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Complications of hardware removal in pediatric upper limb surgery

A retrospective single-center study of 317 patients

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Abstract

Previous studies indicated that hardware removal may lead to increased morbidity and therefore, at least in adults, remains questionable for certain indications. However, risks such as corrosion or local reactions may be less likely in younger patients with current, improved hardware materials. We sought to retrospectively determine complication rates of hardware removal in pediatric upper limb surgery, and establish potential risk factors for increased morbidity.

All children and adolescents who underwent inpatient hardware removal under anesthesia after previous upper limb surgery between 2002 and 2016 were retrospectively evaluated. The following details were extracted at the latest follow-up: demographics, implant location, hardware material, duration of surgery, duration of hardware in situ, and any complications graded according to Goslings et al (grade 0–5) and Sink et al (grade 1–5), respectively. Correlations were calculated to establish potential relationships between specific outcome parameters (e.g., location, duration of surgery etc.) and complication grades.

A total of 2089 children were evaluated of whom 317 patients with 449 interventions (mean age 9.4 years) fulfilled the inclusion criteria for this study. Overall, 203 K-wires (46%), 97 plates (22%), 102 external fixators (23%), 32 intramedullary nails (7%), 6 screws (1%), 4 cerclages (1%) and 1 pin (0.2%) were removed; most common locations were the forearm (34%) and humerus (24%). The mean duration of surgery was 40 minutes (± 50.9), mean time in situ was 194 days (± 319.6). Complication rates were low overall, with most being grade 0 (n = 372; 83%) or 1 (n = 60; 13%) according to Goslings et al and grade 1 (n = 386; 86%) and 2 (n = 42; 9%) according to Sink et al. No severe complications were observed. The following predictors were related to the severity of the complications in linear regression analysis: more distal localizations, external fixators, longer duration of surgery and female sex.

Hardware removal under anesthesia in the pediatric upper extremity has produced a low complication rate with no severe complications and can thus be considered to be safe. Increased morbidity occurred in more distal localizations, external fixators, longer surgeries and females.

Level of Evidence: Therapeutic, Level IV.

Abbreviations: BMI = body-mass-index, CI = confidence interval, ICU = intensive care unit.

Keywords: complications, hardware removal, pediatric hand, upper limb surgery

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1. Introduction

The removal of osteosynthesis material after completed bone healing is common practice in orthopedic surgery. In the pediatric population, this is usually routinely offered as children continue to grow, and the implant could therefore hinder bone remodeling.[1–4] There are several biological effects of such metal implants. In particular, metal corrosion remains an issue, which leads to not only the accumulation of metallic elements in the tissues but also to deterioration of implant stability.[5] The risk of infection is also increased at the metal-tissue junction. Owing to metal hypersensitivity, allergic events may occur as well.[6] There are records of malignant tissue changes in areas adjacent to metal implants in humans and animals. However, all sources related to humans are only individual case descriptions.[7] Implant pain is one of the most common indications for the removal of metal implants.[8] This can also be caused by loosening or yielding of the implant. Occasionally, wound complications may necessitate the rapid removal of a metal implant.[7]

In order to eliminate such complications in children, hardware removal is usually recommended. However, this benefit is juxtaposed with the risk of complications associated with hardware removal, especially when an elective removal of an asymptomatic implant is considered.[3] To date, complication rates of 0% to 40% have been described for elective metal implant removal.[9,10] However, the effects and consequences of hardware removal in a pediatric patient's upper extremity are still not fully understood, and have not been adequately proven by studies. The aim of this study was thus to investigate the complications and influencing factors following hardware removal in the pediatric upper extremity in a retrospective single-center analysis.

2. Materials and methods

The institutional review board approved this study (Ethic commission of the city Vienna, Austria; EK-17-011-VK; 16.2.2017). In this retrospective analysis, data was collected from patients' charts who underwent hardware removal between 2002 and 2016. Inclusion criteria were: age of less than 18 years at the time of explantation, removal of hardware material in the upper extremity after correction of a congenital or acquired malformation, surgery under general anesthesia or sedoanalgesia. Exclusion criteria were: ambulatory/outpatient interventions, and insufficient surgical documentation. All patients who fulfilled the inclusion comprised the definitive sample size. The following prognostic factors were determined and extracted: gender, age, body-mass-index (BMI), previous surgeries, type of hardware material, location of implantation, side and duration of surgery, duration in situ until removal, and complications. Complications were graded according to Goslings et al[11] and Sink et al[12] Gosling's classification has 6 categories: (0) no harm, (1) temporary disadvantage, no [re-]surgery, (2) recovery after [re-]surgery, (3) [probably] permanent damage/disability, (4) death to (5) unclear due to untimely death.[11] Sink's classification has five categories: (1) a complication that requires no treatment and has no clinical relevance, (2) a deviation from the normal postoperative course that requires outpatient treatment, (3) a complication that is treatable but requires surgical or an unplanned hospital admission, (4) a complication that is life threatening, requires ICU admission, or is not treatable with potential for permanent disability to (5) death.[12]

2.1. Statistical analysis

Descriptive and inferential statistical evaluations were carried out using IBM SPSS 20. A result with $P \leq .05$ was considered as significant. The standardized effect size β, according to the effect size classification published by Cohen with values ≥.10 for small weights, ≥.30 for medium weights and ≥.50 for considerable weights, was used in model tests to assess the significance of results in terms of content.[13] Within the framework of inferential statistical procedures, the relationship between two nominal-scaled variables were determined on the basis of cross-tables corresponding to Chi-Square tests. The relationship between two interval-scaled and normally distributed variables was quantified using Pearson's product-moment correlation. As a generalization of the simple linear regression, several predictors (independent variables or covariates) were examined together with respect to a metric criterion within the framework of model tests. The data observed should represent the assumed model in the best possible way.[14] By means of a power analysis (G*Power 3.1.9.4) and taking into account the number of the patients treated surgically (n=317) of the defined significance level (α=5%), and power (1−β) of about 80%, the effect f^2 was calculated, which still achieves a significant result within the framework of multiple linear regression with 20 predictors. Under these assumptions, even small effects from .05 reach a significant level. The comparative juxtaposition of the 2 complication classifications with respect to the correlations with the potential prognostic parameters was based on the calculation of the correlations of the two scores with socio-demographic and surgery-specific variables. For this, the logarithmic Goslings and Sink expressions were used. In addition, the relationship with the dichotomous variables, gender, and previous surgery, were investigated using the Chi-Square test.

3. Results

3.1. Baseline information

A total of 2089 children were evaluated of whom 317 patients (449 surgical interventions) met all inclusion and exclusion criteria. 239 patients (75.4%) underwent hardware removal in the upper extremity once and 78 (24.6%) at least twice during the observation period. The patient population consisted of 151 (47.6%) female and 166 (52.4%) male children with a mean age of 9.4 years (± 4.6) at the time of hardware removal. The mean BMI in kg/m^2 was 18.6±4.7. The average implant duration in situ was 194 days (± 319.6); the average surgery duration was 40 minutes (± 50.9). Table 1 contains a detailed list of the removed materials with respect to locations and sides. The most frequent location for hardware removal in the upper extremity was the humerus (24.1%), radius (20.5%) and ulna (12.5%). The most common type of material removed were K-wires (45.7%) followed by external fixators (22.7%) and plates (21.8%) (Fig. 1). Table 2 shows the frequencies of the removed materials depending on the exact location. The average postoperative follow-up interval comprised 2.3±2.7 years.

3.2. Complications

The mean Goslings grade was 0.2±0.5 (range, 0–3), while the mean Sink grade was 1.2±0.6 (range, 1–4). In 372 surgeries (82.9%), no postoperative complications were observed at all (Table 3). Table 4 shows the distribution of surgeries with respect to the severity of postoperative complications. The two classifications showed a positive correlation with $r=.90$ ($P<.001$; 95% CI [.85 – .94]). Accordingly, an acceptable

Table 1

Frequencies (%) and localizations of hardware removal.

	Side of surgery			
Localization	**Left n**	**Both sides n**	**Right n**	**Total n**
Clavicle	3 (42.9)	0	4 (57.1)	7 (1.6)
Humerus	57 (52.8)	0	51 (47.2)	108 (24.1)
Radius	25 (48.1)	0	27 (51.9)	52 (11.6)
Ulna	22 (50.0)	0	22 (50.0)	44 (9.8)
Carpals	6 (54.5)	0	5 (45.5)	11 (2.4)
Metacarpals	19 (45.2)	0	23 (54.8)	42 (9.3)
Phalanges	18 (50.0)	6 (16.7)	12 (33.3)	36 (8.0)
Radius & Ulna	30 (53.6)	0	26 (46.4)	56 (12.5)
Other localizations	33 (35.9)	7 (7.6)	52 (56.5)	92 (20.5)
Total	214 (47.7)	13 (2.9)	222 (49.4)	449 (100.0)

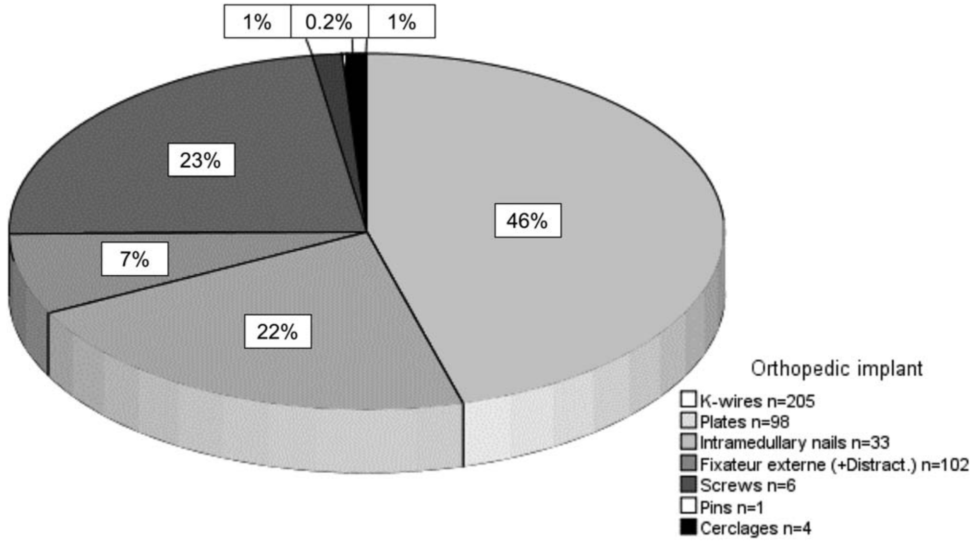

Figure 1. Pie chart showing the number and percentage of removed orthopedic implants (n=449).

Table 2

Types of orthopedic implants based on the localization of implant removal.

	Orthopedic implants							
Localization	**K-wires**	**Plates**	**Intramed nails**	**Fixateur externe (+distract.)**	**Screws**	**Pins**	**Cerclages**	**Total**
Clavicle	2	3	1	0	1	0	0	7
Humerus	**37**	**40**	20	6	3	1	1	108
Radius	**32**	12	4	3	1	0	0	52
Ulna	6	25	3	7	1	0	2	44
Carpals	9	0	0	2	0	0	0	11
Metacarpals	27	1	0	14	0	0	0	42
Phalanges	**36**	0	0	0	0	0	0	36
Radius & Ulna	14	17	5	20	0	0	0	56
Other localizations	**41**	0	0	**50**	0	0	1	92
Total	205 (45.7%)	98 (21.8%)	33 (7.3%)	102 (22.7%)	6 (1.3%)	1 (0.2%)	4 (0.9%)	449 (100%)

Frequencies >30 are highlighted in bold.

reliability of the two scores could be shown on the basis of the present sample. A significantly positive correlation with the two complication classifications could only be found for the duration of the surgery ($r=.097$ and $r=.184$). In contrast, non-significant correlations were observed with regards to age, BMI, and the duration of hardware in situ. Female patients showed more frequently complications of grade 1 and 2 according to Goslings ($\chi^2=9.308$, $P=.015$) and more frequently complications of grade 2 and 3 according to Sink ($\chi^2=7.475$, $P=.050$). Furthermore, there was no significant correlation with respect to the hardware materials used ($\chi^2=28.148$, $P=.249$ or $\chi^2=21.256$, $P=.408$). However, the evaluation showed a significant

Table 3

Frequency (%) and types of complications.

Complications	N
Delayed union	17 (22)
Transient functional limitation	13 (17)
Wound healing disturbance	12 (16)
Fracture	11 (14)
Superficial wound infection	7 (9)
Re-Dislocation	6 (8)
Intensive care unit admission	4 (5)
Transient neurapraxia	3 (4)
Deep infection	1 (1)
Nonunion	1 (1)
Adjacent ligament injury	1 (1)
Permanent nerve injury	1 (1)
Total	77

Table 4

Frequency (%) of complications based on the systems of Goslings et al and Sink et al.

Goslings	Cases N	Sink	Cases N
0	372 (82.9)	1	386 (86.0)
1	60 (13.3)	2	42 (9.3)
2	16 (3.6)	3	16 (3.6)
3	1 (0.2)	4	5 (1.1)
4	0	5	0
5	0	Total	449 (100)
Total	449 (100)		

Table 5

Coefficients of the predictors with significant values in the two models (n=449).

	Goslings					Sink				
Predictor	***B***	***SE***	β	***t***	***P***	***B***	***SE***	β	***t***	***P***
(constant)	.059	.021		2.801	.005	.037	.021		1.735	.083
Gender	-.029	.012	-.108	-2.359	.019*	-.021	.012	-.077	-1.671	.096°
Fixateur ext. (+dis)	.029	.015	.093	1.966	.050*	.028	.015	.088	1.865	.063°
Loc. Radius	.071	.020	.171	3.596	<.001**	.049	.020	.117	2.456	.014*
Loc. Ulna	.071	.021	.158	3.354	.001**	.049	.021	.108	2.288	.023*
Loc. Metacarpals	.054	.021	.119	2.532	.012*	.052	.022	.113	2.382	.018*
Loc. Radius & Ulna	.050	.019	.124	2.624	.009**	.039	.019	.096	2.019	.044*
Duration of surgery	<.001	<.001	.087	1.866	.063°	<.001	<.001	.176	3.772	<.001**
R^2 (R^2_{corr})			8.8% (7.4%)					8.1% (6.6%)		
Durbin-Watson			2.04					1.97		
Tolerance					≥ .428					

**$P \leq .01$, *$P \leq .05$, °$P \leq .10$.
Loc.=localization.

difference in the distribution of Gosling's and Sink's complication grades with respect to localization (χ^2 (24)=49,070, P=.002 and χ^2 (24)=50,134, P=.001). Taking the proportional values into account, complication rates for the radius, ulna, radius *and* ulna, and metacarpals were comparatively higher.

3.3. Multiple linear regression analysis

Finally, the common explanatory value of the potential prognostic factors for the expression of the two complication classifications was investigated by means of multiple linear regressions. The global model summary showed a significant explanatory value for Gosling's criterion with $F(7, 441)=6,089$, $P<.001$ as well as for the Sink's criterion ($F(7, 441)=5,520$, $P<.001$) for 7 identical predictors each. Table 5 shows the explanatory value of the remaining 7 predictor variables as well as the results in a summarizing comparison. The same predictors could be identified for both classifications, while the age at the time of the surgery, the BMI, the presence of previous procedures and the hardware duration in situ were excluded from the model. The locations radius, ulna, radius *and* ulna, and metacarpals showed the comparatively highest weighting, especially for Gosling's classification. In addition, the hardware material *external fixator* was significantly associated with a higher complication grade in Gosling's model and tended to be associated with a higher complication classification in Sink's model. A positive correlation with the severity of the complications could also be derived for Goslings (approaching significance) and Sink (significant) for the duration of the surgery. In our sample, the female sex was a more significant risk factor for the occurrence and severity of a complication after hardware removal with respect to the Gosling and Sink classification. For both models, a significant explanatory value of 8.8% (Goslings) and 8.1% (Sink) could be established for the variability of the criteria.

4. Discussion

In the 449 surgical cases observed, 77 (17.1%) showed some kind of complication. A breakdown of the two grades showed an overall complication rate of 17.1% for Goslings and 14.0% for Sink. The majority of observed abnormalities were, however, mild complications, which did not require operative revisions. We found that 4 patients (0.9%) suffered Gosling‘s grade 1 complications corresponding to Sink‘s grade 4 complications. This can be explained by the fact that in Sink's grading any postoperative stay in an intensive care unit (ICU) is automatically classified as grade 4, regardless of whether a complication occurs or not. In four observed complications, the ICU stay was due to an underlying disease and rather long duration of surgery. It is worth mentioning that there were no complications of grades 4 and 5 according to Goslings and Sink.

No correlation was found between complication classifications and age, BMI, the duration in situ, and the duration of surgery, and a low but significant correlation with the Sink classification. However, these correlations should not be interpreted causally, since it is understandable that more complex surgical cases are usually associated with longer surgery durations and higher complication rates.[10] It should be noted that for the *external fixators* the comparatively lowest complication-free outcomes were observed (74.5% for Goslings; 78.4% for Sink), which is probably directly related to the complexity of the interventions performed. Considering the location, the more distal localizations (forearm, metacarpals) were associated with higher complication rates, which is consistent with the literature.[8,15] Sanderson et al describe in their study a general complication rate of 20%, which rises significantly to 42% in the forearm.[8] Langkamer et al reported a similarly high complication rate in the forearm. In this study of 55 patients with an average age of 26.7 years, a complication rate of 40% was observed.[15] For the complication classifications the variability of the severity of complications after metal removal in the child's upper extremity could be accounted for 8.8% for Goslings and 8.1% for Sink classification. Hence, most of the variance could therefore be accounted for other influencing variables that were not included in the present study.

We found that plates remained longest in situ with an average of approximately 503 days, and wires had the shortest retention time with approximately 71 days. These observations were in line with expectations, as an average retention of 23.7 months for the removed plates had already been determined by Langkamer in 1990.[6,15] The average duration of surgery was approximately 40 minutes in our cohort. These results are comparable to a study by Schmalzried et al, but with significantly fewer hardware removals in the upper extremity.[10] It was found that plates required the longest surgery duration for removal while, as expected, K-wires required the shortest time. This variability confirms that the duration of the surgery depends on the material.[10] The location of the material was also expected to impact surgical time which was previously described by Schmalzried et al.[10]

There are hardly any comparable data on complications after hardware removal published to date, especially regarding the child's upper extremity. The study by Schmalzried et al showed a complication rate of 11% with a low rate of severe complications in 152 patients with an average age of 11.5 years.[10] Due to the low rate of major complications Schmalzried concluded that the procedure is safe despite occasional difficulties.[10] However, this study contains only 5 implant removals in the upper extremity.[10] A study by Sanderson et al described a complication rate of 20% in 182 patients with an average age of 34 years and only a small proportion of hardware removals in the upper extremity.[8] Kahle, in turn, reports a complication rate of 13% in his study of 138 patients with an average age of 10.6 years with mainly lower extremity cases.[3] Moreover, Reith et al. described 382 patients with an average age of 46.3 years. Despite the complication rate described, the patient satisfaction rate after hardware removal was very high. Most complications were wound healing disorders.[9] Recently, Suda et al reported 51 complications among 1494 removals (3.4%). However, the comparison with the present study is difficult due to the significantly higher mean age of the patient population (40 years) and the fact that hardware removal on both the upper and lower limbs had been included.[16] Moreover, contrasting evidence exists whether hardware removal, though in adults, will indeed lead to improvement of clinical outcomes or rather just pain relief.[17,18]

Changes in type and quality of metal alloys have led to decreased complications such as corrosion-related foreign body reactions and thus, general indications for removal should be revisited, especially in children. Based on the data collected, we conclude that hardware removal from upper extremities in children is safe. A comparison of the hardware materials and the occurrence of complications did not show any association. Therefore, it can be assumed that the complication rate and severity is not influenced by specific materials. However, informed consent and counseling of patients and their parents concerning the risks and potential complications is mandatory. Future studies in comparable tertiary referral centers should reveal whether our results are generalizable.

Limitations of this study were its retrospective nature, and we exclusively included patients who underwent hardware removal in an inpatient setting under general/sedoanalgesia. Therefore, it might be assumed that the complication rate recorded in this analysis is certainly higher, since many simpler surgeries (e.g., percutaneous K-wire removal) are often performed in an outpatient setting. It should also be mentioned that the 449 surgeries observed were composed of a relatively high number of combined procedures. An attempt was made to precisely assess the complications that occurred and, in the case of combination interventions, to determine which intervention led to the documented complication. Nevertheless, in some patients it cannot be excluded that a complication is not directly related to the removal itself but to other contributing factors (comorbidities etc.). Nevertheless, this study is one of very few published so far dealing with hardware removal in an exclusively pediatric cohort and, to the best of our knowledge, the first study on specifically upper limb hardware removals.

In summary, hardware removal under anesthesia in the pediatric upper extremity has been shown to be safe, with most complications observed needing no further treatment or surgery. Increased morbidity was observed in distal localizations, females, longer surgeries and especially external fixators. As a consequence, routine removal can still be recommended in patients with upper limb pathologies. However, future studies should be undertaken to confirm these findings and furthermore to evaluate long-term sequelae of hardware which has been kept in situ and not removed.

Author contributions

Conceptualization: Sebastian Farr.
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Investigation: Philipp Scheider.
Methodology: Philipp Scheider, Sebastian Farr.
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Supervision: Sebastian Farr.
Validation: Rudolf Ganger, Sebastian Farr.
Visualization: Sebastian Farr.
Writing – original draft: Philipp Scheider, Sebastian Farr.

References

[1] Wentzensen A, Magin M. Plattenosteosynthese. In: Die Plattenosteosynthese und ihre Konkurrenzverfahren: Von Hansmann bis Ilisarow. Berlin Heidelberg: Springer-Verlag; 1991: 155–7.
[2] Schildhauer T. Metallentfernungen: Zu oft Routine – zu wenig Indikation? Trauma Berufskrank 2007;9:292–6.
[3] Kahle WK. The case against routine metal removal. J Pediatr Orthop 1994;14:229–37.
[4] Stanitski CL. Metal removal in asymptomatic children and adolescents. J Pediatr Orthop 2005;25:557.
[5] Hanson B, van der Werken C, Stengel D. Surgeons' beliefs and perceptions about removal of orthopaedic implants. BMC Musculoskelet Disord 2008;9:73.
[6] Richards RH, Palmer JD, Clarke NM. Observations on removal of metal implants. Injury 1992;23:25–8.
[7] Peterson HA. Metallic implant removal in children. J Pediatr Orthop 2005;25:107–15.
[8] Sanderson PL, Ryan W, Turner PG. Complications of metalwork removal. Injury 1992;23:29–30.
[9] Reith G, Schmitz-Greven V, Hensel KO, et al. Metal implant removal: benefits and drawbacks–a patient survey. BMC Surg 2015;15:96.
[10] Schmalzried TP, Grogan TJ, Neumeier PA, et al. Metal removal in a pediatric population: Benign procedure or necessary evil? J Pediatr Orthop 1991;11:72–6.
[11] Goslings JC, Gouma DJ. What is a surgical complication? World J Surg 2008;32:952.
[12] Sink EL, Leunig M, Zaltz I, et al. Reliability of a complication classification system for orthopaedic surgery. Clin Orthop Relat Res 2012;470:2220–6.
[13] Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. Hillsdale, NJ: Lawrence Earlbaum Associates; 1988.
[14] Field A. Discovering statistics using IBM SPSS. 4th ed.London: Sage; 2013.
[15] Langkamer VG, Ackroyd CE. Removal of forearm plates. A review of the complications. J Bone Joint Surg Br 1990;72:601–4.
[16] Suda AJ, Heilgeist E, Tinelli M, et al. High early post-operative complication rate after elective aseptic orthopedic implant removal of upper and lower limb. J Orthop Res 2018;36:1035–9.
[17] Greenberg A, Kadar A, Drexler M, et al. Functional outcomes after removal of hardware in patellar fracture: are we helping our patients? Arch Orthop Trauma Surg 2018;138:325–30.
[18] Acklin YP, Bircher A, Morgenstern M, et al. Benefits of hardware removal after plating. Injury 2018;49(Suppl 1):S91–5.