Surgical pinning after loss of reduction in Salter–Harris type I–II distal radius fractures does not improve outcomes: A propensity matched cohort study

Melih Oral[a], Ulas Can Kolac[a], Hasan Samil Aydinoglu[a], Serkan Ibik[a], Mert Morkan[a], Mazlum Veysel Sili[a], Hanife Avci[b] and Guney Yilmaz[a]

The objective of this study is to compare the clinical and radiological outcomes of conservative vs. surgical management in pediatric patients with Salter–Harris types I and II distal radius fractures who experienced loss of reduction following initial closed reduction. This retrospective matched cohort study included pediatric patients under 16 years of age treated for Salter–Harris types I and II distal radius fractures with documented loss of reduction. Patients were matched based on age, sex, and Salter–Harris fracture type. Functional outcomes were assessed using the Mayo wrist score, disabilities of the arm, shoulder, and hand (DASH), and patient-rated wrist evaluation (PRWE) scores. Radiographic parameters, including radial height, dorsal angulation, dorsal translation, radial inclination, and physeal alignment, were evaluated at initial trauma, posttreatment, and final follow-up. A total of 96 patients were included in the study: 72 were treated conservatively, and 24 underwent surgical pinning. The mean age was 10.2 ± 2.1 years in the conservative group and 11.1 ± 1.8 years in the surgical group. The overall mean follow-up duration was 60.9 ± 11.5 months. At final follow-up, there were no statistically significant differences between the conservative and surgical groups in Mayo (97.6 ± 2.8 vs. 96.8 ± 4.1; $P = 0.45$), DASH (1.4 ± 2.6 vs. 2.1 ± 3.3; $P = 0.27$), or PRWE scores (0.7 ± 1.5 vs. 1.4 ± 2.3; $P = 0.17$). Radiographic parameters, including dorsal angulation [0° (0–4.4°) vs. 0° (0–0°), $P = 0.12$] and dorsal translation (0 vs. 0%; $P = 0.06$), were similarly restored in both groups. In pediatric Salter–Harris types I and II distal radius fractures with loss of reduction, continued conservative management provided outcomes comparable to surgical pinning. These findings suggest that surgery may not be routinely necessary, particularly in patients with remodeling potential. *J Pediatr Orthop B* **35: 236–244**

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[a]Department of Orthopedics and Traumatology, Hacettepe University Faculty of Medicine and [b]Department of Biostatistics, Hacettepe University, Ankara, Turkey

Correspondence to Melih Oral, MD, Department of Orthopedics and Traumatology, Hacettepe University Faculty of Medicine, A. Adnan Saygun Street, Altındağ, Ankara 06230, Turkey
Tel: +90 0312 305 1704; e-mail: melihoral12@gmail.com

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Introduction

The incidence of pediatric distal radius fractures accounts for ~20–35% of all pediatric fractures [1–3]. Among these, metaphyseal and physeal fractures constitute 20.2 and 15%, respectively [4]. The Salter–Harris classification system categorizes physeal fractures based on the extent and location of the injury relative to the growth plate [5,6]. Among these, Salter–Harris types I and II are the most common, particularly in the distal radius, which is one of the fastest-growing physis in the body and a critical site for longitudinal growth [5,7]. Salter–Harris type II fractures, in particular, are the most frequently encountered and involve both the growth plate and the metaphysis, posing risks of growth disturbances if not managed appropriately [7–9].

Although most Salter–Harris types I and II distal radius fractures can be successfully managed with closed reduction and casting, a subset of cases experience loss of reduction during follow-up, which presents a clinical dilemma [10]. In such situations, the decision to proceed with surgical fixation, typically with percutaneous pinning, is often made based on concerns over malunion, growth disturbance, or functional limitation [11]. However, this approach is not standardized, and the benefits of surgery after loss of reduction remain unclear, particularly in children with significant remodeling potential [11,12].

Prior studies have established acceptable alignment thresholds for nonoperative treatment and have emphasized the remodeling capacity in skeletally immature patients [11,13]. Yet, limited data exist comparing patients who experience similar levels of displacement after reduction loss but are managed either surgically or nonoperatively. Consequently, it is uncertain whether surgical intervention following reduction loss leads to improved clinical or radiological outcomes.

This study aimed to compare the radiological and functional outcomes of pediatric patients with Salter–Harris

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types I and II distal radius fractures who experienced loss of reduction and were managed either surgically or conservatively.

Methods

Study design and patient selection

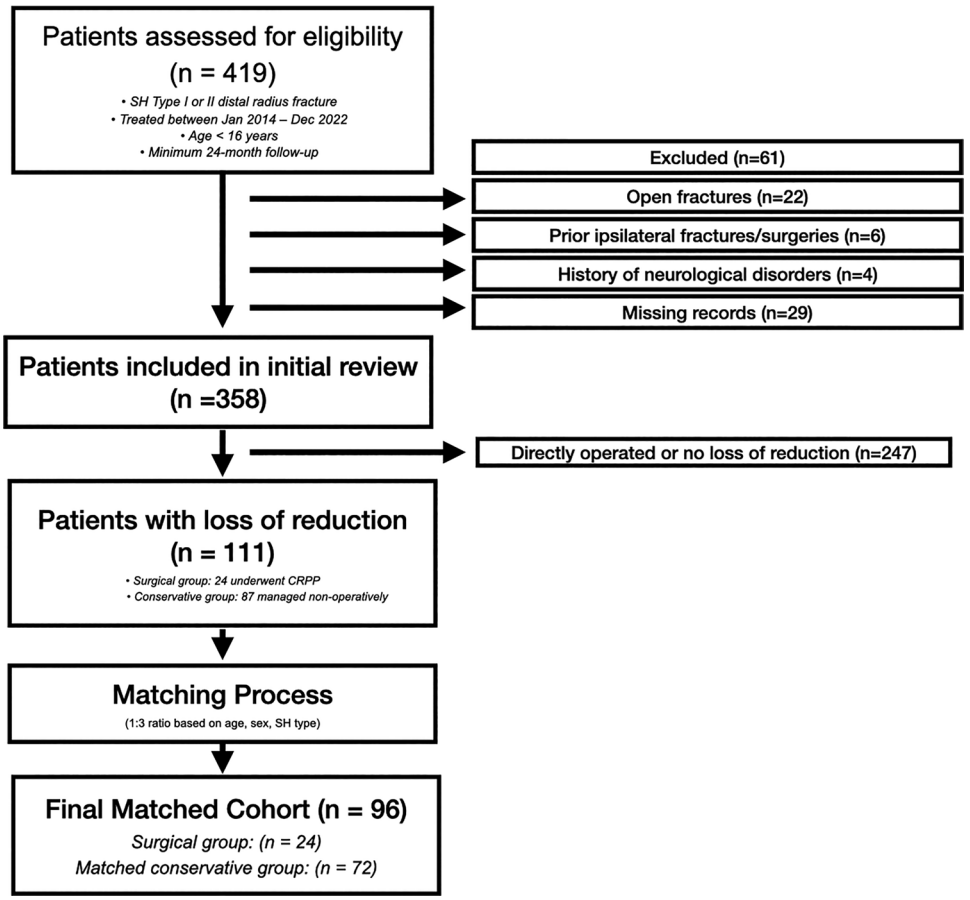
This retrospective matched cohort study was conducted at a tertiary pediatric referral center and included patients under 16 years of age who were treated for Salter–Harris type I or II distal radius fractures between January 2014 and December 2022. Ethical approval for the study was obtained from the institutional review board (IRB No. SBA 24/1045).

A total of 219 patients under 16 years of age with Salter–Harris type I or II distal radius fractures and a minimum follow-up period of 24 months were initially reviewed. Patients were excluded if they had open fractures (eight patients), prior fractures or surgeries on the ipsilateral upper extremity (five patients), neurological disorders (one patient), or missing records (three patients). After applying these criteria, a total of 202 patients were found. Among the 202 patients, 128 (24 surgically treated and 104 conservatively treated) were found to have experienced radiographic loss of reduction after initial closed reduction and casting. Loss of reduction was defined as exceeding one or more of the following thresholds on follow-up radiographs: coronal angulation greater than 10°, sagittal angulation (dorsal or volar) greater than 15°, or translational displacement exceeding 25% of the metaphyseal width.

The surgical group included 24 patients who underwent closed reduction and percutaneous pinning (CRPP) following loss of reduction. The conservative group initially included 104 patients who were managed nonoperatively despite the loss of reduction.

To enable a balanced comparison, 72 patients from the conservative group were propensity matched to the 24 surgical patients at a 1 : 3 ratio, based on age, sex, and Salter–Harris fracture type (I or II) (Fig. 1).

Fig. 1



Flow diagram showing patient selection with inclusion and exclusion criteria for the study. CRPP, closed reduction and percutaneous pinning; SH, Salter–Harris.

Treatment modalities

Initial closed reduction was performed in the emergency department under intravenous sedation, typically with a combination of midazolam and ketamine. Reductions were carried out by orthopedic residents under the supervision of an orthopedic attending. Manual traction and manipulation were used to restore anatomical alignment in both sagittal and coronal planes. A three-point molded long-arm cast was applied with the forearm positioned in neutral position. Postreduction alignment was assessed using anteroposterior (AP) and lateral radiographs. Acceptable alignment following closed reduction was defined using age-specific thresholds. For children aged 4–5 years, angulation less than or equal to 30° and translation less than or equal to 50% were acceptable; for those aged 6–10 years, angulation less than or equal to 20° and translation less than or equal to 50% were used, and for patients aged 11–18 years, the limits were angulation less than or equal to 10° and translation less than or equal to 25% [11].

All initial reductions were performed within 7 days of injury. If loss of reduction was identified on follow-up radiographs at 1, 2, or 4 weeks, the decision to attempt re-reduction was based on the time elapsed since the initial injury. For patients with early redisplacement, defined as occurring within 10 days of injury, a second closed reduction attempt was typically performed under sedation. If redisplacement was identified more than 10 days after the initial injury, re-reduction was not attempted because of early signs of fracture consolidation, and management proceeded with either surgical fixation or continued casting based on fracture alignment, patient age, and surgeon judgment.

Among all included patients, the presence of associated ulnar styloid fractures was recorded. A total of 11 patients demonstrated ulnar styloid involvement on initial imaging. However, the presence of an ulnar styloid fracture did not influence the choice of surgical vs. conservative treatment, and none of these patients underwent ulnar styloid fixation.

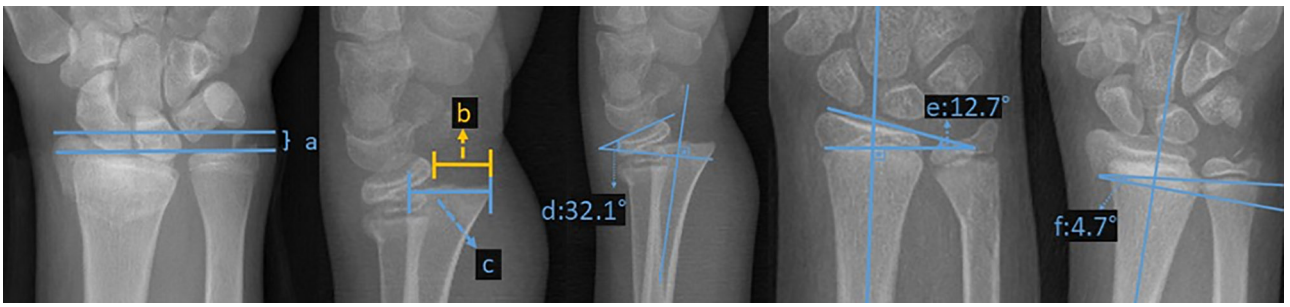
Patients who proceeded to surgery underwent closed reduction and CRPP under general anesthesia. Fixation was performed using two smooth K-wires under fluoroscopic guidance, followed by splint immobilization. K-wires were removed at 3–4 weeks postoperatively, in the outpatient clinic. In patients treated conservatively after loss of reduction, cast immobilization was continued for 6 weeks without additional surgical intervention. All patients were instructed to perform a standardized home-based rehabilitation program after cast or K-wire removal. The program included passive and active range of motion (ROM) exercises initially, with gradual progression to strengthening exercises based on patient tolerance. Referral to formal physical therapy was made based on functional limitations, clinical exam findings, or patient-reported symptoms. Patients were routinely re-evaluated with radiographs at 1, 2, 4, and 6 weeks after injury, then at 3 months and annually as needed to monitor remodeling and detect late complications.

Radiographic analysis

Radiographic assessments were performed at three time points: at the time of initial trauma, immediately after treatment (postreduction or surgery), and at the final follow-up. Standardized AP and lateral radiographs of the wrist were obtained for all patients. All measurements were performed by a post graduation year–5 orthopedic resident (UK).

Radiographic parameters evaluated included radial height, dorsal translation, dorsal angulation, radial inclination, and physis inclination [14–17]. Radial height was measured as the vertical distance between the distal end of the radius and the ulnar styloid, while radial inclination was evaluated as the angle between the articular surface of the radius and its long axis on the AP radiograph

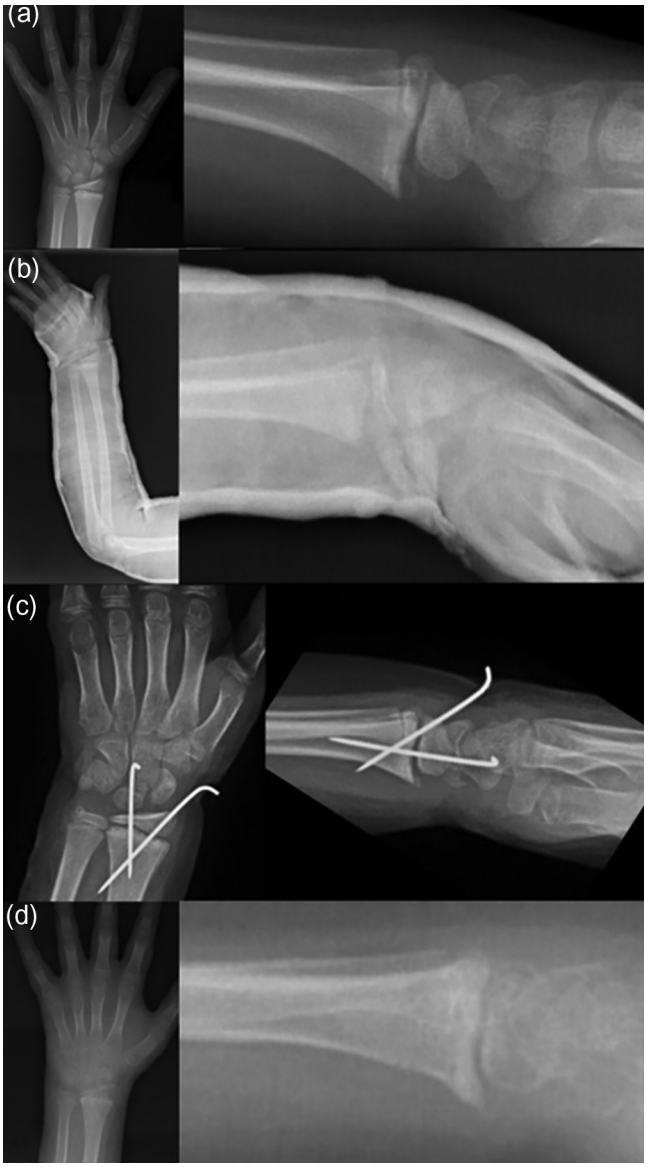
Fig. 2



Radiographic parameters. '*a*' Represents radial height. '*b*/*c*' ratio defines dorsal translation on the lateral view. '*d*' Angle represents the degree of angulation on the lateral view relative to the line perpendicular to the shaft. Angle '*e*' represents the radial inclination on the AP view relative to the line perpendicular to the shaft. Angle '*f*' represents the degree of angulation on the AP view relative to the line perpendicular to the shaft. AP, anteroposterior.

[14,15,18]. Dorsal translation was determined as the percentage of posterior displacement of the distal fracture fragment relative to the metaphyseal diameter on the lateral radiograph, and dorsal angulation was measured as the angle between the distal fragment and the radial shaft in the sagittal plane [14,15]. Physis inclination, an indicator of growth plate alignment, was measured as the angle between the horizontal plane and the physis line to assess potential growth disturbances [14,15]. The method for performing radiographic measurements is shown in Fig. 2. In addition to standard radiographic parameters, follow-up radiographs were examined for signs of physeal bar formation, including localized narrowing, angular deformity, or osseous bridging across the physis. Any evidence suggestive of growth arrest or asymmetrical physeal closure was recorded. However, advanced imaging such as MRI or computed tomography was not routinely performed. Radiographs were also reviewed to detect complications such as malunion, delayed union, or changes in physis orientation (Fig. 3).

Fig. 3



Radiographic evaluation of a 7-year-old male patient with a left distal radius Salter–Harris type I physeal fracture. (a) Initial presentation showing a 32° lateral dorsal angulation. (b) Postreduction radiograph demonstrating residual 20° dorsal angulation. (c) Intraoperative radiograph after closed reduction and fixation with two percutaneous K-wires. (d) Follow-up at 17 months showed complete fracture healing with no residual angulation or abnormalities.

Clinical outcome measures and assessment

Clinical outcomes were assessed using validated scoring systems to evaluate functional recovery, pain, and patient satisfaction. The Mayo wrist score was used as a clinician-based tool to assess pain, functional status, ROM, and grip strength, with scores ranging from 0 to 100, where higher scores indicated better wrist function [19]. In addition, the disabilities of the arm, shoulder, and hand (DASH) score provided a comprehensive patient-reported measure of upper limb function, evaluating activity limitations, symptoms, and pain, with higher scores reflecting greater disability [20]. The patient-rated wrist evaluation (PRWE) score, which focuses specifically on wrist-related pain and functional disability, was also used, where higher scores indicated worse outcomes [21].

ROM, including wrist flexion, extension, radial deviation, and ulnar deviation, was assessed using a goniometer at each follow-up visit to evaluate mobility and functional recovery. During follow-up visits, a detailed physical examination was performed to evaluate for tenderness, deformity, wrist stability, and stiffness (Fig. 4). Compliance with physical therapy and rehabilitation progression was also documented. These assessments were conducted at baseline, during follow-up visits, and at the final evaluation.

Statistical analysis

The analyses were conducted using the free and open-source software R (version 4.4.1, *https://cran.r-project.org*) and the SPSS for Windows Version 23.0 statistical package (Chicago, Illinois, USA), with the assistance of an academic biostatistician. Normality of the data was assessed using the Shapiro–Wilk's test, and variance homogeneity was tested using Levene's test. Descriptive statistics were presented as mean ± SD, median (25^{th}–75^{th} percentile), and frequencies (percentages) as appropriate. To compare the differences between the groups, Student's *t*-test or Mann–Whitney *U* test, as appropriate, was used for continuous variables, and Yates continuity correction Chi-square test or Fisher's exact test was used for categorical variables. Cohen's *d* effect size was calculated for Student's *t*-test, and $r = z/\sqrt{n}$ effect size was calculated for Mann–Whitney *U* test. For within-group comparisons,

Friedman or repeated measures analysis of variance tests were used as appropriate. To reduce confounding and achieve better comparability between treatment groups, a propensity score matching approach was employed. Matching was performed based on potential confounders, including age, gender, and Salter–Harris classification [22]. Propensity scores were estimated using logistic regression, and a 1 : 3 nearest neighbor matching algorithm was applied without replacement. The analysis was conducted in R using the 'MatchIt' package. Postmatching balance diagnostics and graphical assessments were performed, confirming adequate balance between the matched groups.

Least significance difference post-hoc test was applied to find out which time or times caused the differences within the groups. 'ggplot2' and 'reshape2' packages were used for drawing the plots [23,24]. A P value of less than 5% was considered statistically significant.

Results

Patient demographics

A total of 96 pediatric patients were included in the study, with 72 treated conservatively with casting and 24 managed surgically. The mean age was 10.2 ± 2.1 years in the conservative group and 11.1 ± 1.8 years in the surgical group (P = 0.43). The overall mean follow-up duration was 60.9 ± 11.5 months, with a mean of 58.0 ± 11.1 months in the conservative group and 71.0 ± 8.2 months in the surgical group (P = 0.19). The male-to-female distribution was not significantly different between the groups (P = 0.25; Table 1).

Radiological outcomes

Radial height increased from 7.6 ± 2.2 mm at initial trauma to 12.5 ± 3.8 mm at final follow-up in the conservative group, and from 8.2 ± 2.4 to 13.1 ± 2.7 mm in the surgical group. There were no statistically significant differences between groups at any time point (P = 0.07 and 0.39, respectively). Dorsal translation was significantly higher in the surgical group both at the time of trauma [55% (37.5–67.5%) vs. 20% (0–52.5%), P = 0.003] and posttreatment [6% (1.5–14.5%) vs. 0% (0–2.5%), P = 0.004]. At the final follow-up, both groups demonstrated full correction, with no residual translation observed (P = 0.06; Table 2, Fig. 5a).

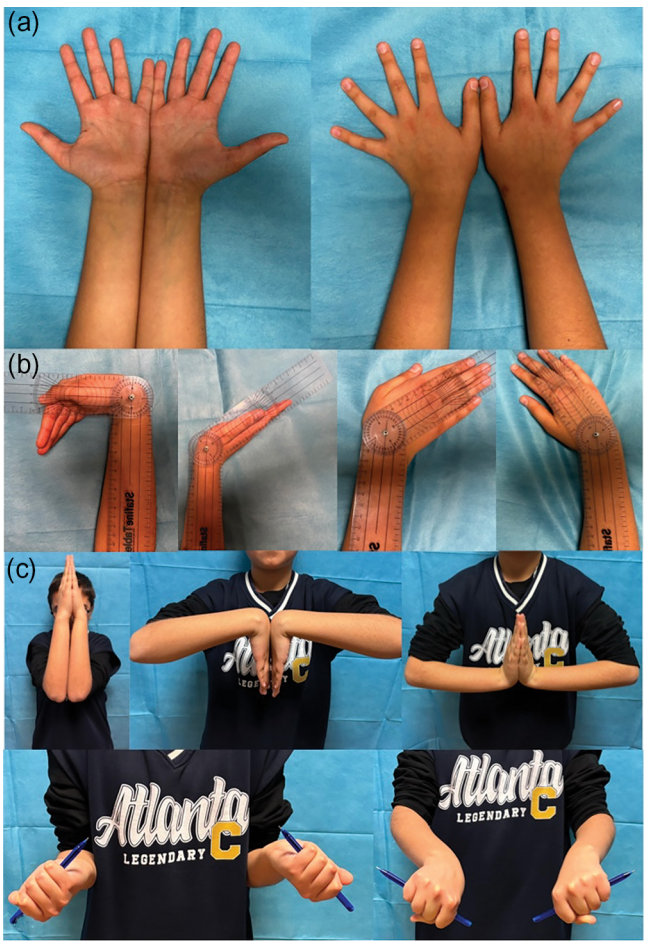
Dorsal angulation was also greater in the surgical group at the time of injury [24.5° (13.6–27.6°) vs. 12.4° (3.3–25.4°); P = 0.03] and posttreatment [3.1° (0–8.1°) vs. 0° (0–0°); P = 0.02]. By the final follow-up, dorsal angulation had improved in both groups, with no statistically significant difference [0° (0–4.4°) vs. 0° (0–0°); P = 0.12].

Radial inclination increased following treatment and remained stable at final follow-up in both groups, with no significant differences observed (final values: 20.5 ± 2.2° vs. 21.1 ± 2.9°; P = 0.29). Similarly, physeal inclination showed mild improvement posttreatment and remained within acceptable ranges at the final follow-up (21.4 ± 3.1° in the conservative group vs. 20.2 ± 2.1° in the surgical group; P = 0.29), without significant intergroup differences. Mean cast index was 0.74 ± 0.05 in the surgical group and 0.77 ± 0.06 in the conservative group, with no significant difference (P = 0.18).

Clinical outcomes

At the final follow-up, Mayo, DASH, and PRWE scores did not differ significantly between the two groups. The mean Mayo score was 97.6 ± 2.8 in the conservative group and 96.8 ± 4.1 in the surgical group (P = 0.45). The mean DASH score was 1.4 ± 2.6 in the conservative group and 2.1 ± 3.3 in the surgical group (P = 0.27). The mean PRWE score was 0.7 ± 1.5 in the conservative group and 1.4 ± 2.3 in the surgical group (P = 0.17). Mild

Fig. 4



Clinical evaluation of patients. The patient exhibited no pain, limitations, or abnormalities in wrist and forearm movements, including pronation-supination, flexion-extension, and radial-ulnar deviation.

ROM restriction was observed in two patients (2.8%) in the conservative group and two patients (8.3%) in the surgical group ($P = 0.23$; Table 1, Fig. 5b).

Table 1 Comparison of demographics and final follow-up functional outcomes between groups

Variables	Conservative treatment ($n = 72$) (mean ± SD)	Surgical treatment ($n = 24$) (mean ± SD)	*P*-value
Age (years)	10.2 ± 2.1	11.1 ± 1.8	0.43[a]
Gender, *n* (%)			
Male	49 (68.1%)	21 (87.5%)	
Female	23 (31.9%)	3 (12.5%)	0.25[b]
Mean follow-up duration (months, range)	58 ± 11.1	71 ± 8.2	0.19[c]
SH classification, *n* (%)	19 (26.4%)	8 (33.3%)	0.16[b]
1	53 (73.6%)	16 (66.7%)	
2			
Mayo wrist score at final follow-up	99 ± 3	97 ± 9	0.24[c]
DASH score at final follow-up	1.2 ± 4.2	2.8 ± 8.4	0.22[c]
PRWE score at final follow-up	0.4 ± 1.5	2 ± 4.6	0.15[c]
Active ROM at final follow-up	70 (97.2%)	22 (91.7%)	>0.05[d]
Full	2 (2.8%)	2 (8.3%)	
Restricted			

Data are presented as mean ± SD and median (25th–75th percentile). Categorical variables reported as frequency (%). Differences between groups were analyzed using followings:
[a]Student's *t*-test,
[b]Yates continuity correction Chi-square test,
[c]Mann–Whitney *U* test, and
[d]Fisher's exact test.
DASH, disabilities of the arm, shoulder, and hand; Mayo, modified Mayo wrist score; PRWE, patient-rated wrist evaluation; ROM, range of motion; SH, Salter–Harris.

Complications

No major complications, such as malunion, delayed union, or growth disturbances, were reported in either group. Although the surgical group presented with greater dorsal translation and angulation at the time of trauma, both groups achieved similar alignment and functional recovery by the final follow-up.

Discussion

Our study demonstrated that in pediatric patients with Salter–Harris types I and II distal radius fractures who experienced loss of reduction after initial closed treatment, subsequent surgical pinning did not lead to superior clinical or radiological outcomes compared with continued conservative management. Both treatment approaches resulted in excellent functional scores and satisfactory radiographic alignment at final follow-up, suggesting that surgery may not be necessary in cases of mild-to-moderate displacement following reduction loss.

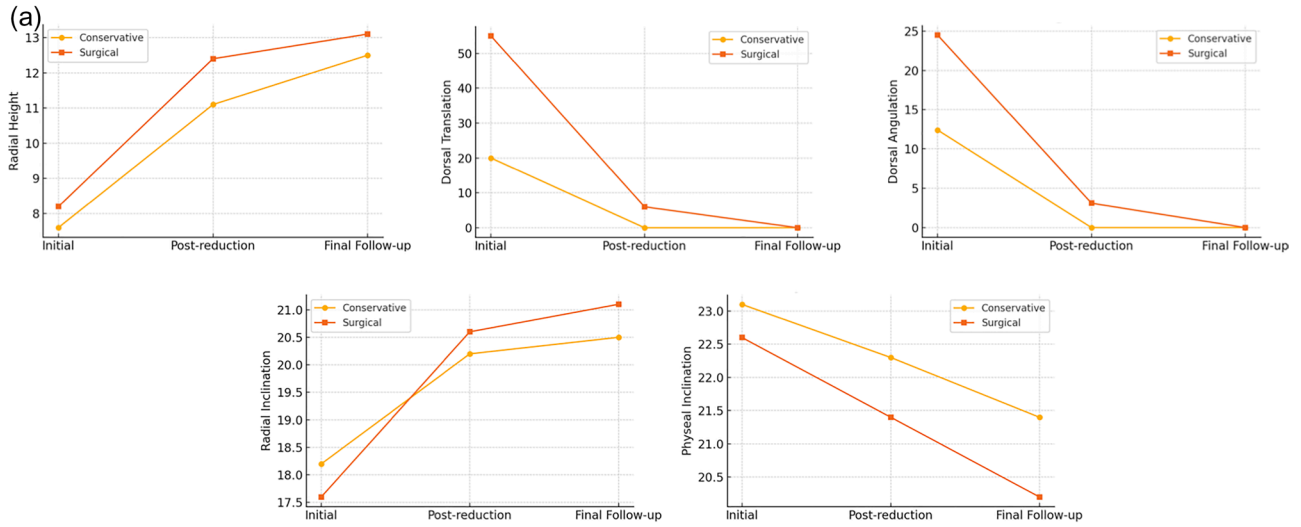
There is no consensus on the optimal treatment for Salter–Harris types I and II fractures, particularly in cases where loss of reduction occurs after initial closed treatment [25]. While closed reduction and casting are typically used for minimally displaced fractures, surgical fixation is often considered when displacement recurs or progresses during follow-up. However, the necessity and the benefit of surgical intervention following loss of reduction remain unclear. Previous studies have primarily focused on initial treatment strategies, leaving a gap in the literature regarding outcomes after secondary displacement. Our study addresses this gap by directly

Table 2 Comparison of radiological outcomes between and within groups in patients treated conservatively or surgically

Radiological parameters	Assessment period	Conservative treatment ($n = 72$) (mean ± SD)	Surgical treatment ($n = 24$) (mean ± SD)	*P*-value (between groups)	Effect size
Radial height (mm)	Initial trauma	7.6 ± 2.2	8.2 ± 2.4	0.07[b]	0.266
	Postreduction	12.1 ± 3.3	12.1 ± 2.5	0.91[b]	−0.017
	Final follow-up	12.5 ± 3.8	13.1 ± 2.7	0.39[b]	−0.264
	P-value (within groups)	<0.001[c]	<0.001[c]		
Dorsal translation (%)	Initial trauma	20% (0–52.50%)	55% (37.5–67.50%)	0.003[a]	0.453
	Postreduction	0% (0–2.50%)	6% (1.50–14.50%)	0.004[a]	0.428
	Final follow-up	0% (0–0%)	0% (0–0%)	0.06[a]	0.255
	P-value (within groups)	<0.001[c]	<0.001[c]		
Dorsal angulation (°)	Initial trauma	12.4 (3.3–25.4)	24.5 (13.6–27.6)	0.03[a]	0.299
	Postreduction	0 (0–0)	3.1 (0–8.1)	0.02[a]	0.344
	Final follow-up	0 (0–0)	0 (0–4.4)	0.12[a]	0.210
	P-value (within groups)	<0.001[c]	<0.001[c]		
Radial inclination (°)	Initial trauma	12.2 ± 7.0	12.9 ± 5.2	0.81[b]	−0.114
	Postreduction	20.2 ± 3.5	19.3 ± 3.7	0.34[b]	0.304
	Final follow-up	20.5 ± 2.2	21.1 ± 2.9	0.29[b]	0.136
	P-value (within groups)	<0.001[c]	<0.001[c]		
Physeal inclination (°)	Initial trauma	17.6 ± 5.3	17.8 ± 5.1	0.78[b]	0.055
	Postreduction	21.3 ± 3.7	20.6 ± 2.7	0.41[b]	0.261
	Final follow-up	21.4 ± 3.1	20.2 ± 2.1	0.29[b]	0.262
	P-value (within groups)	0.011[d]	0.036[d]		

Data are presented as mean ± SD or median (25th–75th percentile). Categorical variables reported as frequency (percent). Differences between groups were analyzed using followings:
[a]Mann–Whitney *U* test,
[b]Student's *t*-test,
[c]Friedman test, and
[d]repeated measures ANOVA.
ANOVA, analysis of variance.

Fig. 5



(a) Changes over time in radiographic parameters, including radial height, dorsal angulation, radial inclination, and physis inclination in the conservative and surgical treatment groups. (b) Changes over time in clinical outcome scores, including Mayo wrist score, disabilities of the arm, shoulder, and hand (DASH) score, and patient-rated wrist evaluation (PRWE) score.

comparing outcomes between surgical and conservative management in patients who experienced displacement after initial reduction.

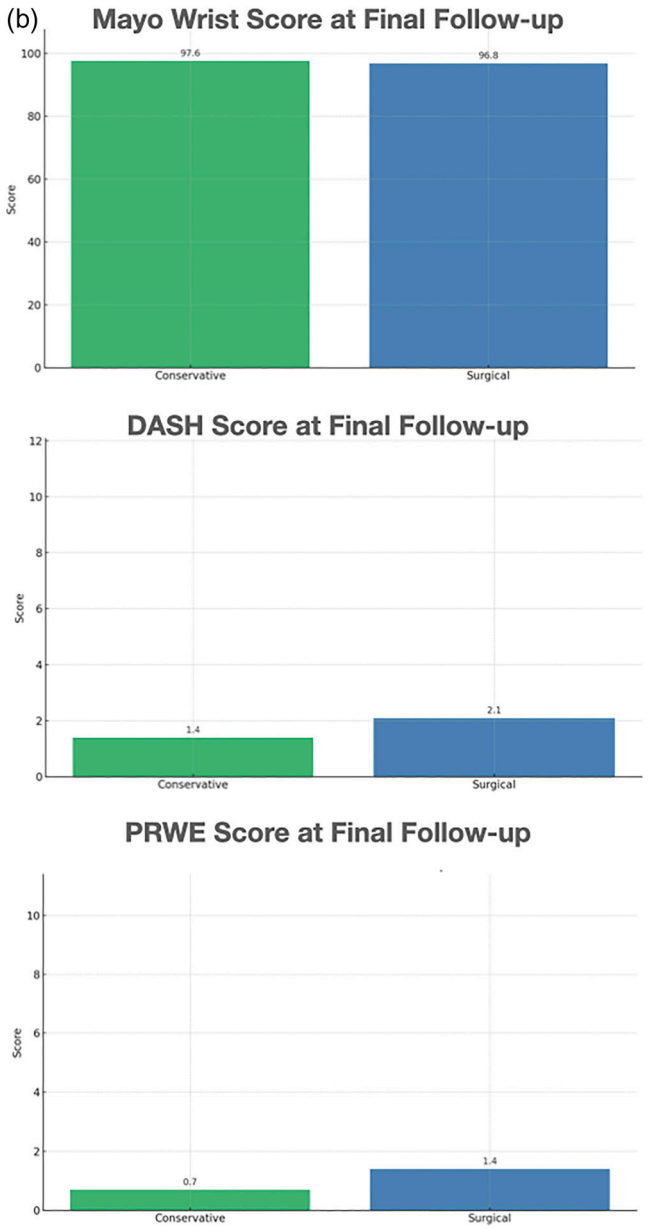
Although previous literature has emphasized the role of age and initial displacement in guiding treatment decisions, few have evaluated outcomes following redisplacement. Rivera *et al.* [10] found that patient age, rather than fracture displacement, was the most significant predictor for surgical fixation in Salter–Harris type II fractures, reflecting variability in treatment preferences. Similarly, Shah *et al.* [11] identified multiple risk factors for loss of reduction, including initial fracture displacement and inadequate cast molding, but did not evaluate outcomes based on subsequent treatment. Lee *et al.* [26] recently reported that remodeling can occur even in patients with up to 51% sagittal displacement, supporting the notion that some redisplaced fractures can still heal well without surgical intervention. These findings align with our results, which suggest that even after loss of reduction, conservative treatment may provide similar outcomes in many cases. However, we believe that treatment should be individualized based on the patient's expected growth potential. For example, a 6-year-old with substantial growth remaining may remodel well despite significant translation, while a 13-year-old with limited remaining growth may benefit from CRPP if the fracture is not adequately aligned.

The high remodeling potential of the distal radius physis in children likely accounts for the lack of significant differences in radiological or functional results [13]. Larsen *et al.* [13] demonstrated complete remodeling of angulated distal radius fractures in children under 10 years of age, even when initial deformity exceeded accepted limits. Lee *et al.* [26] further supported this by reporting excellent outcomes and alignment in conservatively treated patients with moderate displacement. In our cohort, dorsal angulation and translation improved progressively in both groups, with no residual deformity observed at final follow-up. These radiographic improvements were accompanied by high Mayo, DASH, and PRWE scores in both cohorts, reinforcing the clinical reliability of nonoperative management following redisplacement.

The decision to proceed with surgical fixation after loss of reduction is often based on concerns about malunion, persistent deformity, or functional impairment. However, the current literature questions whether these outcomes justify the risks of surgery. Hu *et al.* [27] outlined indications and surgical techniques for physeal fractures of the distal radius, suggesting that surgery is primarily warranted in severely displaced, unstable, or irreducible fractures. Jerome [12] demonstrated acceptable outcomes with both conservative and surgical approaches, though their cohort emphasized initial fracture severity rather than postreduction changes. Liebs *et al.* [28], in a study of pediatric forearm fractures, noted excellent long-term function and health-related quality of life in nonoperatively treated patients, further supporting the role of conservative management when feasible.

This study has several limitations. Its retrospective design introduces potential selection bias, as treatment decisions may have been influenced by surgeon preference or parental concerns. Although we used 1 : 3 matching,

Fig. 5



Continued

a complete balance in variables such as age or displacement may not have been achieved. Radiographic evaluation relied on plain radiographs, which may miss subtle or rotational deformities. While no growth disturbances were noted, long-term imaging specifically targeting physeal arrest was not routinely performed, limiting our ability to detect subtle or partial growth arrests. Eleven patients had concomitant ulnar styloid fractures, which did not alter treatment or outcomes in our cohort, though their impact on distal radioulnar joint stability warrants further study. In addition, clinical outcomes were assessed using standard PROMs without patient satisfaction measures or long-term growth assessments. Finally, the follow-up duration may not fully capture late complications.

Conclusion

In pediatric patients with mild to moderately displaced Salter–Harris type I or II distal radius fractures who experience loss of reduction, surgical pinning did not yield superior outcomes compared with continued conservative management. Both approaches resulted in excellent final alignment and function. Further randomized studies are needed to refine treatment indications and guide clinical decision-making.

Acknowledgements

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Ethical approval for this study was obtained from the Hacettepe University Faculty of Medicine local ethics committee (IRB No. SBA 24/1045).

Patients gave written informed consent for participation in the study.

The data and materials that support the findings of this study are available from the corresponding author (M.O.) upon reasonable request.

Conflicts of interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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