

## OPEN REDUCTION AND INTERNAL FIXATION COMPARED WITH ORIF AND PRIMARY SUBTALAR ARTHRODESIS FOR TREATMENT OF SANDERS TYPE IV CALCANEAL FRACTURES: A RANDOMIZED COMPARATIVE PROSPECTIVE STUDY

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### Abstract

**Background:** The present study was conducted to open reduction and internal fixation compared with ORIF and primary subtalar arthrodesis for treatment of sanders type IV calcaneal fractures

**Methods:** Randomized comparative prospective trial conducted on Calcaneum fracture cases attending with orthopaedics department of S.M.S. Medical College and Hospital, Jaipur (Rajasthan, India)

**Results:** SF 36, MFA, AHS and VAS score showed almost same results in both groups at 3 months which showed statistically non significant results.

**Conclusion:** A randomized trial was unable to demonstrate any significant difference between ORIF compared with ORIF + PSTA for the treatment of isolated Sanders type IV fractures with respect to long-term outcome. ORIF + PSTA however, should be considered for patients with Sanders type IV fractures, and the health care system as they heal at a much more rapid rate, and will not require additional surgery. This must be considered as the choice of treatment may have profound economic effects on the patient. More research is needed to find the best solutions for these difficult fractures.

**Keywords:** ORIF, PSTA, Fracture.

### Introduction:

The calcaneus is the most commonly fractured tarsal bone and accounts for approximately 2% of all fractures.<sup>1</sup> The mechanism of injury and pathoanatomy has been studied in great detail. Most fractures of the calcaneus are intra-articular with involvement of the subtalar joint (and calcaneocuboid joint) in up to 75% of cases. Change in life style because of residual pain and stiffness can cause significant socioeconomic hardship for these otherwise fit individuals and may have associated public cost.<sup>2</sup>

Currently, open reduction and internal fixation (ORIF) is considered the reference standard treatment of displaced intraarticular fractures of the calcaneus, because anatomic reduction is important for feet and ankles to have functional outcomes. Also, ORIF is the best method for achieving calcaneal morphology restoration and anatomic reduction of the articular surface. However, the need for bone grafting in the treatment of displaced intraarticular calcaneal fracture is still controversial. Orthopedic surgeons who insist on bone grafting believe it will stimulate fracture healing, leading to early full weight bearing, preventing post-traumatic arthritis, and increasing mechanical strength, and, thus, helping to prevent significant late collapse. Those who do not prefer bone grafting have suggested that internal fixation can adequately support the articular surface and that auto grafting could increase the infection rate, blood

loss, postoperative pain, donor site morbidity, and complications.<sup>3,4</sup>

The present study was conducted to open reduction and internal fixation compared with ORIF and primary subtalar arthrodesis for treatment of sanders type IV calcaneal fractures.

### Material and Methods

#### Study area

Patients in the department of orthopaedics in teaching hospital attached to S.M.S. Medical College and Hospital, Jaipur.

#### Study design

Randomized comparative prospective trial.

#### Study duration

Data collection was started first after the approval from institutional research review board and ethical committee upto June 2021 or till sample size was achieved, whichever was earlier. It was take another month for follow up and one month for data processing and writing thesis.

**Sample size**

Sample size calculated 42 subjects for each of two group at alpha error 0.05 and power 80% expecting minimum difference of means to be deducted in SF 36 score of ORIF & primary subtalar arthrodesis in these cases  $7 \pm 11.4$  (as per seed article). So for the study purpose 50 cases was taken for ORIF and 50 cases for ORIF + PSTA.

**Study universe**

Calcaneum fracture cases attending with orthopaedics department of S.M.S. Medical College and Hospital, Jaipur (Rajasthan, India)

**Inclusion criteria**

- Patients presenting or referred to the contributing institutions with a Sanders IV DIACF.
- Age 16–59 inclusive
- Clear demonstration of at least 3 fracture lines across the posterior subtalar facet, dividing it into at least 4 fragments and the fragments being displaced by at least 2 mm, as seen on the coronal and axial CT scans (classified as Sanders IV)
- Ability to provide informed consent
- Available for follow-up for at least 2 years after injury

**Exclusion criteria**

- Medical contraindications to surgery
- Previous calcaneal pathology (infection, tumor etc)
- Previous calcaneal surgery
- Co-existent foot or ipsilateral lower limb injury
- Open calcaneal fractures

- Injury more than 3 weeks old
- Head injured patients
- Inability to obtain preoperative CT scans or accurately classify the fractures as per Sanders classification system
- Inability to comply with advice to diminish smoking after the injury Patients with metal allergy
- Extremely comminuted intraarticular fractures of calcaneus, deemed impossible to reconstruct by the treating surgeon. (nonoperable or mangled foot)
- Any concerns either on the part of the treating surgeon or the patient about harvesting autograft needed for fusion

**Plan for data collection and study**

After obtaining clearance and approval from the institutional ethical committee and patients fulfilling the inclusion/ exclusion criteria was included in the study after obtaining informed consent.

Detailed history was obtained using the study proforma with special attention to mechanism of injury.

**Data Management and Analysis**

IBM SPSS Statistics 19.0 for Windows (SPSS, Chicago, IL) was used for data management and statistical analysis. Categorical variables are summarized as frequencies and percentages. Normally distributed data are presented as the mean and SD, and differences between groups on continuous variables were computed using an independent measures t test. All statistical tests were 2-sided with a 0.05 significance level.

**Results****Table 1: General characteristics**

Age (mean±SD)	33.8±10.27 Yrs
Male : Female	78 : 22
RTA : FFH	60:40

Age 20-30 years and 30-40 age years patients were 50% and 30%. Mean age 33.8 years. Male was 78% and female was 22%. RTA injuries was 60% and FFH was 40%.

**Table 2: comparison of study variable at 2 weeks among groups**

		Mean	Std. Deviation	P value
SF 36	ORIF	37.10	1.502	0.21
	PSTA	37.52	1.843	
MFA	ORIF	40.92	.829	0.82
	PSTA	40.88	.918	
AHS	ORIF	68.04	.755	0.38
	PSTA	67.66	.848	
VAS	ORIF	38.62	1.159	0.54
	PSTA	38.08	1.047	

SF 36, MFA, AHS and VAS score showed almost same results in both groups at 2 weeks which showed statistically non significant results.

**Table 3: comparison of study variable at 6 weeks among groups**

		Mean	Std. Deviation	P value
SF 36	ORIF	35.04	1.384	0.27
	PSTA	35.38	1.677	
MFA	ORIF	38.64	1.120	0.25
	PSTA	37.86	1.400	
AHS	ORIF	65.46	.973	0.14
	PSTA	65.14	1.178	
VAS	ORIF	35.58	1.180	0.2
	PSTA	35.30	1.015	

SF 36, MFA, AHS and VAS score showed almost same results in both groups at 6 weeks which showed statistically non significant results.

**Table 4: comparison of study variable at 3 months among groups**

		Mean	Std. Deviation	P value
SF 36	ORIF	32.60	1.325	0.26
	PSTA	32.92	1.523	
MFA	ORIF	36.30	1.282	0.27
	PSTA	35.34	1.154	
AHS	ORIF	61.48	1.313	0.98
	PSTA	61.48	.995	
VAS	ORIF	30.56	1.215	0.53
	PSTA	31.12	.918	

SF 36, MFA, AHS and VAS score showed almost same results in both groups at 3 months which showed statistically non significant results.

## Discussion

Conservative treatment was preferred over surgical treatment until modern imaging methods, osteosynthesis materials, improvements of less invasive surgical techniques and the presence of effective and adequate antibiotic treatments have been developed. However current treatment protocol of calcaneal fractures has shifted in favour of ORIF. Open reduction and internal fixation is preferable to conservative treatment for displaced calcaneal fractures in a selected group of healthy patients.

Primary subtalar arthrodesis is one of the surgical techniques that can be applied for comminuted calcaneal fractures. This technique may be preferred especially for four or more-part fractures of the posterior facet of the subtalar joint. Despite ORIF is the best method for achieving anatomic reduction and calcaneal restoration soft tissue problems should be taken into account.

In our small underpowered randomized trial, we found that there was no statistical difference in general health outcome surveys when treating Sanders type IV calcaneal fractures with ORIF compared with ORIF + PSTA. This trial is the

first randomized clinical trial comparing 2 standard surgical treatment options for the Sanders IV calcaneal fracture.

Both treatment groups scored poorly on general health outcome surveys (SF-36). This reflects the severity of this type of fracture and the detrimental impact it has on a patient's life. But on regular follow up it was improved general health. This fracture affects all domains of life (physical, emotional, psychologic and financial) and perhaps regardless of which currently available treatment is provided, patients will still be physically challenged. Sanders IV fractures generally produce guarded outcomes. Our previous trial noted that there was only a small difference in results with respect to ORIF compared with nonoperative treatment when looking at the Sanders type IV fractures in particular.<sup>5</sup> Sanders R et al discussed treating Sanders IV fractures with ORIF + PSTA but no literature has ever compared ORIF versus ORIF + PSTA.<sup>6</sup> On the SF-36, ORIF + PSTA scored higher than ORIF alone with a non-significant p value at every time intervals in our study. Our study may be interpreted as a pilot study comparing the 2 treatment modalities and we recommend further investigations of the treatment of Sanders IV type fractures treated with ORIF + PSTA.

It is interesting to note, our mean SF-36 physical component scores for primary fusion is slightly higher than scores found by Schepers T (2010)<sup>7</sup> et al for late or secondary fusions (65% initially treated nonoperatively and 35% initially treated operatively). Our ORIF + PSTA SF-36 physical component mean score was 37 to 35 at various time intervals, whereas Schepers secondary subtalar fusion mean score was 33; maximum score is 100. Although this comparison may not be valid, it suggests patients may function better physically with a primary fusion than a late subtalar fusion.

In the study, we have found non significant association of Musculoskeletal Functional Assessment (MFA), American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale (AHS) and VAS score between ORIF + PSTA and ORIF alone. We did not any found single published article to justify the our results. This is first kind of study to initiate future treatment on behalf of this comparison.<sup>8</sup>

In a meta-analysis, Fan et al. compared the clinical results after minimally invasive techniques to those after ORIF. The study reported a lower soft tissue complication rate, and reduced duration of the operative procedure itself. Also, functional results were almost equivalent for the two groups.<sup>9</sup>

Wallin KJ (2014)<sup>10</sup> et al. published a systematic review on the clinical results after minimally invasive techniques used to treat calcaneal fractures. The functional results after Sanders type II-IV compared with ORIF were promising, although most of the studies had low levels of evidence. Soft tissue complications and duration of the procedure were lower in the minimally invasive group. They did not discuss whether minimally invasive techniques or ORIF led to better anatomic reductions and functional results.

Comparisons between the different methods of minimally invasive techniques and ORIF methods are difficult due to a lack of standardized measures, different techniques, and a low number of patients.<sup>11</sup>

The subtalar arthrodesis rate of 0% described by Park et al. was based on a relatively low number of patients and only 1 year follow-up. In extremely complex intra-articular fractures, a primary subtalar arthrodesis is deemed the method of choice to achieve satisfactory results in the given situation.<sup>12,13</sup>

After conservatively treated calcaneal fractures, a 6-fold higher likelihood of arthrodesis has been published compared to primarily surgically treated patients. Furthermore, patients with Sanders Type IV, and patients with a Bohler angle of 0 degrees had a notably increased risk of secondary subtalar arthrodesis.<sup>14</sup> In general, operative reconstruction of calcaneal fractures provides a better tissue situation in cases which require a secondary subtalar arthrodesis thereby also leading to better long-term results.<sup>15</sup>

It has been argued that in Sanders type IV fractures, articular comminution and cartilage injury are severe enough to preclude satisfactory joint reduction and thus primary ORIF and subtalar arthrodesis is an option. Buckley R (2014)<sup>16</sup> et al in a small randomized controlled trial were unable to demonstrate a significant difference in outcomes between ORIF alone and ORIF with subtalar fusion for Sanders type IV fractures. However, the authors stated that a primary fusion may decrease time away from work and may be economically beneficial.

Dhillon MS (2014)<sup>17</sup> et al responded to Buckley et al.'s results stating that advocating primary fusion in Sanders IV type fractures was incorrect since only 25% of patients would eventually need fusion. Furthermore, patients with subtalar fracture dislocations, bilateral Sanders IV were not assessed for primary fusion.

Currently, there is no clear evidence to refute or favour primary subtalar arthrodesis.

### Conclusion

A randomized trial was unable to demonstrate any significant difference between ORIF compared with ORIF + PSTA for the treatment of isolated Sanders type IV fractures with respect to long-term outcome. ORIF + PSTA however, should be considered for patients with Sanders type IV fractures, and the health care system as they heal at a much more rapid rate, and will not require additional surgery. This must be considered as the choice of treatment may have profound economic effects on the patient. More research is needed to find the best solutions for these difficult fractures.

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