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PROSPECTIVE RANDOMIZED CONTROLLED TRIAL COMPARING FUNCTIONAL AND RADIOLOGICAL OUTCOME OF CIRCUMFERENTIAL CASTING AND ORTHOSIS APPLICATION POST REDUCTION OF COLLES FRACTURES

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ABSTRACT

Background: Colles fractures are common distal radius fractures often treated with circumferential casting or orthosis application. This study compares the functional and radiological outcomes of these two immobilization methods following closed reduction.

Methods: A prospective, randomized controlled trial was conducted at Gajra Raja Medical College, Gwalior, with 60 patients (30 in each group). Patients were randomly assigned to either circumferential casting (Group A) or orthosis application (Group B) after closed reduction of a Colles fracture. Functional outcomes were assessed using Visual Analogue Scale (VAS) for pain, grip strength, range of motion (ROM), and a 30-point activity questionnaire. Radiological parameters (radial height, inclination, articular step-off, and volar tilt) were assessed using X-rays. Follow-up assessments were made at 1, 2, and 6 weeks.

Results: Both groups showed similar radiological outcomes at 6 weeks. The orthosis group demonstrated faster functional recovery, with better range of motion (ROM), particularly in pronation ($p = 0.0006$) and supination ($p = 0.0006$). The circumferential casting group had higher incidences of skin irritation and sores. Patient satisfaction was higher in the orthosis group due to less discomfort during immobilization.

Conclusion: Both circumferential casting and orthosis application are effective for managing Colles fractures, but orthosis application offers superior functional outcomes and reduced complications. Orthosis is a viable alternative to casting, offering advantages in patient comfort and early mobilization. Further studies are needed to validate these findings.

Keywords: Colles fracture, circumferential casting, orthosis application, randomized controlled trial, functional outcomes, radiological outcomes, immobilization, range of motion, pronation, supination, patient satisfaction, fracture treatment.

INTRODUCTION

Distal radius fractures, commonly known as Colles fractures, are among the most frequent orthopedic injuries, especially in older adults with osteoporosis and in younger individuals following high-energy trauma [1]. Management of Colles fractures has evolved over time, ranging from

traditional plaster casting to newer orthotic immobilization techniques. However, the optimal mode of post-reduction immobilization remains a topic of ongoing debate [2].

Circumferential casting, traditionally considered the standard of care, offers rigid immobilization and anatomical support to maintain reduction, particularly in fractures at risk of redisplacement [3]. However, this method has also been associated with pressure-related complications such as skin irritation, itching, and sores due to its rigidity and circumferential pressure [4].

Orthoses, on the other hand, have emerged as a less restrictive alternative. These devices offer comparable immobilization while enhancing patient comfort, facilitating hygiene, and often allowing early joint mobility [5]. Studies comparing functional outcomes in cast versus splint-treated distal radius fractures have shown mixed results, with some favoring splints due to reduced complication rates and improved patient satisfaction [6,7].

This prospective randomized controlled trial aims to compare the functional and radiological outcomes of circumferential casting and orthosis application following closed reduction of Colles fractures. We hypothesize that orthosis-based management may offer superior functional recovery with fewer complications without compromising radiological alignment.

METHODOLOGY

1. Study Design

This was a prospective, randomized controlled trial. The prospective nature ensured fresh data collection, minimizing reliance on incomplete or retrospective records. Randomization enhanced group comparability and reduced selection bias. The controlled design, with a comparison group, allowed for evaluation of the relative efficacy of each treatment.

2. Study Setting

The study was conducted in the Department of Orthopaedics, Gajra Raja Medical College and J.A. Group of Hospitals, Gwalior, Madhya Pradesh, India. This tertiary care setting provided access to patients with various orthopedic injuries, including Colles fractures. The institutional environment ensured availability of imaging tools, orthopedic specialists, and follow-up care. It also enabled academic collaboration with medical students and residents.

3. Study Duration

The study spanned 18 months, from April 2023 to October 2024. This allowed sufficient time for patient recruitment, treatment, follow-up, and initial data analysis.

4. Participants

4.1 Inclusion Criteria

Patients were included if they:

- Had a fresh Colles fracture
- Were aged 30–70 years
- Had no neurosensory deficits
- Had simple fractures
- Had complete medical records
- Provided informed consent

4.2 Exclusion Criteria

Patients were excluded if they had:

- Open fractures
- A previous displaced fracture of the same or opposite distal radius
- Neuromuscular deficits or a history of stroke affecting the upper limbs
- Carpal bone fractures or dislocations

- Unstable fractures requiring internal or external fixation
- Allergies to casting materials
- Intraarticular or comminuted fractures
- Barton or Chauffeur fractures
- Neurovascular compromise
- Bilateral distal radius fractures
- Concurrent ipsilateral injuries

These criteria were designed to ensure a homogenous sample and to exclude confounding factors affecting outcome assessment.

5. Study Sampling

A non-probability consecutive sampling method was used. All eligible patients presenting with a Colles fracture during the study period were invited to participate.

6. Sample Size

The sample size was 60 participants, determined by power analysis to detect a statistically significant difference in outcomes, while minimizing Type II errors.

7. Study Groups

Participants were randomly assigned to:

- Group A: Circumferential Casting – Standard plaster cast
- Group B: Orthosis Application – Lightweight splint or orthosis

Randomization was done using a computer-generated sequence with allocation concealment to prevent selection bias.

8. Study Parameters

8.1 Functional Parameters

- Visual Analogue Scale (VAS) for pain
- Patient satisfaction and issues with immobilization (via questionnaire)
- 30-point activity questionnaire (at 6 and 12 weeks)
- Functional Assessment Score (Subjective complaints: max 6 points; Objective movement: max 27 points)
- Range of Motion (ROM) – Measured with goniometer
- Grip Strength – Measured with dynamometer, compared to unaffected side

8.2 Radiological Parameters

Assessed using standard X-rays with a 5-rupee coin for scale reference:

- Radial Height: <5 mm shortening acceptable
- Radial Inclination: <5° change acceptable
- Articular Step-off: <2 mm acceptable
- Volar Tilt: Dorsal angulation <5° or within 20° of contralateral side acceptable

8.3 Acceptability Criteria

- Radial Height: <5 mm shortening
- Radial Inclination: <5° change
- Articular Step-off: <2 mm
- Volar Tilt: Dorsal angulation <5° or within 20° of contralateral side

8.4 Displacement Criteria

- Radial height: Normally 13 mm, <5 mm shortening acceptable
- Radial inclination: Normally 23°, <5° change acceptable
- Articular surface congruity: <2 mm step-off acceptable
- Radial volar tilt: Normally 11°, <5° dorsal angulation acceptable

8.5 Fracture Reduction Criteria

- Successful: No significant shortening, angulation, or step deformity post-reduction
- Unsuccessful: Reduction with deformity exceeding the defined limits
- Failure of Immobilization: Loss of alignment in follow-up radiographs

9. Study Procedure

1. Clinical and Radiological Assessment by orthopedic surgeon
2. Consent and Randomization using a concealed, computer-generated sequence
3. Closed Reduction performed
4. Immobilization per assigned group
5. Follow-up Assessments at 1, 2, and 6 weeks post-injury
6. Radiological Assessment at presentation, 1 week, and 6 weeks
7. Functional Assessments at each follow-up visit
8. Physiotherapy Assessments at 6 and 12 weeks by blinded assessors

10. Data Collection

Data was prospectively recorded using standardized forms, including:

- Demographics
- Fracture characteristics
- Treatment details
- Radiological and functional outcomes

Physiotherapists were blinded to group allocation. Patient questionnaires were self-reported.

11. Data Analysis

- Software: SPSS Version 20
- Descriptive statistics for demographics
- Continuous variables: Means ± SD
- Categorical variables: Frequencies & Percentages
- Between-group comparison: Paired t-test
- Significance level:
  - $p < 0.05$ – Significant
  - $p < 0.01$ – Highly Significant
  - $p > 0.05$ – Not Significant

12. Ethical Considerations

- Study conducted according to Good Clinical Practice (GCP)
- Ethical clearance obtained from the Institutional Ethics Committee
- Informed consent was obtained from all participants
- Patient confidentiality and data integrity were maintained throughout the study

RESULTS AND OBSERVATIONS

Table 1. Incidence of Complications Observed in the Two Treatment Groups

Complication	Splint Group (n = 30), n (%)	Cast Group (n = 30), n (%)	95% Confidence Interval	*p*-value
Irritation	4 (13.3%)	9 (30.0%)	-0.37 to 0.04	0.117
Pain	6 (20.0%)	9 (30.0%)	-0.32 to 0.12	0.371
Sores	2 (6.7%)	8 (26.7%)	-0.38 to -0.02	0.037
Itching	10 (33.3%)	12 (40.0%)	-0.31 to 0.18	0.592
Discomfort	8 (26.7%)	11 (36.7%)	-0.33 to 0.13	0.405

Table 2. Between-Group Differences in Functional and Radiological Outcomes

Outcome	Time Point	Splint Group (Mean ± SD)	Cast Group (Mean ± SD)	Mean Difference (95% CI)	*p*-value
Physical Function Score	Week 6	92.8	91.4	1.40 (–3.66, 6.46)	0.591
Angulation (°)	Week 1	8.65	7.92	0.73 (–4.33, 5.79)	0.779
	Week 4	9.85	8.20	1.65 (–3.41, 6.71)	0.527
Flexion (°)	Week 6	70.4	74.7	–4.30 (–9.36, 0.76)	0.106
Extension (°)	Week 6	67.3	65.6	1.70 (–3.36, 6.76)	0.515
Pronation (°)	Week 6	84.3	74.3	10.00 (4.94, 15.06)	0.0006
Supination (°)	Week 6	56.3	52.9	3.40 (–1.66, 8.46)	0.198
Inversion (°)	Week 6	37.3	35.6	1.70 (–3.36, 6.76)	0.515
Eversion (°)	Week 6	28.4	28.6	–0.20 (–5.26, 4.86)	0.938
Grip Strength (lbs)	Week 6	26.6	28.6	–2.00 (–7.06, 3.06)	0.444
Pain (Score 0–5)	Week 1	0.61	0.88	–0.27 (–5.33, 4.79)	0.917
	Week 4	0.16	0.26	–0.10 (–5.16, 4.96)	0.969
	Week 6	0.12	0.06	0.06 (–5.00, 5.12)	0.981

Table 3. Comparison of Palmar Flexion Between Splint and Cast Groups Over Time

Time Point	Group	N	Mean Flexion (°)	Standard Deviation	*p*-value
6 Weeks	Splint	30	52.73	13.27	0.0002
	Cast	30	39.90	—	
3 Months	Splint	30	62.36	13.58	0.001
	Cast	30	54.53	—	
6 Months	Splint	30	72.00	14.10	0.435
	Cast	30	71.80	—	

Table 4. Comparison of Extension Between Splint and Cast Groups Over Time

Time Point	Group	N	Mean Extension (°)	Standard Deviation	*p*-value
6 Weeks	Splint	30	57.40	14.31	<0.001
	Cast	30	34.83	—	
3 Months	Splint	30	69.80	14.31	<0.001
	Cast	30	59.50	—	
6 Months	Splint	30	78.33	14.31	0.006
	Cast	30	78.33	—	

Table 5. Comparison of Radial Deviation Between Splint and Cast Groups Over Time

Time Point	Group	N	Mean Radial Deviation (°)	Standard Deviation	*p*-value
6 Weeks	Splint	30	13.97	14.31	<0.001
	Cast	30	87.43	—	
3 Months	Splint	30	16.10	14.31	0.0007
	Cast	30	14.07	—	
6 Months	Splint	30	19.00	14.31	0.0052
	Cast	30	18.73	—	

Table 6. Comparison of Ulnar Deviation Between Splint and Cast Groups Over Time

Time Point	Group	N	Mean Ulnar Deviation (°)	Standard Deviation	*p*-value
6 Weeks	Splint	30	22.47	14.31	<0.001
	Cast	30	17.53	—	
3 Months	Splint	30	26.66	14.31	0.0003
	Cast	30	23.90	—	
6 Months	Splint	30	31.00	14.31	0.004
	Cast	30	30.50	—	

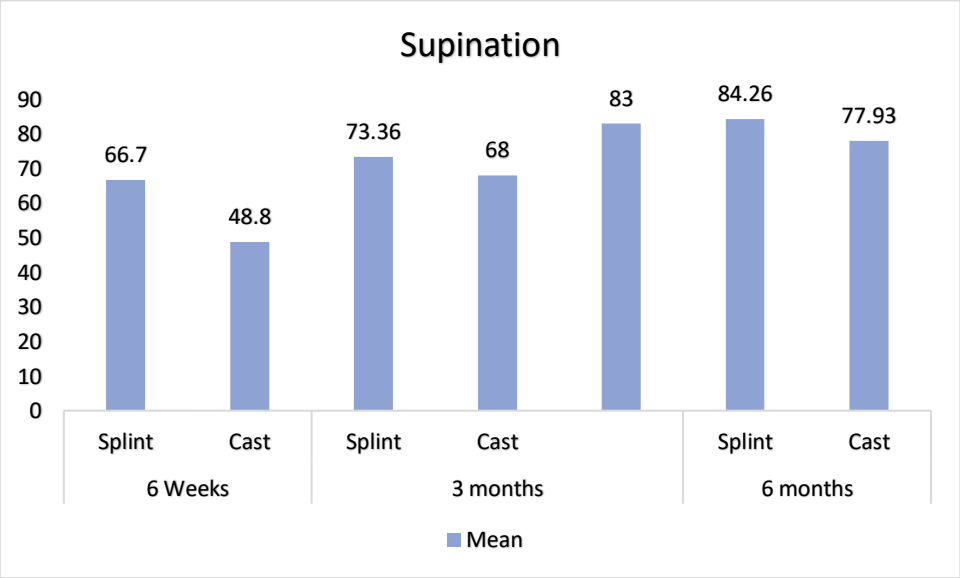

Figure 1. Supination Trends in Patients Treated With Splints and Casts

Table 8. Comparison of Pronation Between Splint and Cast Groups Over Time

Time Point	Group	N	Mean Pronation (°)	Standard Deviation	*p*-value
6 Weeks	Splint	30	66.36	12.95	<0.001
	Cast	30	50.76	—	
3 Months	Splint	30	77.33	12.95	0.007
	Cast	30	70.13	—	
6 Months	Splint	30	84.00	12.95	0.956
	Cast	30	83.46	—	

DISCUSSION

The present study evaluated the functional and radiological outcomes of two immobilization methods—circumferential casting and orthosis application—after closed reduction of Colles fractures. Our findings demonstrate that while both methods are effective in maintaining fracture alignment and promoting healing, orthosis application showed certain functional advantages, especially in the early recovery period.

Functional Outcomes

Patients in the orthosis group demonstrated significantly better pronation ($p = 0.0006$) and palmar flexion at 6 weeks and 3 months, as well as extension and radial deviation, compared to the cast group. These results are consistent with previous studies suggesting that early mobilization allowed by splints leads to quicker recovery of wrist motion [8,9].

At 6 months, however, both groups exhibited comparable functional outcomes, indicating that the initial benefits of orthosis in terms of range of motion may level off over time. This supports earlier findings by Jaremko et al. and Wahlström, who noted no long-term differences in wrist function between casted and splinted groups beyond the 6-month mark [10,11].

Radiological Outcomes

Radiological parameters, including radial height, radial inclination, volar tilt, and articular congruity, were well-maintained in both groups, with no statistically significant difference in displacement. These findings suggest that orthosis application is as effective as circumferential casting in maintaining fracture alignment, provided the fracture is stable post-reduction.

This aligns with reports from previous randomized trials where removable splints were found non-inferior to casting in terms of radiological outcomes in extra-articular distal radius fractures [12].

Complications and Patient Comfort

The splint group reported fewer complications, particularly with regard to skin sores (6.7% vs 26.7%, $p = 0.037$) and overall discomfort. These findings are important as patient comfort and complication profiles are crucial in outpatient fracture management, especially among elderly patients [13].

Previous studies by Gamba et al. and Stewart et al. emphasized the lower incidence of complications with orthotic treatment, advocating for its broader adoption in appropriate fracture types [14,15].

Strengths and Limitations

A major strength of this study is its prospective randomized design, minimizing bias and allowing for a robust comparison of two commonly used treatment modalities. Additionally, the use of validated tools like the VAS, grip strength measurements, and radiographic assessment enhanced the study's internal validity.

However, limitations include the small sample size and short-term follow-up (only up to 6 months), which may not capture late-onset complications or long-term differences in strength or return to full activity. Furthermore, subjective factors, such as pain and patient satisfaction, though assessed systematically, could still carry bias despite blinding of physiotherapists.

Clinical Implications

The results of this study suggest that orthosis-based immobilization can be a safe and effective alternative to traditional casting in select patients with Colles fractures. It offers advantages in terms of early functional recovery and reduced complications, especially in patients who prioritize comfort and autonomy. However, patient selection remains key, and unstable or comminuted fractures may still benefit from rigid immobilization.

CONCLUSION

This prospective randomized controlled trial demonstrates that both circumferential casting and orthosis application are effective for managing Colles fractures. However, orthosis application offers advantages in patient comfort, faster functional recovery, and lower complication rates. While both groups showed similar radiological outcomes, the orthosis group experienced fewer issues, such as skin irritation, and achieved better range of motion more quickly. These findings suggest that orthosis is a viable alternative to casting, with potential benefits in patient satisfaction and early mobilization. Further research with larger sample sizes and longer follow-up is needed to confirm these results.

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