Supplementary article data

Open reduction and internal fixation aided by intraoperative 3-dimensional imaging improved the articular reduction in 72 displaced acetabular fractures

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1 Aim and Background

The risk of coxarthrosis increases with the size of steps and incongruences in acetabular roof that go along with acetabular fractures. Therefore, it is of high priority during a surgery to reduce these steps as much as possible. The standard imaging procedures for acetabular fracture surgery is two-dimensional fluoroscopic views. However, several studies found that 2D fluoroscopy performes poorly in detecting clinically significant steps. Therefore, in October 2010 the University Hospital Copenhagen purchased the so called "O-arm" that is used for intraoperative 3D imaging to improve fracture reduction and plate fixation.
If available, the O-arm was used for acetabular fracture surgery, elsewise standard 2D fluoroscopy was applied.

The purpose of this retrospective study was to test whether 3D imaging is superior to standard 2D fluoroscopic views regarding articular reduction in dislocated acetabular fracture surgery.

All data were collected at the University Hospital Copenhagen.

2 Methods

2.1 Analysis Set

The **full analyses set (FAS)** consists of all patients included in the study (intervention(3D) and control(2D) group) and was used for all analyses.

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2.2 Demographic and Baseline Characteristics

Demographic and baseline characteristics are summarized for intervention and control group. Categorical variables are presented as frequencies and percentages (Table 1), continuous variables as mean, standard deviation, median, 1st and 3rd quartiles, minimum and maximum (Table 2). Intervention and control group were tested for differences in these demographic and baseline characteristics using the Mann-Whitney test for continuous variables and Fisher's exact test for categorical variables. P-values were not adjusted for multiple comparisons. Pre-operative displacement was significantly larger in the intervention group as compared to the control group (Table 2).

Table 1: Categorical demographic and baseline characteristics grouped by intervention and control group

Variable	Levels	n_{2D}	$\%_{2D}$	n_{3D}	$\%_{3D}$	n_{all}	$\%_{all}$
gender	female	14	33.3	23	31.9	37	32.5
	male	28	66.7	49	68.1	77	67.5
p = 1.00	all	42	100.0	72	100.0	114	100.0
type	ant column+post hemi	2	4.8	10	13.9	12	10.5
	Ant. column	11	26.2	15	20.8	26	22.8
	Ant. wall	1	2.4	1	1.4	2	1.8
	both column	4	9.5	10	13.9	14	12.3
	Non-classifiable	1	2.4	1	1.4	2	1.8
	Post. column	2	4.8	2	2.8	4	3.5
	Post. wall	6	14.3	8	11.1	14	12.3
	t type	9	21.4	12	16.7	21	18.4
	Transverse	2	4.8	11	15.3	13	11.4
	post column post wall	2	4.8	0	0.0	2	1.8
	transverse+post wall	2	4.8	2	2.8	4	3.5
p = 0.37	all	42	100.0	72	100.0	114	100.0
number.of.scans	1	0		36	50.0	36	50.0
	2	0		30	41.7	30	41.7
	3	0		6	8.3	6	8.3
	all	0		72	100.0	72	100.0
reason.for.scan	0	0		5	13.2	5	13.2
	reduc	0		14	36.8	14	36.8
	screw	0		17	44.7	17	44.7
	strategy	0		2	5.3	2	5.3
	all	0		38	100.0	38	100.0

Table 2: Continuous demographic and baseline characteristics grouped by intervention and control group: *n*: number of patients, *Min.*: minimum, *q1*: 1st Quantile, $\tilde{x}$: median, $\bar{x}$: mean, *q3*: 3rd Quantile, *Max.*: maximum, *s*: standard deviation, #NA: number of missing values

Variable	Levels	n	Min	q_1	$\tilde{x}$	$\bar{x}$	q_3	Max	s	#NA
age	2D	42	18	44.5	62.0	58.2	73.5	95.0	19.5	0
	3D	72	20	44.8	62.5	58.0	72.2	93.0	20.1	0
p = 0.96	all	114	18	44.2	62.0	58.1	72.8	95.0	19.8	0
pre.op.displacement	2D	20	0	0.0	5.3	4.8	8.0	12.9	4.2	22
	3D	71	0	6.0	8.0	9.0	11.6	30.4	5.5	1
p = 0.0025	all	91	0	5.0	7.5	8.1	10.1	30.4	5.5	23

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2.3 Propensity Score

In order to balance potential bias due to the non-randomised study design we calculated propensity scores, estimating the average treatment effect (ATE – addresses the question of how outcomes would differ if everyone in the sample were given the treatment versus everyone being given the control (Wooldridge, 2010)). The propensity score model included *age*, *pre-operative displacement* and *fracture type* as known potential confounders.

A histogram of the propensity scores by group is shown in the Appendix (Fig. 1). Typically, the intervention group (3D) has higher propensity scores than the control group (2D).

2.4 Primary Objective

The primary objective was to test for the superiority of the 3D imaging (O-Arm) in articular reduction as compared to standard 2D fluoroscopic views.

2.4.1 Primary Endpoint: resampling

The primary outcome was *postoperative articular incongruity* (articular reduction), which was available as ordered categorical variable:

- anatomic/perfect: <1mm
- imperfect: 1-3mm
- unsatisfactory/poor: >3mm

The analysis of this ordered categorical endpoint would have required ordered logistic regression – a less commonly used method, which often proves difficult for interpretation by non-experts. Instead, we converted the categorical postoperative articular incongruity to a metric scale, using a resampling approach. Each category of postoperative articular incongruity corresponds to a certain range of incongruity measured in millimeters as follows: anatomic/perfect: 0 – 0.99mm; imperfect: 1.00 – 3.00mm; unsatisfactory/poor: 3.01 – 5.00 mm. For each patient, we randomly drew a value for postoperative articular incongruity in millimeters from the range of the corresponding category of postoperative articular incongruity, assuming a uniform distribution. For example, for a patient with imperfect articular reduction, a value between 1 and 3 mm was drawn. This *simulated postoperative articular incongruity (spai)* was used as primary endpoint.

In order to get robust results for this simulated endpoint, this resampling procedure was repeated 999 times, resulting in 999 simulated data sets.

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2.4.2 Analysis method

For each simulated data set, we performed a one-way ANOVA, applying propensity score *inverse probability weighting (IPW)* of receiving treatment (Heinze & Jüni, 2011), to estimate the difference in the primary endpoint between intervention and control group (a negative difference indicates that *spai* is smaller in the intervention group). The overall mean with 95% confidence interval of the 999 estimated differences in primary endpoint were calculated. Superiority of the 3D imaging method was declared if the upper limit of the 95% confidence interval did not exceed zero, thus rejecting the nullhypothesis of no difference.

2.5 Secondary objective

The secondary objective was to test for a difference between control and intervention group in

1. duraton of surgery
2. ocurence of infection

2.5.1 Secondary endpoint

Secondary endpoints were the duration of surgery in minutes (continuous variable), and occurence of infection (binary variable 0/1).

2.5.2 Analysis method

Duration of surgery was log-transformed and analysed using a one-way ANOVA, applying propensity score inverse-probability weighting.

Occurence of infection was analysed using propensity score inverse-probability weighted logistic regression.

3 Results

3.1 Primary Objective

We observed a mean simulated postoperative articular incongruity of 1.28 mm for the intervention group and 1.83 mm for the control group. The corresponding mean difference in simulated postoperative articular incongruity was -0.54 mm [95% CI: -0.72 mm; -0.37 mm].

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Since the upper limit of the 95% confidence interval of the mean difference did not exceed zero, we conclude that 3D imaging is superior to standard 2D fluoroscopic views regarding postoperative articular incongruity.

3.2 Secondary Objectives

3.2.1 Duration of surgery

We found no significant difference in duration of surgery (Table 3). The duration of surgery in the intervention group is $e^{\beta_{3D}} = 1.04 \times$ the duration in the control group ($(e^{\beta_{3D}} - 1) \times 100 = 4.2\,\%$ longer). The corresponding weighted means are 165.7 for the intervention group and 162.3 for the control group.

Table 3: **Secondary endpoint duration of surgery.** Log-transformed estimate of the difference in surgery duration (log(min)) for intervention vs. control (3D vs. 2D) group, n = 113.

	Estimate	95% CI	t	p
group.name3D	0.041	[-0.113,0.195]	0.53	0.599

3.2.2 Infections

In total there were four infections each in the intervention and the control group (5.6% and 9.5% respectively). We found no significant difference in the occurence of infections between intervention and the control group (odds ratio with 95% confidence interval: 0.73 [0.15; 3.59], p-value = 0.704).

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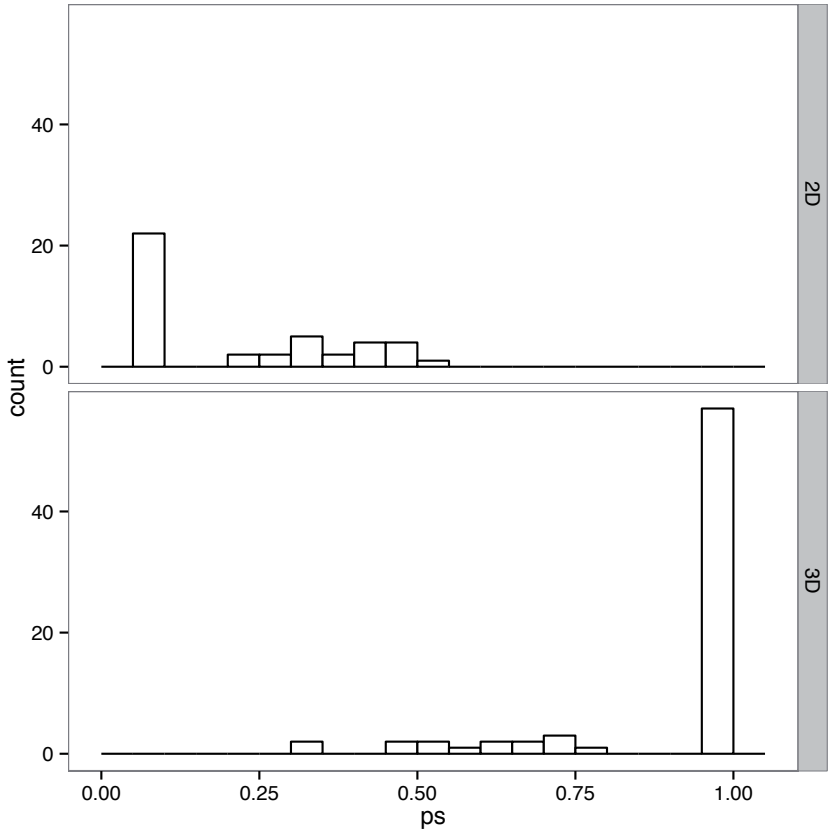
4 Appendix

Figure 1: Distribution of the propensity score of the treated (intervention, 3D) and the untreated (control, 2D) group.



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