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RESEARCH

[Translated article] Randomized clinical trial on the usefulness of 3D printing in intra-articular fractures of the distal radius



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KEYWORDS

3D printing; Wrist fracture; Distal radius

Abstract

Objectives: We evaluated the utility of 3D printing technology for preoperative planning in the treatment of intra-articular fractures of the distal radius in relation to the improvement of surgical technique, radiological and clinical results.

Material and methods: A total of 30 patients with 2B and C fractures of the AO classification were operated on by a single surgeon with a volar plate, randomly divided into two groups, 15 of them with conventional planning (Rx and CT) and 15 adding a 3D model of the fracture and the previous simulation of the intervention. Simulation time, surgical time in minutes, radioscopy time in minutes, loss of material expressed in lost screws were recorded. Clinical evaluation based PRWE questionnaire and full radiographic analysis was done for all patients with a mean follow-up of 6 months by an independent, blinded observed.

Results: No statistically significant differences were observed in the PRWE questionnaire (p=0.22), nor were we observed differences in the radiological values, except in relation to the articular step (p=0.028), which represents statistical significance, but in both groups the median was of 0.0 (0.0-0.0). We also did not see statistically significant differences in surgical times (p=0.745), radioscopy (p=0.819) or in the loss of synthesis material (p=0.779).

Conclusions: 3D printing has not improved the parameters studied in relation to routinely operated patients.

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PALABRAS CLAVE

Impresión 3D; Fractura de muñeca; Radio distal

Ensayo clínico aleatorizado sobre la utilidad de la impresión 3D en las fracturas intraarticulares de radio distal

Resumen

Objetivos: Evaluamos la utilidad de la tecnología de impresión 3D para la planificación preoperatoria en el tratamiento de las fracturas intraarticulares de radio distal en relación con la mejora de la técnica quirúrgica, los resultados radiológicos y clínicos.

Material y métodos: Un total de 30 pacientes con fracturas 2B y C de la clasificación de la AO fueron intervenidos por un solo cirujano con placa volar, divididos en dos grupos de forma aleatoria: 15 de ellos mediante planificación convencional (radiología simple y TC) y 15 añadiendo un modelo 3D de la fractura y la simulación previa de la intervención. Se registró el tiempo de la simulación, el tiempo quirúrgico en minutos, el tiempo de radioscopia en minutos, la pérdida de material expresada en tornillos desechados en quirófano. A los 6 meses de seguimiento se realizó una evaluación funcional de la muñeca basada en el cuestionario PRWE y análisis radiológico completo por un observador independiente y cegado.

Resultados: No se observaron diferencias estadísticamente significativas en el cuestionario PRWE (p = 0.22), y tampoco observamos diferencias en los valores radiológicos, salvo en relación al escalón articular (p = 0.028), lo cual representa una significación estadística, pero en ambos grupos la mediana fue de 0.0 (0.0-0.0). Tampoco vimos diferencias estadísticamente significativas en los tiempos quirúrgicos (p = 0.745), de radioescopia (p = 0.819) o en la pérdida de material de síntesis (p = 0.779).

Conclusión: La impresión 3D no ha mejorado los parámetros estudiados en relación con los pacientes intervenidos de rutina.

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Introduction

Three-D printing (3D-P) has now made its mark in medicine.
The use of 3D biomodels for preoperative planning in OTS is one of the uses which has aroused the most interest in recent years.
Computerised tomography (CT) images of injured areas can be used to print the exact fracture presented by a patient in 3 dimensions. This model improves anatomical understanding the fracture which aids precision preoperative planning.

In recent years multiple communications have reported on the usefulness of 3D-P in the treatment of joint fractures. 4-11 In treating distal radius fractures (DRF) specifically, 3D-P seems to be a model that aids preoperative assessment and serves to help in planning surgical treatment, 12 enabling a reduction in intervention time and exposure to fluoroscopy, 13 and improving the final functional results in this type of fracture.

We designed a study that determined the clinical effectiveness of 3D-P models in the treatment of DRF to improve wrist functionality 6 months after surgery, based on the Spanish adaptation of the Patient-Rated Wrist Evaluation (PRWE)¹⁴ questionnaire. It also enabled us to assess the possible reduction in surgical times; radioscopy times; the saving of material; optimisation of positioning material, in addition to the improvement of radiological results.

Material and methods

Study design

Double-blind randomized controlled clinical study conducted on patients from the Traumatology Department of the Hospital General Universitario Dr. Balmis in Alicante, by a single surgeon, from May 2018 to November 2021, in which the effectiveness of 3D-P models in intra-articular fractures of the distal radius was evaluated.

Inclusion criteria: aged > 18 < 80 years, unstable fractures according to the Lafontaine¹⁵ criteria, irreducible fractures, intra-articular fractures of the distal radius types B and C of the AO classification, and patients with the ability to read and understand all relevant information regarding the study.

Exclusion criteria: bilateral fractures; previous wrist fractures or previous contralateral alteration; non-displaced fractures; stable fractures; open fractures; associated fractures; inflammatory diseases affecting the wrists; fractures of more than 2 weeks' duration, and associated diseases that prevent proper rehabilitation (mental illness, neurological illness, etc.).

A total of 30 patients with intra-articular wrists fractures were studied, without calculating the sample size and with the inclusion of all the patients who were viable during the study period, who were divided into two groups: the

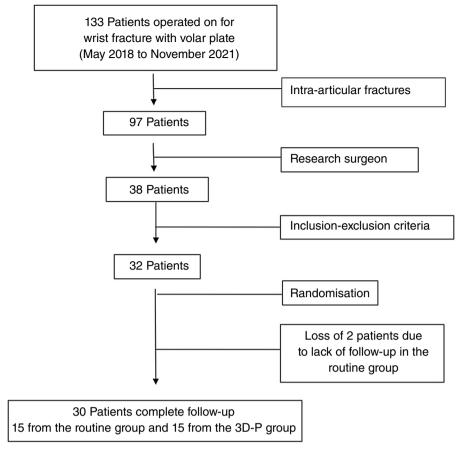


Figure 1 Flow diagram of patient selection and follow-up.

non-exposed group was routinely osteosynthesised with a volar plate (n=15) and the exposed group was operated on after the creation of a 3D-P model of the fracture, which was analysed and served as a basis for the synthesis. This group was also operated on with a volar plate (n=15).

Patients were randomly and blindly assigned to one of the two groups by one of the authors who was not involved in the intervention or follow-up, using the Random Sample Generator© computer programme, once the patient had authorised their participation in the study (Fig. 1).

The primary variable collected was the difference in PRWE questionnaire scores between the group treated with 3D-P (exposed group) versus the group treated without the 3D-P model (unexposed group) at 6 months of the study.

Other variables were surgical time (minutes); fluoroscopy time (minutes) and material loss (measured as the number of patients in whom material loss occurred and as the number of materials lost). The radiological parameters that were measured were the radial inclination angle (degrees); volar inclination angle (degrees); radial height (millimetres); joint step (millimetres); plate height according to the Soong classification¹⁶ that relates the position of the plate in relation to the watershed line and the protrusion of the distal screws.

Surgical times, radioscopy times, and material loss due to surgical exclusion were recorded by the operating room nurses, who were unaware of the group to which the patient belonged.

The PRWE data collection and radiological studies were performed by an independent and study-blinded observer.

The 3D model explanatory variables were recorded: yes/no, age, sex, dominant side, injured side, fracture mechanism, and fracture classification.

Statistical analysis

The statistical data were analysed by an independent researcher from the Preventive Medicine Service of our hospital using the statistical programme IBM*_SPSS Statistics v 25.0. A descriptive analysis of the study patient characteristics was performed (age; sex; fracture of the dominant limb; injury mechanism; fracture classification and mean time spent on 3D-P preparation (minutes) for all patients included and based on the assigned group (routine group and 3D-P model group) to establish homogeneity between both groups. The intraoperative parameters were evaluated: duration of the intervention in minutes; fluoroscopy time in minutes and loss of material (number of screws discarded).

The mean and standard deviation were used when the variables followed a normal distribution and the median and the 25th and 75th percentiles when they followed a non-parametric distribution; the Kolmogorov–Smirnov test was performed to determine the type of distribution of the quantitative variable. For the qualitative variables, absolute and

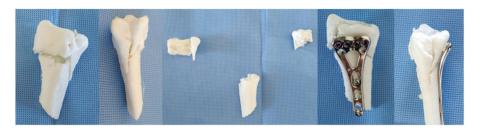


Figure 2 3D Model preparation and simulation.

relative frequencies were used in percentages. The intraoperative parameters were subsequently compared in both groups using the Student's t-test for variables with a parametric distribution or the Mann–Whitney U test for variables with a non-parametric distribution. Finally, a study of the variables evaluated at 6 months after the intervention was conducted: PRWE and radiological variables. The mean and standard deviation were used when the variables followed a normal distribution and the median and the 25th and 75th percentiles when this was a non-parametric distribution. To study the association between both groups, the Chi-square test was used for the qualitative variables and the Student's t test or the Mann–Whitney U test was used for the quantitative variables. The level of statistical significance was set at p < .05.

Ethical aspects and authorisations

The researchers adhered to the declarations of Helsinki and Oviedo on biomedical research. The clinical trial was approved by the Clinical Research Ethics Committee of the Hospital General Universitario Dr. Balmis de Alicante (CIEC P12017/92). All patients included in the study gave their written consent for participation in the study and for the surgical intervention provided by the Spanish Society of Orthopaedic Surgery and Traumatology.

3D printing and surgical simulation

For the 3-D R&D we used CT images with a slice thickness of 1 mm that we printed with the Ultimaker S5© printer model, with polylactic acid (PLA) as material and an apposition thickness of 2 mm. The simulation was performed on the 3D-P after reproducing the fracture by separating the fragments. We then reduced the fragments and fixed them with a synthesis plate and screws similar to the one used in the intervention and supplied as training material by Synthes© (DePuySynthes Synthes GmbH Eimattstrasse 3 4436 Oberdorf, Switzerland) (Fig. 2). The preparation and simulation time of the intervention was recorded and included in the study.

Surgical technique and follow-up

All patients were operated on by a single surgeon using the Synthes VA LCP plate. General or local anaesthesia was performed, antibiotic prophylaxis with 2g of intravenous cefazolin, preventive ischaemia with Esmarch and pneumatic cuff at 250 mmHg. A Henry Schein catheter was used,

which was extended to an Orbay catheter in cases where appropriate, and intraoperative fluoroscopy was performed. A compressive bandage was placed postoperatively and the patients were reviewed at 1, 3, and 6 months. None of the patients had postoperative complications.

Results

Mean age was 60.6 ± 7.7 years in the routine intervened group and 54.1 ± 13.8 years in the group in which the 3D-P technology was used. In both groups the dominant mechanism was an incidental accident. In the first group there were 10 women and 5 men and in the second group 9 women and 6 men. Laterality corresponded to 10 left and 5 right wrists in the routine group and 8 left and 7 right wrists in the 3D-P group. Regarding the classification of fractures by groups, the routine group had 4 fractures of the AO Classification of 2R3C3.2, 6 of 2R3C3.1, 1 of 2R3C2.2, 1 of 2R3C1.2, 1 of 2RC1.1, 1 of 2R3B2.2 and 1 of 2R3B2.1 and the 3D-P group had 4 2R3C3.2 fractures, 8 classified as 2R3C3.1, 1 of 2R3C2.2 and finally 2 of 2R3C1.3.

For statistical correlation we grouped the fractures into two groups: in the first we gathered the type B2 and type C type 1 and 2 with a total of 8 fractures, and in the second those belonging to type C type 3, with 22 fractures. Thus, the patients of the routine group presented 5 fractures of type B and type C group 1 and 2 (33.3%) and 10 of type C group 3 (66.7%) and the patients with 3D-P presented 3 fractures of type B and type C group 1 and 2 (20%) and 12 of type C group 3 (80%).

The groups were homogenous in the parameters studied (Table 1).

In one case in the 3D-P group, when performing the simulation, we found it impossible to stabilise the "volar rim" fragment in a satisfactory manner with the standard plate, which forced us to change the surgical strategy and use another plate model, the Volar Rim from Synthes. This was included in the study due to the information obtained with the model.

The simulation time of the intervention was $123.86 \pm 20.5 \, \text{min}$.

Time in surgery was 60.07 ± 7.7 min in the routine group and 61.33 ± 11.84 min in the 3D-P group with a p = .745.

The fluoroscopy time in the routine group was .50 min and had a median of .50 (.27–1.00) min and in the 3D-P group it was .42 min, with s median of .42 (.28–1.00) p = .819.

Regarding the material excluded during the intervention, 5 screws were used in 3 patients (20%) median .00 (0-2) in

	Routine	3D-P	р
Age (years) mean \pm SD	$\textbf{60.6} \pm \textbf{7.7}$	54.1 ± 13.8	.126
Sex n (%)			
Man	33.3 (5/15)	40.0 (6/15)	.705
Woman	66.7 (10/15)	60.0 (9/15)	
Fractured side n (%)			
Right	33.3 (5/15)	46.7 (7/15)	.456
Left	66.7 (10/15)	53.3 (8/15)	
Dominant side n (%)			
Right	33.3 (5/15)	53.3 (8/15)	.269
Left	66.7 (10/15)	46.7 (7/15)	
Mechanism n (%)			
Traffic	6.7 (1/15)	6.7 (1/15)	.341
Sport	13.3 (2/15)	.0 (0/15)	
Incidental	80.0 (12/15)	93.3 (14/15)	
AO classification n (%)			
B2/C1/C2	33.3 (5/15)	20.0 (3/15)	.682
C3	66.7 (10/15)	80.0 (12/15)	

Qualitative variables: absolute and relative frequencies; Quantitative variables: mean and standard deviation (SD).

the routine group and 5 screws in 4 patients in the 3D-P group (26%) median .00 (0-2) p = .779.

Following radiological analysis, in the routine group one patient was observed with a joint step greater than 2 mm and in another patient it could not be determined whether or not he had a step, median .0 (.0-.0) while in the 3D-P group this step was seen in 3 patients, median .0 (.0-.0) p = .028.

We only obtained one case of dorsal protrusion of a screw in a patient from the routine group.

The radial inclination angle was $22.07 \pm 3.164^{\circ}$ in the routine group while in the 3D-P model group it was $22.53 \pm 3.74^{\circ}$ p = .719. The volar inclination angle was $11.20 \pm 3.56^{\circ}$ in the routine group compared to $10.37 \pm 6.17^{\circ}$ p = .664 in the 3D-P group. The radial height in the routine group was 10.5 ± 2.9 mm and in the 3D-P it corresponded to 10.1 ± 3.2 mm p = .763. In the Soong classification of plate positioning in the patients of the first group we obtained 9 Soong 0, 5 Soong 1 and 1 Soong 2, median .0 (.00–1.00) while in the second group we obtained 7 Soong 0, 5 Soong 1 and 3 Soong 2 median .0 (.00–1.00) p = .322 (Table 2).

Discussion

The PRWE score did not show a statistically significant difference (p = .220). Chen's study on wrist fractures using the Gartland–Werley questionnaire found no significant difference between the two groups. ^{11,17} It should be noted that in our study the highest PRWE scores corresponded to fractures classified as 2R3C3.2, that is, the most severe, fractures and the result was therefore more related to the severity of the fracture than to the use or not of the 3D-P model.

The times in surgery of the two groups were similar, with the 3D-P model not improving this parameter. We do not agree with previous studies on wrist fractures^{11–13,17} which reported an improvement in surgical times in the 3D-P groups.

A systematic review of the use of 3D-P model for preoperative planning in surgeries of other surgical specialties published that of the 89 studies reviewed, 48 (53.93%) observed a reduction in surgical time. Two studies (2.24%) mentioned an increase in time and 37 (41.57%) did not mention any impact on the duration of surgery. Of all the studies reviewed reporting the reduction in surgical time, only 13 supported this claim with real numbers or statistics.¹

A systematic review and meta-analysis of orthopaedic pathology concludes that intraoperative time using printed models is reduced by 19.85%.¹⁹ In 2021, a meta-analysis by Yang et al. also concluded that surgical time was reduced in patients with a printed model.²⁰

The fluoroscopy time in our study was similar in both groups, which did not coincide with the reduction in radiation time reported by other authors. ^{11,13,17} In the aforementioned systematic review by Tack et al., ¹⁸ exposure to ionising radiation was not studied in 77 of the publications (86.51%), 8 reported decreased exposures and three publications reported increased exposure. Later systematic reviews do report a reduction in fluoroscopy time. ^{19,20}

We were unable to find any references in the scientific literature regarding possible saving of osteosynthesis material, mainly over-or-under sized screws. In our study we had the same number of discarded materials in both groups. Thus, in 2 patients in the routine group, 2 screws were discarded and, in the 3D-P group, we 2 screws were also discarded. This seems to indicate that the greater the difficulty in the

³D-P: treated with X-ray, CT and 3D printing; Routine: treated with X-ray and CT.

p < .05 considered statistically significant for quantitative variables comparing routine and 3D-P (t-Student or Mann-Whitney U test).

p < .05 considered statistically significant for qualitative variables comparing routine and 3D-P (Chi-square test).

Table 2 Results.					
	Routine	3D-P	р		
PRWE. Mean \pm SD	16.00 ± 9.52	23.53 ± 20.95	.220		
Time in surgery. Mean \pm SD	60.07 ± 9.11	61.33 ± 11.84	.745		
Scoping time (minutes). Median (p25-p75) (minutes	.50 (.27-1.00)	.42 (.28-1.00)	.819		
Patients with discarded material n (%)	20.0 (3/15)	26.7 (4/15)	1		
Discarded material (number of screws). Median (p25-p75)	.00 (0-2)	.00 (0-2)	.779		
Radial inclination angle (degrees). Mean \pm SD	22.07 ± 3.164	22.53 ± 3.74	.719		
Volar inclination angle (degrees). Mean \pm SD	11.20 ± 3.56	10.37 ± 6.17	.654		
Radial height (millimetres). Mean \pm SD	$\textbf{10.5} \pm \textbf{2.9}$	$\textbf{10.1} \pm \textbf{3.2}$.763		
Step. Median (<i>p</i> 25- <i>p</i> 75)	.0 (.00)	.0 (.00)	.028		

Mean and standard deviation (SD) for quantitative variables with normal distribution.

Median and 25th and 75th percentiles for quantitative variables with non-parametric distribution. Qualitative variables: absolute and relative frequencies.

- I-3D: treated with X-ray, CT and 3D printing; PRWE: Patient-rated Wrist Evaluation; Routine: X-ray and CT.
- p < .05 considered statistically significant for quantitative variables comparing routine and 3D-P (Student t-test or Mann–Whitney U test).
- p < .05 considered statistically significant for qualitative variables comparing routine and 3D I (Chi-square test).

osteosynthesis of a fracture the greater the number of measurement errors.

Soong classification. Median (p25-p75)

Another parameter we found in the medical literature and that we did not incorporate in our study is blood loss, which is reported to be less with the use of digital printing technology, ^{19–22} even in wrist fractures. ^{11,13,17} In our experience, blood loss is difficult to quantify, as it is concentrated in the first moments of trauma. When performing the intervention with ischaemia, we do not consider blood loss to be a significant parameter.

The time spent preparing the model by separating the fracture fragments, removing the support materials and residual manufacturing materials and/or substances that must be removed as completely as possible, 23 plus the subsequent joining together using screws and plate was $123.9\pm20.5\,\mathrm{min}$ on average. This coincides with the results of Shen et al. who spent $118.50\pm15.31\,\mathrm{min}^4$ and Chen who spent $150\,\mathrm{min},^{11}$ which is far from the $30\,\mathrm{min}$ reported by some authors, 24,25 applying it only to the removal of support material. Perhaps new materials that are less rigid than PLA will make this process faster.

Regarding the radiographic measurements carried out 6 months after the intervention, the radial and volar inclination angles and the radial height were not found to be different in eithr group, and the Soong classification did not present significant statistical differences. The joint step found at the end of the radiological study offered a p = .028, which represents a statistical significance, but in both groups the median was .0 (.0-.0).

Chen's radiological measurements also concluded that there were no differences between both groups in relation to the radiological parameters. ^{11,17} A study published by Zheng, on calcaneal fractures, does refer to better results with the 3D-P models in the Gissane and Böhler angles, with width and height of the calcaneus in the 3D-P group. ¹⁰

The strengths of this study are that it is a prospective, randomized, double-blind study with a single surgeon and the same osteosynthesis material. Its limitation is the number of cases studied. Should the number be higher, the consistency of the results would be greater.

Conclusions

.00(.00-1.00)

3D printing has not improved wrist functionality at 6 months as measured by the PRWE questionnaire.

1.00(.00-1.00)

.322

It has not improved surgical times, fluoroscopy, or material loss, it has not improved plate positioning according to the Soong classification, nor has it improved measurements of radial deviation angle, volar angle, radial length distance, or reduction with respect to the joint step.

The model preparation time is greater than the surgical time.

3D printing has not improved the parameters studied in relation to patients undergoing routine surgery.

Level of evidence

Level of evidence II.

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Conflict of interests

The authors have no conflict of interests to declare.

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