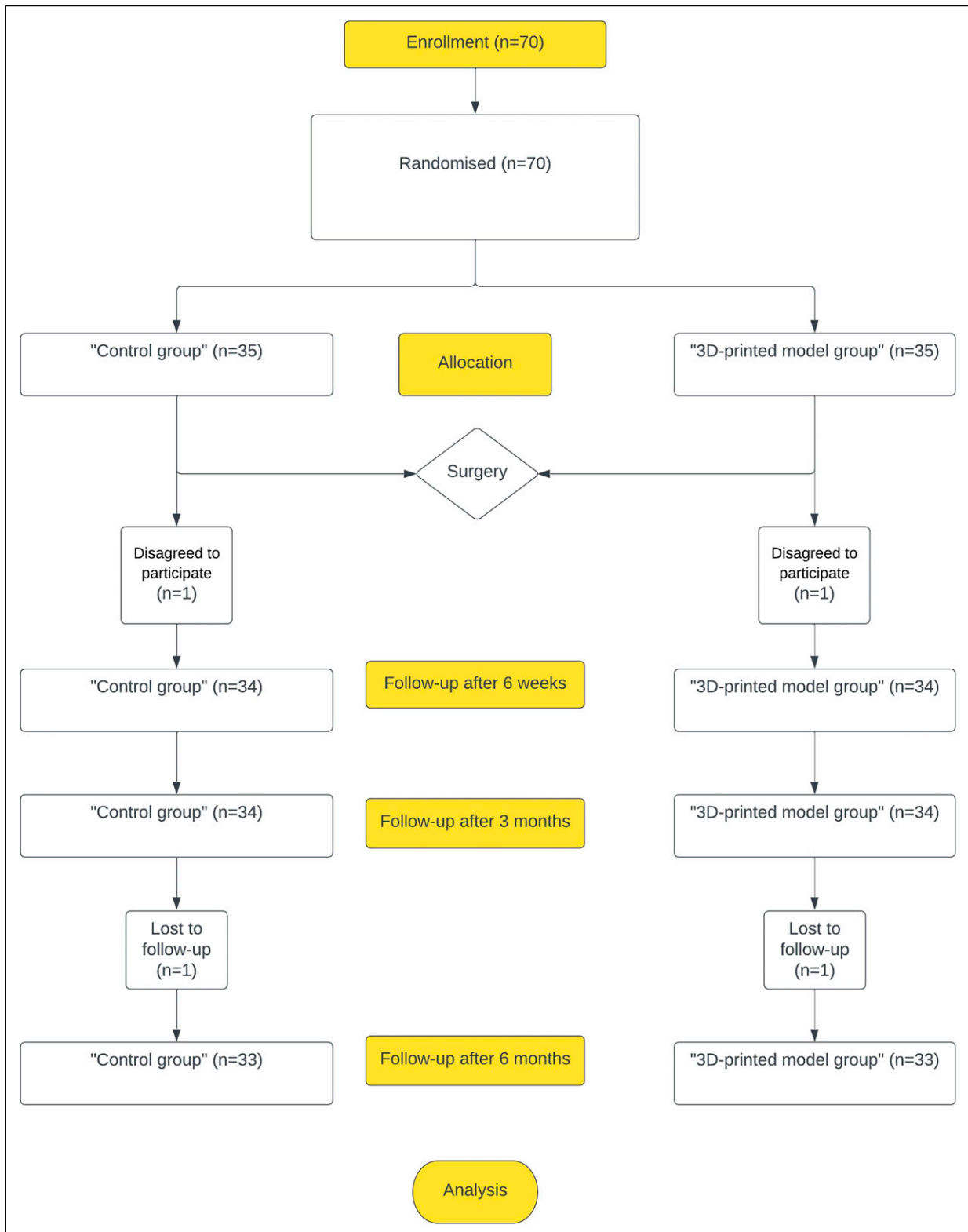


Figure 1. Flowchart of the study.

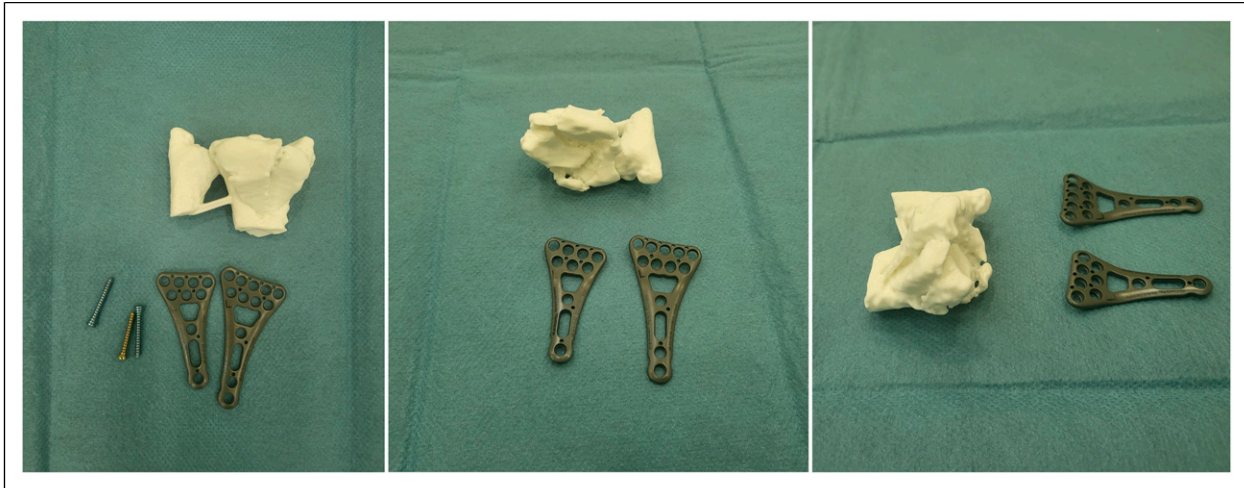


Figure 2. Preoperative planning using a 3D-printed model.

distal radius fracture without carpus was printed from *Poly-lactic Acid* (PLA) material. 3D-printed models were personalized, real-size models, printed on a scale of 1:1, and support materials were removed. The 3D-printed models were not sterilized. Prior surgery surgeons could handle and rotate 3-D printed models in all directions for up-close inspection of articular surface dislocation, rotational deformity and test the position of the plate and screws (Figure 2).

Setting outcomes

The primary outcomes of this study were a subjective 15-item Patient-Rated Wrist Evaluation (PRWE) self-reporting questionnaire focusing on wrist pain and disability in daily activities¹⁹ and an 11-item Quick Disabilities of the Arm, Shoulder and Hand Score (QuickDash) self-reporting questionnaire for evaluating symptoms and function of the upper extremity.²⁰ Complications were registered. Major complications (requiring reoperation): loss of reduction, intra-articular screw penetration, implant failure, tendon rupture, and deep wound infection. Minor complications: too-long screw with symptoms, tendon irritation, superficial wound infection, carpal tunnel syndrome (CTS), nerve irritation, traumatic osteoarthritis. The secondary outcomes were: measurement of the difference in range of motions (ROM) of the injured wrist compare to the healthy wrist (flexion, extension, radial and ulnar deviation, supination, and pronation), radiological evaluation (ulnar variance, volar tilt, radial inclination, radial length), the visual analogue scale (VAS),²¹ a measurement of the difference in grip strength compared with a healthy wrist.²²

Assessments for both groups were measured at 6 weeks, 3 months, and 6 months intervals during hospital outpatient clinic visits with the researchers.

Data collection and management

All participants' general information about age, sex, dominant hand, AO/OTA classification, approach to the DRF, presence of the ulnar styloid fracture or not, the Soong classification,²³ operation time, and hospitalization time were collected and registered. Data collection was done by two independent researchers, who did not participate in surgical procedures. The researchers were trained to ensure the accuracy of outcome assessments and data collection. Each participant was assigned an identification code and listed in the database which was safeguarded. General data were similar in both groups and are presented (Table 1).

Sample size

The sample size was calculated using the primary outcome PRWE questionnaire. Based on a previous study, a clinically important difference was set at 11.5 points²⁴ to detect the difference between the two groups. Effect size was calculated $d = 0.869$. The total sample size was calculated at $n = 56$ ($n = 28$ in each group) will have 90% power to detect a significant difference using a *Two-sided independent means t test* with a 0.05 significance level (G*Power software, Version 3.1.9.4, Germany). The dropout rate was set to 15% and the total sample size expanded to $n = 70$ ($n = 35$ in each group).

Statistical analyses

Statistical analyses were calculated using R software, version 4.0.4. Quantitative variables were tested for normal distribution using the *Shapiro-Wilk test* and variances were tested using the *Two Variances F test*. Normally distributed data were calculated using the *Independent Samples t test*.

Table 1. General data.

Group		“Control group” <i>n</i> = 33	“3D printed model group” <i>n</i> = 33	<i>p</i> -value
Age		53.1 ± 11.7	48.1 ± 14.3	.128
Sex	Female	22	17	.211
	Male	11	16	
Injured hand	Left	22	15	.082
	Right	11	18	
Dominant hand	Left	2	2	1
	Right	31	31	
AO classification	C3	<i>n</i> = 30	<i>n</i> = 31	.613
	C2	<i>n</i> = 0	<i>n</i> = 1	
	C1	<i>n</i> = 3	<i>n</i> = 1	
Approach	Volar with ^a VLP	<i>n</i> = 33	<i>n</i> = 30	.238
	Dorsal with ^b DLP	<i>n</i> = 0	<i>n</i> = 2	
	Combine with VLP and DLP	<i>n</i> = 0	<i>n</i> = 1	
Ulnar styloid fracture	Yes	<i>n</i> = 27	<i>n</i> = 28	.741
	No	<i>n</i> = 6	<i>n</i> = 5	
Soong classification		<i>n</i> = 33	<i>n</i> = 31 ^c	.329
	0	<i>n</i> = 6	<i>n</i> = 10	
	I	<i>n</i> = 24	<i>n</i> = 20	
	II	<i>n</i> = 3	<i>n</i> = 1	
Hospitalization time (days)		1.3 ± 0.5	1.33 ± 0.4	.664
Operation time (min)		65.1 ± 15.2	72.1 ± 17.5	.072

^aVLP: volar locking plating.

^bDLP: dorsal locking plating.

^cFor two participants were applied only dorsal approach with dorsal locking plating.

For data with non-normal distributions, nonparametric statistics *Two-Sample Wilcoxon Test* was used. Quantitative data were summarized as a mean with standard deviation (SD). Qualitative variables were tested using the *Chi-squared test* (or *Fisher exact test* when appropriate) and were summarized as numbers. For complications, data incidence rates (using *Fisher exact test*) were calculated and summarized as numbers and percentages. Statistical significance was considered $p < .05$.

Results

Two participants disagreed to participate in the study after the surgery (one in each group) and two patients were lost to follow-up (one in each group). The final sample size consisted of 66 patients (“control group” ($n = 33$) and “3D model group” ($n = 33$)) with follow-up points at 6 weeks, 3 and 6 months.

Primary outcomes

There was no statistically significant difference between the groups comparing PRWE score and QuickDash score (Table 2). Complications were registered and present in (Table 3). Six major complications were observed in the “Control group”: three of loss of reduction and three of

intra-articular screw penetration registered at 6 weeks postoperatively. With a similar accident, minor complications such as a too-long screw with symptoms and tendon irritation were observed in both groups at 3 months postoperatively. In the “Control group” CTS was observed at 6 months postoperatively. During 6 months of follow-up, there was a statistically significant difference comparing the total complications rate in the “Control group” 10 (30.3%) and 2 (6.1%) in the “3D model group”, $p = .022$. No other complications were observed during follow-up.

Secondary outcomes

There were no statistically significant differences between the groups comparing secondary outcome measurements VAS and grip strength, $p > .05$ (Table 2). Adequate reposition of distal radius fracture fragments was achieved in both groups according to the American Association of Orthopaedic Surgeons (AAOS) standard.²⁵ In all cases DRUJ (distal radioulnar joint) were stable and no ulnar styloid fixation was performed. Statistically, a significant difference was obtained only in “Ulnar height” between groups after X-rays post operation in “Control group” 0.54 ± 2.4 compared with -0.69 ± 1.7 in “3D-printed model group”, $p = .022$ (Table 4).

Table 2. PRWE score, QuickDash score, VAS, grip strength.

Group	6 weeks mean \pm SD			3 months mean \pm SD			6 months mean \pm SD		
	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value
QuickDash score	50.17 \pm 24.0	41.81 \pm 18.2	.116	30.21 \pm 20.2	23.06 \pm 14.9	.143	23.59 \pm 20.2	14.93 \pm 13.1	.094
PRWE score	46.41 \pm 23.8	37.32 \pm 18.6	.089	26.51 \pm 21.9	21.38 \pm 13.1	.763	19.55 \pm 20.8	13.76 \pm 2.4	.342
VAS (mm)	23.72 \pm 22.8	18.73 \pm 18.8	.563	16.01 \pm 17.3	10.47 \pm 9.6	.329	10.39 \pm 12.5	7.95 \pm 8.4	.554
Grip strength (kg)	12.4 \pm 5.6	10.41 \pm 5.1	.14	10.06 \pm 5.0	8.71 \pm 3.7	.193	6.914 \pm 3.9	6.47 \pm 5.3	.305

Table 3. Registered complications during 6 months follow-up.

Group	“Control group” n = 33		“3D model group” n = 33		p-value
	n (incidence rate %)				
Total	10 (30.3%)		2 (6.1%)		.022
Loss of reduction	3 (9.1%)		—		—
Intra-articular screw penetration	3 (9.1%)		—		—
Too-long screw with symptoms	2 (6.1%)		1 (3.0%)		—
Tendon irritation	1 (^a FPL) (3.0%)		1 (^b EDT) (3.0%)		—
CTS	1 (3.0%)		—		—

^aFPL: flexor pollicis longus irritation.

^bEDT: extensor digitorum tendons irritation associated with dorsal plating.

CTS: carpal tunnel syndrome.

Table 4. Radiographic measurements.

Group	X-ray post operation mean \pm SD			X-ray after 6 weeks mean \pm SD			X-ray after 3 months mean \pm SD		
	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value
Ulnar height (mm)	0.54 \pm 2.4	-0.69 \pm 1.7	.022	1.0 \pm 2.6	0.26 \pm 1.7	.185	1.15 \pm 2.3	0.32 \pm 1.8	.254
Radial height (mm)	11.41 \pm 2.4	10.66 \pm 2.6	.23	11.77 \pm 2.5	10.83 \pm 2.5	.145	11.75 \pm 2.5	10.82 \pm 2.7	.161
Radial inclination (°)	22.2 \pm 7.1	23.85 \pm 6.5	.335	23.34 \pm 8.6	24.72 \pm 6.2	.46	22.46 \pm 7.9	24.9 \pm 6.2	.17
Volar tilt (°)	4.5 \pm 8.3	5.0 \pm 4.3	.635	4.67 \pm 8.3	4.22 \pm 4.9	.243	4.29 \pm 8.7	3.65 \pm 4.9	.158

In the “3D-printed model group” there was a statistically significant lower difference in the ROM compared with the healthy wrist at 6 weeks: flexion and ulnar deviation and at 3 months: flexion, extension, ulnar deviation and supination. At 6 months of evaluation between the groups, there was no statistically significant difference in ROM (Table 5).

Discussion

This study used 3D-printed models to facilitate preoperative planning for surgically treating DRF AO/OTA C type. In both groups, radiological and functional outcomes showed acceptable results. In the “Control group” were

observed six major complications compared with none of such in the “3D-printed model group”. Retrospectively, there were no specific fracture types associated with major complications.

The study showed that DRF AO/OTA C type has a significantly higher incidence of complication rate up to 16.4% using for preoperative planning conventional radiological evaluation X-rays and CT scans.⁷ In our study, in the “Control group” participants’ complications incidence was 30.3% because the majority of cases of DRF were AO/OTA C3 type, but this wasn’t higher compared to the other studies where complication rate was 44%⁸ and 52.8%.⁹

Table 5. Measurement of the difference in ROM.

Group	6 weeks mean ± SD			3 months mean ± SD			6 months mean ± SD		
	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value	“Control group” n = 33	“3D model group” n = 33	p-value
Flexion (°)	36.63 ± 15.9	19.72 ± 10.2	<.001	18.88 ± 10.7	9.96 ± 6.6	<.001	12.06 ± 10.1	7.5 ± 5.9	.06
Extension (°)	33.9 ± 15.5	28.41 ± 12.5	.119	20.61 ± 12.7	12.39 ± 7.9	.006	13.68 ± 12.58	8.71 ± 8.4	.107
Ulnar deviation (°)	20.39 ± 10.4	14.76 ± 8.6	.02	16.3 ± 9.5	11.52 ± 6.9	.023	13.75 ± 10.4	9.51 ± 7.1	.12
Radial deviation (°)	15.66 ± 9.3	15.03 ± 8.0	.768	10.13 ± 6.7	9.58 ± 5.2	.902	6.28 ± 4.6	8.16 ± 5.6	.156
Supination (°)	18.69 ± 18.0	10.77 ± 2.4	.128	5.02 ± 6.6	2.25 ± 8.0	.011	2.0 ± 5.3	1.28 ± 4.5	.692
Pronation (°)	15.06 ± 17.9	8.56 ± 11.4	.155	2.84 ± 5.3	1.99 ± 4.1	.764	1.68 ± 5.07	0.96 ± 2.9	.926

3D-printed models showed an improved understanding of fracture morphology and articular surface fragments displacement.^{26,27} We found that the integration of the 3D-printed model in preoperative planning decreased complication incidence significantly – from 30.3% in the “Control group” to 6.1% in the “3D model group”. Furthermore, the evaluation of CT scans alone can lead to confusion by misunderstanding irrelevant “small” or clinically insignificant fragment displacement leading surgeons to plan unrealistic fixation.^{28,29}

We assume that our study presented X-rays and CT scans with carpal bones could provide less information about fracture personality, especially attention to the rotational dislocation of the fragments and implant selection and positioning. With 3D-printed models without carpal bones, surgeons could precisely evaluate the actual view of the articular joint from the inside and choose an appropriate surgical approach. In addition, 2D and 3D CT scans are still presented on a monitor screen and don’t show a true three-dimensional view. In our opinion, because of these advantages, the 3D-printed model reduces the complication rate.

Chen et al.¹⁴ in their study didn’t find improvements in the range of motion of the wrist with 3D-printed models. Our study confirmed a better wrist flexion and ulnar deviation at 6 weeks and at 3 months better wrist flexion, extension, ulnar deviation and supination in the “3D-printed model group”, $p < .05$. At 6 months there was no statistically significant difference between groups. We assume these changes hypothetically may be accrued because major complications had an impact on the early results in the “Control group” participants.

During the 6 months of follow-up, our study shows a tendency for better functional outcomes in the “3D-printed model group” comparing PRWE score, QuickDash score, VAS and grip strength with the “Control group”, but statistically non-significant. The lack of randomized clinical studies prevents comparing our results with other researchers.

3D-printed models may not provide the whole information for the fracture reduction simulation – because there

is no soft tissue attachment to the fragments. In addition, dislocation of the fragments which are less than 0.4 mm. Can’t be presented. These disadvantages can affect the evaluation of the fracture and realistic reduction scenarios. In our opinion, the benefit of handling and rotating a 3D-printed model of DRF in all directions without carpus reduces these limitations.

The 3D-printed models were not sterilized and surgeons couldn’t handle them during surgery. Sterilised 3D-printed models could be beneficial in understanding the fracture morphology for surgeons, especially for the less experienced ones. Approximately 3 to 4 h took to create and print the 3D-printed model, furthermore, surgery simulation for the adequate repositioning of the fracture fragments and plate and screw positioning required an additional investment of the surgeon’s time. The time required was not part of this study as it could potentially decrease significantly with surgeon experience with the use of 3D printed models.

In our study, we provide results after 6 months of follow-up – because participants achieve optimize functional results after 3–6 months.³⁰ Our study shows that the detected difference in range of motion differs after 6 weeks and 3 months of follow-up, however, after 6 months there is no significant difference, $p > .05$. Nevertheless, participants will be followed until 1-year follow-up.

In this study, we didn’t evaluate X-rays of distal radius fracture after 6 months, because in both groups all distal radius fractures healed at 6 weeks to 3 months period. Further, we didn’t measure the duration of intraoperative fluoroscopy and a postoperative CT scan was not performed to evaluate distal radius fracture.

Conclusion

Our study suggests that using the 3D-printed models for preoperative planning surgically treating distal radius fracture AO/OTA C type can help minimize the complication rate, however, they can’t improve functional outcomes in the short-term results. Further research is required

to determine indications for using 3D-printed models in the treatment of distal radius intra-articular fractures.

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Author contributions

A.G, A.M concept of the study. A.G, V.U and A.M designed the study. P.M, G.P and T.S contributed to data collection and analysis. T.S, G.P and P.M contributed to the interpretation of data. A.G, V.U contributed to drafting the article. A.M, G.P, and P.M contributed to a critical review of the article. All authors read and approved the final version of the article.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Vilnius Regional Biomedical Research Ethics Committee (approval No. 2021/01-1299-777).

Informed consent

Written informed consent was obtained from all subjects before the study.

ORCID iD

Aleksandr Grinčuk  <https://orcid.org/0000-0002-0782-1712>

Data availability statement

The [data](#) used and analysed during the study are available from the corresponding author upon reasonable request.

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