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ORIGINAL ARTICLE

Heterotopic ossification following severe radial head fractures: Clinical outcome and associated factors

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ABSTRACT

Objectives: This study aimed to evaluate clinical outcome, prevalence, severity, location, range of motion, and possible risk factors of heterotopic ossification (HO) following severe radial head fractures.

Patients and methods: In this retrospective study, 73 patients (40 males, 33 females; mean age: 51.4±15 years; range, 20 to 82 years) with Mason-Johnston type 3 and 4 radial head fractures were surgically treated with osteosynthesis or radial head arthroplasty (RHA) between September 2014 and February 2021. Fifty-one were examined in person, while 22 participated via questionnaire. The clinical outcome was assessed by the range of motion, the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH), and the 36-item Short-Form Health Survey (SF-36). Operative and postoperative details and the intake of HO prophylaxis were reviewed. Heterotopic ossification severity and location was evaluated on radiographs.

Results: Heterotopic ossification was present in 52.1%, while in 31.5% of all participants, RHA was needed. Overall, 46.6% received additional ligamental refixation. The mean time to surgery was 8.9±11.9 days, and the mean DASH was 13.7±16.6. In patients treated with osteosynthesis, more HO was observed for Mason-Johnston type 4 injuries compared to Mason-Johnston type 3 injuries (p=0.028). Overall, more HO was present in Mason-Johnston type 4 injuries (63.6%) compared to Mason-Johnston type 3 injuries (42.5%), without reaching significance (p=0.072). No significant association between HO and time to surgery (p=0.716), implantation of RHA (p=0.127), or ligamental refixation (p=0.121) was detected. Regardless of intake of HO prophylaxis, nearly the same amount of HO (51.7% *vs*. 53.8%) was present. No differences between the HO and non-HO group were detected in the DASH (p=0.553) and the SF-36 (physical component, p=0.728; mental component, p=0.275).

Conclusion: Over 50% surgically treated radial head fractures classified as Mason-Johnston types 3 and 4 developed HO, while more severe injuries led to a higher prevalence of HO. No increased rates of HO were determined for delayed surgery, surgical treatment methods, and use of HO prophylaxis. Therefore, regular HO prophylaxis might not be needed. Additionally, no significant differences in functional scores and quality of life were detected between patients with and without HO.

Keywords: Clinical outcome, elbow, heterotopic ossification, Mason-Johnston injury types 3 and 4, radial head fractures, range of motion.

Radial head fractures represent one third of fractures around the elbow with increasing incidence.[1] Following surgical repair, the development of heterotopic ossification (HO) can be a significant complication, with rates up to over 50%.[2] Heterotopic ossification refers to the formation of mature lamellar bone and the underlying mechanisms are not completely understood.[3] Heterotopic ossification inducing events are trauma, severe soft tissue damage, traumatic brain and spinal cord injuries, or extensive burns.[4] Patients who develop HO may experience pain and limited range of motion (ROM), substantially impacting their overall quality of life.[5] Most studies on HO after elbow trauma refer to a heterogeneous sample of fractures around the

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elbow.[6-10] Limited data are available on high-grade radial head fractures classified as Mason-Johnston types 2 and 4.[11] For isolated radial head fractures, an incidence of HO up to 50% is described by Hong et al.,[12] while 31% had clinically impaired ROM. In terrible triad injuries, 58% developed HO. In Monteggia-like lesions, similar incidences were observed.[13] When comparing radial head fractures and the combination of radial head fracture with dislocation of the elbow (Mason-Johnston type 4), significantly more HO was detected in patients with Mason-Johston type 4 injuries.[14] For radial head arthroplasty (RHA) different studies showed an incidence of HO around 50%.[15,16] Additionally, higher rates were described for bipolar RHA.[17] Risk factors for HO are considered to be higher injury complexity,[10] surgical approach,[18] time to surgery,[12] time to mobilization after surgery,[6] and multiple attempted closed reductions in dislocated situations.[9] Despite this knowledge, limited prophylactic approaches are available. Different drugs and localized radiotherapy have been described. However, these therapies can cause complications such as bony nonunions and radiation-induced sarcoma.[4] Few data is available on HO following elbow trauma,[12] so many different prophylaxis strategies are present.[19] Therefore, this study aimed to evaluate *(i)* the postoperative clinical outcome following high-grade radial head fractures classified as Mason-Johnston types 3 and 4 and *(ii)* the prevalence, severity, and location of HO and possible risk factors, as well as the influence of HO prophylaxis.

PATIENTS AND METHODS

In this retrospective study, adult patients with radial head and elbow injuries classified as Mason-Johnston types 3 and 4,[11] who underwent operative treatment at the BG Unfallklinik Tübingen, Department of Traumatology and Reconstructive Surgery, a level-one trauma center, between September 2014 and February 2021 were included. Mason-Johnston type 4 fractures were classified more specifically into terrible triad and Monteggia-like lesions. One hundred sixty-five possible participants were selected. Due to a change in address or phone number, 73 could not be contacted. Out of the remaining 92 participants, nine declined participation due to personal reasons. Seven participants had to be excluded due to multiple revision operations on other extremities. One participant was not eligible due to polytraumatized injury. Two participants had to be excluded due to a lack of radiological follow-up. Consequently, 73 participants (40 males, 33 females; mean age: 51.4±15 years; range, 20 to 82 years) were included in the analyses. The participants were invited to undergo a physical examination. Fifty-one participants (mean age: 50.3±13.3 years) attended in person. Twenty-two (mean age: 54.0±16.8 years) participated via questionnaire due to personal reasons (e.g., living far away and the COVID-19 pandemic; Figure 1). The study protocol was approved by the Eberhard Karls University Tübingen Ethics Committee (date: 28.07.2021; project number: 974/2020BO2). Each participant gave written informed consent. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Surgical procedure

If possible, the patients were treated by open reduction and internal fixation (ORIF) with mini screws or plates. In extensively comminuted and displaced fractures, on table reconstruction *ex situ* was performed. If the reconstruction was not possible due to the fracture pattern, an anatomic RHA was implanted. Intraoperatively, elbow stability was tested. In case of instability, ligaments were reattached by anchors. Each surgical site was rinsed extensively with sterile fluid. Each patient was operated by a senior trauma surgeon of the level-one trauma center.

Postoperative HO prophylaxis was applied on surgeons' preference. Patients with contraindications such as renal insufficiency, allergies, intolerances, or interactions with other medication did not receive HO prophylaxis. Additionally, our analgesic medication scheme did not include nonsteroidal anti-inflammatory drugs (NSAIDs) primarily. Patients with compensated pain did not receive NSAIDs in a standardized manner. Postoperatively, patients without luxation wore a brace with 90° flexion in neutral rotation for one week. Passive mobilization was started on the first postoperative day. After two weeks, free ROM without additional weight bearing was allowed. In patients with luxation, a flexible brace was applied for six weeks with free ROM after two weeks. Individual postoperative restrictions were applied on surgeons' preference in complex cases.

Assessment of the heterotopic ossification

All present radiographic imaging was investigated for the presence or absence as well as location and severity of HO by one trained observer. Good intra- and interobserver reliability was determined by assessing 15 patients twice with an interval of two weeks by one observer.

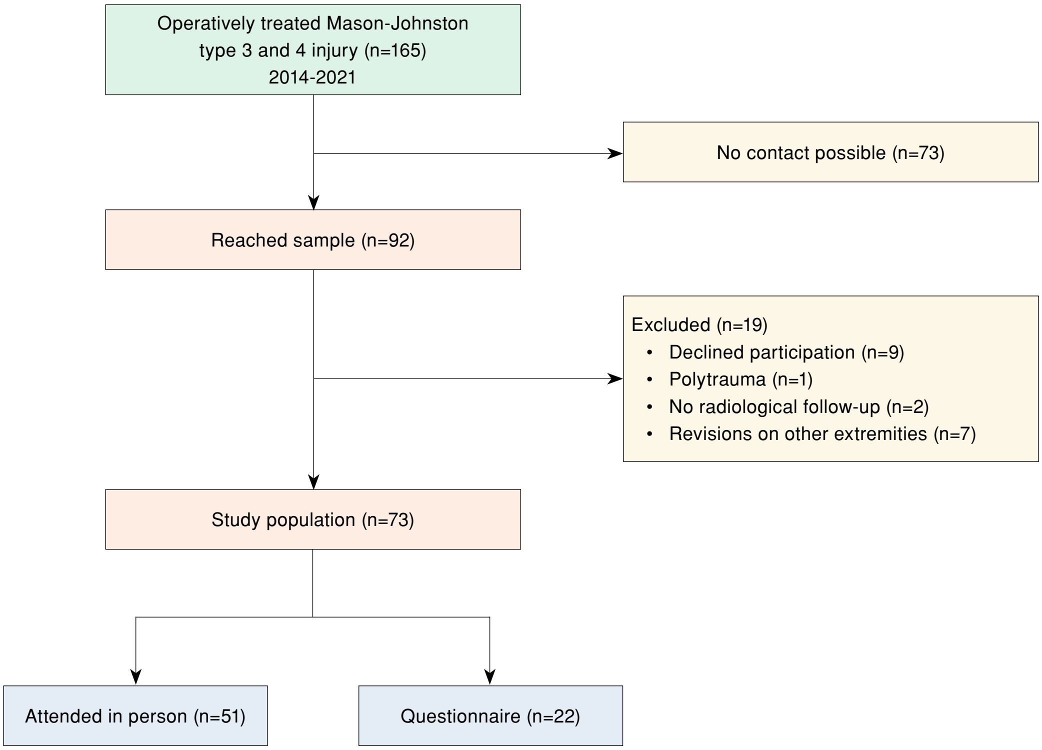

FIGURE 1. Flow chart of the cohort from inclusion to the final study population.

These cases were measured again by a second observer (Cohen's kappa=1.0). According to Leyder et al.,[20] the severity of HO was determined by the biggest HO. It was classified into four groups. Additionally, the localization of the biggest HO was assessed (radial, ulnar, posterior, and anterior). Grade 1 was considered if the biggest HO was smaller than the radial head diameter (Figure 2a). Grade 2 described a HO bigger than the radial head diameter (Figure 2b). In Grade 3, the HO formed a brace, while in Grade 4 a radioulnar synostosis was present. Combined with the ROM and the radiological picture of the HO, the Hastings and Graham[21] classification was determined.

Patient-related parameters

For each participant, age, sex, trauma pattern, fracture dislocation, time to surgery, intake of medication for HO prophylaxis, and intraoperative findings were recorded. Every patient performed the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, as well as the 36-item Short-Form Health Survey (SF-36). Additionally, the questionnaire for self-determination of ROM for the elbow of Schnetzke et al.[22] was performed. For personally attending participants, a clinical examination was conducted.

Statistical analysis

Data were analyzed using IBM SPSS version 28.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics such as mean values, standard deviations (SD), ranges, medians, and percentiles were used to describe the sample. The Mann-Whitney U test was used for numerical continuous variables. Categorical data was examined with Pearson's chi-square test. If the expected frequency was <5, the data was analyzed with the Fisher-Freeman-Halton exact test. Correlations were calculated by Spearman's correlation coefficient, and odds ratios (ORs) with 95% confidence intervals (CIs) were determined. A p-value <0.05 was considered statistically significant.

RESULTS

The mean clinical follow-up was 39.5±23.3 (range, 7 to 80) months. The mean radiological follow-up was 24.8±26.1 (range, 4 to 80) months. Forty patients had Mason-Johnston type 3 fractures, and 80% of these patients could be treated by ORIF, while 30% required additional ligamental repair. In comparison, 45% of the Mason-Johnston type 4 injuries had to be treated by RHA, while 67% needed

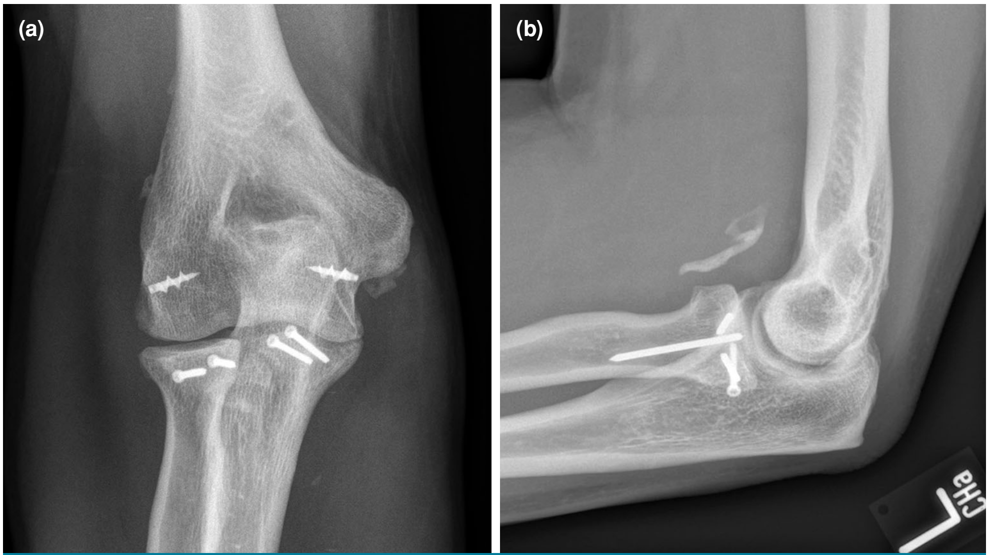

FIGURE 2. Heterotopic ossification classification according to Leyder et al.[20] **(a)** ulnar HO smaller than the radial head diameter = HO Grade 1u **(b)** anterior HO bigger than the radial head diameter = HO Grade 2a.
HO: Heterotopic ossification.

ligamental repair. Further information on fracture type and therapy is provided in Table I.

Heterotopic ossifications were present in 52.1% of participants. According to the HO classification of Leyder et al.,[20] the severity of HO ranges between 1 and 2, while the biggest ossifications were either anterior (55.3%) or radial (44.7%). Regarding the classification of Hastings and Graham,[21] the maximal grade was Grade 2C (Table II).

A higher, presence of HO was observed in Mason-Johnston type 4 injuries compared to Mason-Johnston type 3 injuries in the ORIF group (OR=3.82, 95% CI: 1.13-12.96, p=0.028). In the smaller RHA group, this difference was not significant (OR=0.50, 95% CI: 0.07-3.36, p=0.657). A higher but statistically nonsignificant presence of HO was present in Mason-Johnston type 4 injuries compared to Mason-Johnston type 3 injuries (63.6% *vs.* 42.5%; OR=2.37, 95% CI: 0.92-6.10, p=0.072), as well as in injuries with additional ulna fracture (OR=2.18, 95% CI: 0.84-5.67, p=0.107). The mean time to surgery was 8.9±11.9 days with no significant association to HO (p=0.716). Moreover, participants with RHA implantation (OR=2.20, 95% CI: 0.79-6.12, p=0.127) or ligamental refixation (OR=2.09, 95% CI: 0.82-5.34, p=0.121) did not have a higher rate of HO compared to patients with ORIF or patients without ligamental refixation.

TABLE I
Demographic data, fracture type, and therapy

	Mason-Johnston III			Mason-Johnston IV			Terrible triad	Monteggia-like	"Simple" Mason-Johnston IV
	n	Mean±SD	Range	n	Mean±SD	Range	n	n	n
Age (years)		51.0±15.7	20-82		51.9±14.4	25-76			
Sex	15			18					
Female									
Total	40			33			18	7	8
Therapies									
ORIF	32			18			9	4	5
Radial head arthroplasty	8			15			9	3	3
Ligamental repair	12			22			15	3	4

SD: Standard deviation; ORIF: Open reduction and internal fixation; Mason-Johnston IV divided in subgroups terrible triad, Monteggia-like lesion and "simple" Mason-Johnston IV.

TABLE II
Distribution of the HO according to severity and localization

	Total		MJ III		MJ IV		ORIF		RHA		Lig. repair	
	n	%	n	%	n	%	n	%	n	%	n	%
Leyder et al.[20]												
No HO	35	47.9	23	57.5	12	36.4	27	54.0	8	34.8	13	38.2
Severity 1	31	42.5	15	37.5	16	48.5	19	38.0	12	52.1	16	47.1
Anterior	16	51.6	4	10.0	12	36.4	7	14.0	9	39.1	9	26.5
Radial	15	48.4	11	27.5	4	12.1	12	24.0	3	13.0	7	20.6
Severity 2	7	9.6	2	5.0	5	15.2	4	8.0	3	13.0	5	14.7
Anterior	5	71.4	2	5.0	3	9.1	3	6.0	2	8.7	4	11.8
Radial	2	28.6	0	0	2	6.1	1	2.0	1	4.3	1	2.9
Severity 3	0	0	0	0	0	0	0	0	0	0	0	0
Severity 4	0	0	0	0	0	0	0	0	0	0	0	0
Hastings and Graham[21]												
No HO	35	47.9	23	57.5	12	36.4	27	54.0	8	34.8	13	38.2
1	8	11.0	5	12.5	3	9.1	6	12.0	2	8.7	4	11.8
2A	12	16.4	5	12.5	7	21.2	6	12.0	6	26.1	5	14.7
2B	7	9.6	3	7.5	4	12.1	3	6.0	4	17.4	6	17.6
2C	11	15.1	4	10.0	7	21.2	8	16.0	3	13.0	6	17.6
3A-C	0	0	0	0	0	0	0	0	0	0	0	0

HO: Heterotopic ossification; ORIF: Open reduction and internal fixation; RHA: Radial head arthroplasty; Lig. repair: Ligamental repair; MJ: Mason-Johnston.

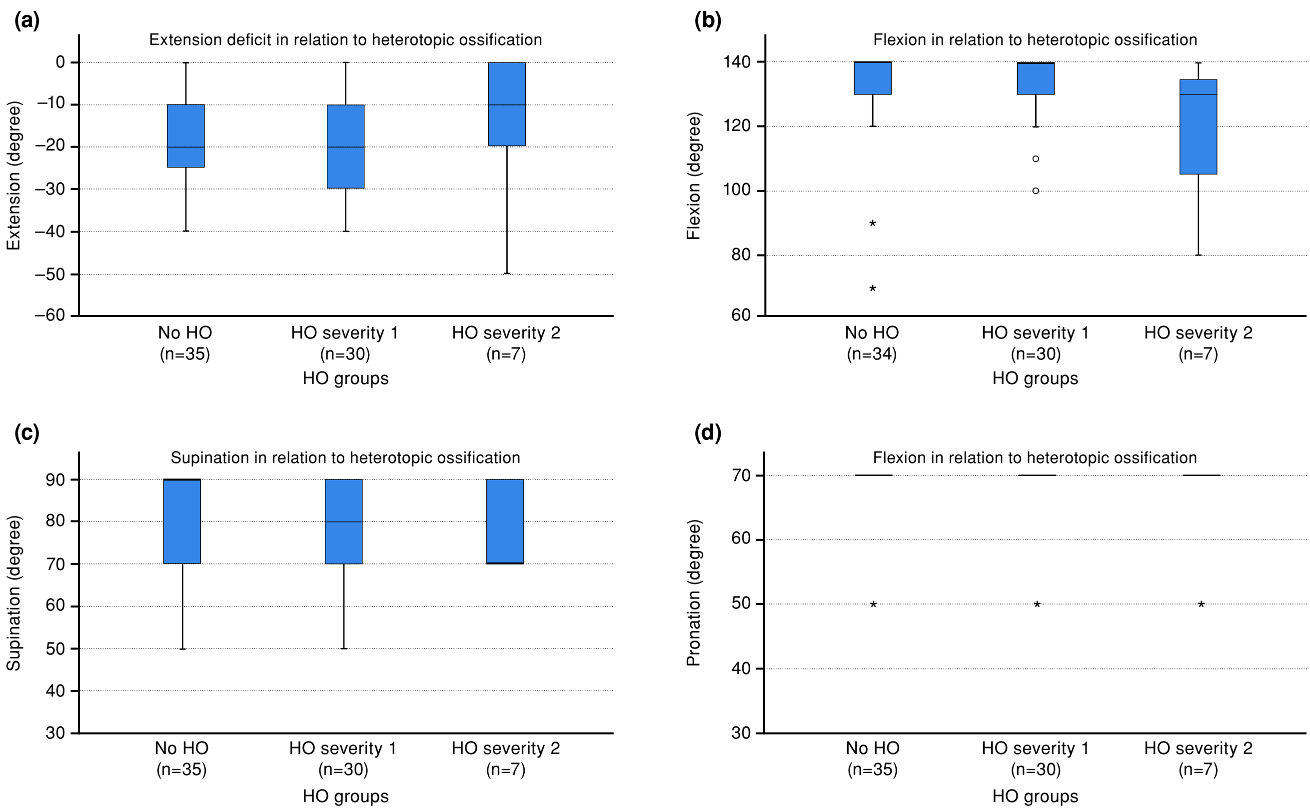

FIGURE 3. (a-d) Box plots of the ROM divided into HO groups according to the classification of Leyder et al.[20]: absent HO, HO severity of 1, and HO severity of 2.
ROM: Range of motion; HO: Heterotopic ossification.

TABLE III
Range of motion in relation to the location of the heterotopic ossification

	n	Mean±SD	Min-Max	25th percentile	Median	75th percentile	*p*
Flexion							
Severity 1A	12	129.17±11.84	100-145	125.0	130	137.5	0.007
Severity 1R	11	138.18±8.15	120-145	140.0	140	145.0	
Severity 2A	5	121.00±21.33	85-140	120.0	30	130.0	
Severity 2R	1	145.00±0.00	145-145	145.0	145	145.0	
Extension deficit							
Severity 1A	12	–18.33±14.35	–40-0	–30.0	–20	–2.5	0.084
Severity 1R	11	–9.09±13.57	–40-0	–10.0	–5	0.0	
Severity 2A	5	–12.00±10.95	–3-0	–10.0	–10	–10.0	
Severity 2R	1	0.00±0.00	0-0	.0	0	0.0	
Supination*							
Severity 1A	12	69.17±24.57	30-90	45.0	85	90.0	
Severity 1R	11	71.82±24.01	30-90	50.0	80	90.0	
Severity 2A	5	61.00±36.47	10-90	35.0	80	90.0	
Severity 2R	1	80.0±0.00	80-80	80.0	80	80.0	
Pronation*							
Severity 1A	12	77.08±24.35	20-90	70.0	90	90.0	
Severity 1R	11	79.09±22.45	25-90	80.0	90	90.0	
Severity 2A	5	82.00±17.89	50-90	90.0	90	90.0	
Severity 2R	1	90.00±0.00	90-90	90.0	90	90.0	

SD: Standard deviation; A: Anterior; R: Radial; * No difference in median between all radial and anterior heterotopic ossifications; *p* values were obtained between all radial and anterior heterotopic ossifications.

No significant decrease of ROM between patients with and without HO was detected for flexion (p=0.757), extension (p=0.160), supination (p=0.161), and pronation (p=0.083). However, with enhancing severity of HO according to the classification by Leyder et al.,[20] differences in means were detected (Figures 3a-d). Since 70° was the maximum of the self-determined pronation, nearly all patients reached this level. Due to the small number of severity (n=2), statistical analysis was not conclusive.

Regarding the localization of the HO, participants with a radial HO showed a median flexion of 140°, whereas participants with anterior HO had a median active flexion of 130°. Statistically, this finding was significant for participants who attended examination in person (p=0.007). All other directions of motion did not show any significant association to the HO (Table III). Interestingly, this significance disappeared despite the same medians in the questionnaire for self-determined ROM (p=0.323).

Sixty participants took HO prophylaxis with NSAIDs by ibuprofen (56.7%), indomethacin (41.7%), and diclofenac (1.6%). In regard to the surgical treatment, a similar percentage of the participants took the HO prophylaxis (ORIF, 86%; RHA, 74%; ligament repair, 82%). However, the two groups with and without HO prophylaxis showed nearly the same amount of HO (51.7% *vs.* 53.8%). No significant correlation was present between HO prophylaxis and HO classification according to Leyder et al.[20] (r=–0.077) or Hastings and Graham[21] (r=0.032).

The mean DASH of the whole sample was 13.7±16.6, with no significant difference between participants with (14.7±16.6) and without HO (12.7±16.8; p=0.553). Patients with and without HO showed no significant differences in SF-36 scores. This applied for the standardized physical component summary (p=0.728), as well as for the standardized mental component summary (p=0.275).

DISCUSSION

Heterotopic ossification is a frequent complication after injuries involving the radial head and can cause reduced function and quality of life. Among surgically treated high-grade radial head fractures classified as Mason-Johnston types 3 and 4, 52.1% developed HO. Heterotopic ossification prevalence varies in recent literature between 4%[18] and 58%[12] for severe elbow fractures. The majority of these studies investigated a heterogeneous group of injuries.[8,12]

In our relatively homogeneous sample, there was a trend (42.5% *vs.* 63.6%) that HO was more likely for Mason-Johnston type 4 injuries compared to Mason-Johnston type 3, as well as for the terrible triad and Monteggia-like injuries. For the ORIF group, this difference was significant (p=0.028). In the RHA group this difference was not present. This might be explained by the smaller sample size. However, the present trend that HO is more likely for more severe injuries supports previously published results.[8,10,12] In patients with operatively treated elbow fractures, Wiggers et al.[10] determined an odds ratio of 2.38 for HO and ulnohumeral dislocation with additional fracture, whereas fracture location was not associated with HO. A higher prevalence of HO was determined in distal humeral fractures, terrible triad injuries, and transolecranon fracture dislocations,[8] as well as floating elbow injuries and combined olecranon/radial head fractures.[12] Schneiders et al.[14] documented more HO in patients with ligamentous injury. In the present sample, patients with ligamental refixation had no higher rate of HO. Nevertheless, our results support the hypothesis that more severe injuries lead to a higher rate of HO.

After surgical therapy of radial head fractures with RHA, HO is reported up to 64%.[16] Some small sample studies reported good clinical results following RHA with nearly no HO or no influence of HO on the clinical outcome.[23,24] However, different results with significantly decreased ROM following RHA due to HO are described.[15,25] Compared to ORIF, Zwingmann et al.[26] described in their review on clinical results after operative treatment of radial head fractures more HO following RHA. In our study, there was a difference in the rate of HO between RHA and ORIF, although it was not statistically significant (46% *vs.* 65.2%, p=0.127).

It is generally accepted that HO can lead to severe elbow stiffness with a decrease of the elbow ROM[12] in flexion,[27] extension,[7] as well as pronation and supination.[28] In our sample, no significant differences in ROM between patients with and without HO were present, while patients with the most pronounced HO anterior showed impaired flexion. However, no high-grade HO was present in our sample. Additionally, separate calculations regarding ROM had to be performed since 70° was the maximum of the self-determined pronation. Further studies with bigger sample sizes should be performed to validate these results because impaired motion on the site of the HO can be expected. A reason for the low rate of high-grade HO in our sample might be that every surgery was performed by a senior trauma surgeon of a level-one trauma center with high expertise for difficult cases or the consequent rinsing of every surgical site.

Heterotopic ossification prophylaxis after elbow trauma is a controversially discussed issue. Prophylactic approaches with possible side effects, such as localized radiotherapy and NSAIDs, are often used. For localized radiotherapy, risks such as delayed wound healing, nonunion, and oncogenesis are possible. Moreover, a wide range of radiation doses are currently described, while the efficacy in joints other than the hip are not sufficiently studied.[3] Hamid et al.'s[29] study on prophylactic radiation in elbow trauma was terminated prior to completion due to an unacceptably high number of adverse events. For prophylaxis with NSAIDs after elbow surgery unconclusive results are present as well.[15] Nevertheless, it is used although several risks such as gastric ulcers, the nephrotoxic and cardiotoxic potential, as well as a nonunion risk of the fracture are present.[4,15] This lack of knowledge on the efficacy might lead to variable medication[3] and duration, which is described by Winkler et al.[19] For example, indomethacin is used in doses between 25 mg thrice daily[18] up to 75 mg twice daily.[16] Atwan et al.[30] revealed no difference between indomethacin and placebo for HO prophylaxis. The review of Henstenburg et al.[5] did not discover a difference in HO development or final ROM between prophylaxis with NSAIDs or localized radiation following elbow trauma. Bauer et al.[6] did not apply any prophylaxis and reported a low rate of HO. Our sample did not show a correlation between HO prophylaxis and HO. Consequently, there is no strong evidence for a distinct HO prophylaxis following elbow injuries.

Another possible risk factor for HO development is time to surgery.[2,12] Hong et al.[12] determined an increased risk for HO and clinical relevant HO with ROM limitation for surgery later than one week after fracture, whereas Ilahi et al.[2] suggested that surgery within 48 h may reduce HO. The calculated models of Foruria et al.[8] determined an increased risk for HO of 7.5% per day that surgery was delayed. Nevertheless. this association did not reach significance in their sample. However, other authors did not find any difference in HO development for patients with surgery after more than 48 h[9] and 72 h.[15] Our study did not find any association between time to surgery and presence of HO. Although, direct comparison between the study samples might not be possible since few of our patients were treated within 48 h due to the secondary transfer of many complex trauma patients. Due to the same reason, no information was present on the number of reduction attempts, which could be another risk factor for HO formation.[9]

This study had several limitations. Regarding postoperative joint immobilization, a timespan longer than two weeks was detected as an independent risk factor for elbow stiffness[31] and HO.[6] Due to the complexity of our fractures, there was no standardized postoperative treatment. Therefore, no conclusive investigation could be performed. Additionally, cause-and-effect relationships could not be established due to the retrospective design. A distinct sample of high-grade radial head and elbow-dislocation fractures was investigated in the present study. However, some injury types were too rare to perform adequately powered calculations. Regarding radiographic assessment, patients without any physical complaints did not receive additional radiographs due to ethical reasons. Therefore, a change of HO between the last radiograph and the clinical examination might be possible but unlikely. A further limitation might be the development of HO or improvement of ROM occurring in patients with longer follow-up.

In conclusion, HO was present in over 50% of the surgically treated patients with high-grade radial head fractures classified as Mason-Johnston types 3 and 4, and a trend that more severe injuries led to a higher prevalence of HO was observed. A tendency for decreasing ROM according to the location of the HO was observed. No increased rates of HO were determined for delayed surgery, surgical treatment method, and use of HO prophylaxis. Therefore, the findings do not support a regular HO prophylaxis for severe radial head fractures. Additionally, no significant differences in functional scores and quality of life were detected between patients with and without HO. This information is useful for patient counseling regarding their risks of HO and the following outcome after high-grade radial head fractures.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: C.F. and P.Z. conceptualized and designed the study. C.F. was responsible for drafting the scientific subsumption. J.P. conducted all measurements and performed the statistical analyses. D.L., T., and D.S. contributed by providing critical advice on the study design. All authors revised and approved the manuscript.

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