Difficulty in locking head screw removal

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Title page Title: Difficulty in Locking Head Screw Removal Running title: Difficulty in LHS removal

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1	Title: Difficulty in Locking Head Screw Removal
2	
3	Introduction
4	Locking plates are an internal fixation material useful in the treatment of bone
5	fractures, which provides effective stabilization between the plate and locking
6	head screws (LHSs) via the locking mechanism. However, difficulty in removing
7	LHSs is relatively common, and such cases can require long surgical procedures
8	or use of special removal equipment. Few studies have reported the causes and risk
9	factors for difficulty in screw removal [1,2]. Therefore, the purpose of this study
10	was to report the incidence and risk factors for difficult removal of LHSs.
11	
12	Patients and Methods
13	During the 5-year 6-month period from April 2006 to September 2011, 83 locking
14	plates containing a total of 482 LHSs were removed in 80 patients at our
15	institution. All locking plates and LHSs were made of titanium. In all cases, after we
16	confirmed bony union radiographically and clinically, the locking plates were
17	removed only when patients requested implant removal. However, for the LCP
18	Clavicle Hook Plate (Synthes, Paoli, PA), we recommended removal within 6
19	months to prevent loss of shoulder motion. Patients who required a second
20	operation within 3 months of the first operation owing to infection, malalignment,
21	nonunion, or another reasons were excluded from this study. "Removal difficulty"
22	was defined as screw removal that was difficult using only a screwdriver, such
23	that additional procedures were required. The following types of plate were
24	removed: 18 clavicular, 2 humeral, 16 ulnar, 24 radial, 1 femoral, 15 tibial, and 7
25	fibular (Table 1). Plates that had more than 1 LHS with removal difficulty were as

	26	follows: 1 clavicular, 1 humeral, 3 ulnar, 1 radial, 4 tibial, and 1 fibular (Table 2).
1 2	27	In the 482 LHSs in 83 locking plates, the incidence of removal difficulty was
3 4		
5	28	examined on the basis of screw diameter. In addition, risk factors were assessed in
7 8	29	only LHSs with a 3.5-mm diameter. For LHSs with a 3.5-mm diameter, the
9 10	30	removed screws were divided into 2 groups: the difficult removal group (D group)
11 12 13	31	and the easy removal group (E group), and the data were examined based on age,
14 15	32	sex, time between insertion and removal, and screw position. In addition, the
16 17 18	33	incidence of removal difficulty in 3.5 mm-diameter screws was examined every 6
19 20	34	months between insertion and removal.
21 22 23	35	Comparisons of age and time from internal fixation to removal were
24 25	36	performed using Welch's t test. Comparisons of sex and screw location were
26 27 28	37	performed using Fisher's exact test. A P value of $< .05$ was considered statistically
29 30	38	significant. All patients were informed of the risk of difficult LHS removal, for
31 32	39	which they provided written informed consent. This study was approved by the
33 34 35	40	institutional review board.
36 37	41	
38 39	42	Results
40 41 42	43	Difficulty in removal was encountered in none (0%) of 118 LHSs with a
43 44	44	2.4-2.7-mm diameter, 15 (4.9%) of 308 LHSs with a 3.5-mm diameter, and none
45 46 47	45	(0%) of 56 LHSs with a 5.0-mm diameter (Table 3). When only LHSs with 3.5-mm
48 49	46	diameters were considered, the mean ages of the patients in the D group and the E
50 51 52	47	group were 32.1 and 45.6 years, respectively. There were 12 LHSs in men and 3
53 54	48	in women in the D group, whereas there were 207 LHSs in men and 86 in women
55 56 57	49	in the E group. The average time between insertion and removal was 529.2 days
58 59 60 61	50	in the D group and 389.2 days in the E group. In terms of location, 10 LHSs were
62 63 64		

diaphyseal and 5 were metaphyseal in the D group, whereas 166 LHSs were
diaphyseal and 127 were metaphyseal in the E group (Table 4). These findings
indicate that removal difficulty occurred for only LHSs with a 3.5-mm diameter,
and tended to occur with longer time from insertion to removal and in younger
patients; these findings were statistically significant.

In addition, the incidence of removal difficulty in LHSs with a 3.5-mm diameter was examined every 6 months between insertion and removal. Removal was difficult in 0 of 31 LHSs in <6 months from insertion to removal, 0 of 112 LHSs in 6 months to 1 year, 10 (8.7%) of 115 LHSs in 1 year to 1 year 6 months, 2 (8.3%) of 24 LHSs in 1 year 6 months to 2 years, and 3 (11.5%) of 26 LHSs in >2 years (Table 5). Therefore, removal difficulty occurred in 15 (9.1%) of 165 LHSs in >1 year from insertion to removal. One of the 15 LHSs had been inserted in an inappropriate direction. Of the 15 LHSs, 8 were removed with conical removal screws and 3 were removed by bending the plates and then rotating the screws with the plates. The screw heads of the remaining 4 LHSs were destroyed with a carbide drill, and the screw shafts left in the bone were removed using removal bolts and emergency reamer tubes.

69 Discussion

LHSs are an internal fixation material used in the treatment of bone fractures.
However, cases of screw removal difficulty are occasionally reported. According
to the AO Manual of Fracture Management, the following commonly cause
difficulty in LHS removal: damaged screw head recess, LHSs that are locked too
tightly, jamming the screw head into the plate hole, excessive self-drilling,
self-tapping LHSs, and bone growth into the LHS [3]. The use of LHSs has

become widespread over the last 10 years; however, few reports have focused on
the difficulties encountered in their removal. A study by Bae et al. showed that of
159 LHSs with a 5.0-mm diameter and 279 LHSs with a 3.5-mm diameter, 24
were difficult to remove, all of which were 3.5-mm–diameter screws [1]. Suzuki
et al. reported screw removal difficulty in 37 (10.6%) of 349 LHSs, and
investigated the predictors of screw removal difficulty, but found no significant
differences among the cases [2].

In this study, the incidence of removal difficulty in 3.5-mm-diameter LHSs with >1 year elapsed between insertion and removal was 9.1%; this rate seems considerably high. Since a locking plate is inserted by multiple LHSs, the possibility of removal difficulty reaches 24.9% in a plate with 3 LHSs, 43.6% with 6 LHSs, and 57.6% with 9 LHSs, theoretically. Actually, our study had 25 locking plates inserted by 3.5-mm-diameter LHSs with >1 year elapsed between insertion and removal. Eleven (44%) of these 25 plates, with a mean number of 6.6 LHSs inserted, had at least 1 LHS removal difficulty. This rate of removal difficulty was much higher than we expected.

When a surgeon plans to remove a locking plate with 3.5-mm-diameter LHSs with >1 year elapsed between insertion and removal, he should explain the high risk of removal difficulty, which reaches approximately 50%, to his patient. This study suggests that (1) the use of LHSs with a 3.5-mm diameter is necessary condition for difficulty in screw removal, and that (2) longer time from internal fixation to removal, and (3) younger age are risk factors for it. The risk associated with screw diameter appears to be related to the depth of screwdriver insertion into the screw head, bone quality, and length of the screw (Table 5). Typically, 2.3 to 2.7 mm-diameter screws are used in the distal radius, and the

101	depth of screwdriver insertion into the screw head is shallow. However, removal
102	difficulty is considered unlikely because of poor underlying bone quality due to
103	osteoporosis, and the short screw length. In some locking plates used in the distal
104	radius, LHSs with difficult-to-strip, star-shaped heads were used in this study.
105	However, even with standard hexagonal-head screws, which were used in the
106	majority of cases, there was no occurrence of screw removal difficulty. In contrast,
107	5.0 mm-diameter screws are long and used in sites with good bone quality, such
108	as the femur and tibia. However, the screw head is unlikely to be stripped because
109	the depth of screwdriver insertion into the screw head is deep. Longer
110	3.5-mm-diameter screws are used in regions with good bone quality; for example,
111	the diaphyseal screws that are used with the LCP Distal Tibia Plate in younger
112	patients are likely to be stripped and should be removed very carefully. In such
113	regions, star-shaped screw heads, 5.0 mm-diameter screws, or stainless steel
114	screws may be appropriate. The risk associated with longer time between insertion
115	and removal suggests that the biocompatibility of the screws allows them to bind
116	firmly with bone due to the long time period, whereas the risk associated with
117	younger age suggests that high-quality underlying bone leads to screw removal
118	difficulty. In addition, insertion in an inappropriate direction and excessive
119	tightening are factors that contribute to screw removal difficulty, and that care
120	should be taken during the initial surgery.
121	Considering the risk of removal difficulty, indications for the use of
122	locking plates for fractures should be determined carefully, including whether
123	sufficient stabilization will be achievable with conventional plates, and whether
124	plate removal is possible due to soft tissue irritation or other reasons. As a reference,

 $\begin{array}{c} 18\\ 19\\ 20\\ 21\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ \end{array}$

 $\mathbf{5}$

126	removal difficulty with conventional screws was found to be only 5 (0.6%) of 890
127	screws, indicating that conventional screws are much easier to remove than LHSs.
128	Regarding the methods for removal of broken hardware, Hak et al. stated that
129	screw extractors, trephines, and extraction bolts are useful for removing stripped
130	or broken screws, and that carbide drills and high-speed metal cutting tools are
131	necessary to remove cold-welded screws [4]. At our institution, the methods used for
132	dealing with difficult-to-remove screws are as follows (in the order of ease of
133	removing): (1) inserting a foil from a suture into the stripped screw head [5], (2)
134	using a conical removal screw, (3) bending a flexible plate and then rotating the last
135	screw together with the plate, and (4) destroying the screw head with a carbide
136	drill and then removing the plate. In practice, the methods using a foil are difficult
137	for LHSs with a 3.5-mm diameter, but are possible for those with a 5.0-mm diameter.
138	Although there was no case of removal difficulty of LHSs with a 5.0-mm
139	diameter in our study, difficulty in removal may occur rarely [2]. When using a
140	conical removal screw, it is important to use a screwdriver with a thick handle,
141	which allows for the application of sufficient force. However, our experience has
142	shown that this method often fails, and in this case, it is important to avoid trying
143	this again, and an alternative method should be used instead. Bending a plate is
144	feasible only with flexible plates such as the LCP Reconstruction Plate 3.5
145	(Synthes) or the LCP Metaphyseal Plate 3.5 (Synthes), with only 1 screw
146	remaining. If available, a metal cutting bar or thread wire saw are helpful to cut
147	the plate around the screw head. Destroying the screw head will certainly remove
148	the plate, but after removal of the plate, the screw shafts left in the bone must be
149	removed using removal bolts and emergency reamer tubes. Destroying the screw
150	head also will cause metal powder to scatter over the surrounding tissue; therefore,

151 it must be covered with a sterile adhesive film.

153 Conclusions

154	We investigated cases with difficulty in LHS removal at our institution. This study
155	suggests that (1) the use of LHSs with a 3.5-mm diameter is necessary for
156	difficulty in screw removal, and that (2) longer time from internal fixation to
157	removal and (3) younger age are risk factors for <u>difficulty in removal</u> . When
158	removing LHSs with a 3.5-mm diameter, proper instruments and sufficient
159	training are necessary.
160	
161	Conflicts of interest
162	None of the authors of this manuscript received any type of support, benefits or
163	funding from a commercial party related directly or indirectly to the subject of this

164 article.

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 - 177 removing screws. Injury. 1999; 30:74–5.

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Table 1	Characteristics of the	nlates and locking	head screws that	were removed in	this study
		plates and looking			tino otuay

Site	Plate	Screw diameter (mm)	Plate number	Screw number
clavicle	LCP Clavicle Hook Plate ¹	3.5	14	58
	LCP Reconstruction Plate 3.5 ¹	3.5	4	19
humerus	PHILOS ¹	3.5	1	11
	LC-LCP 4.5/5.0 narrow ¹	5.0	1	6
ulnar	LCP Olecranon Plate ¹	3.5	7	60
	LC-LCP 3.5 ¹	3.5	7	21
	LCP Metaphyseal Plate 3.51	3.5	2	12
radius	VariAx Distal Radius Locking Plate ²	2.7	7	33
	Acu-Loc Distal Radius Plate ³	2.3 and 3.5 ^₄	6	53
	Locking Distal Radius Plate ¹	2.4	4	26
	Matrix SmartLock Plate ²	2.7	3	21
	LC-LCP 3.5 ¹	3.5	4	17
femur	LCP Distal Femur ¹	5.0	1	9
tibia	LCP Distal Tibia Plate ¹	3.5	8	64
	LC-LCP 4.5/5.0 broad ¹	5.0	4	18
	LCP Proximal Lateral Tibia ¹	5.0	1	8
	LCP Proximal Tibia Plate 3.5 ¹	3.5	1	9
	LC-LCP 3.5 ¹	3.5	1	4
fibula	LCP Metaphyseal Plate 3.5 ¹	3.5	7	33

LCP: locking compression plate

LC-LCP: limited contact-LCP

1; (Synthes, Paoli, PA, USA)

2; (Stryker Osteosynthesis, Freiburg, Germany)

3; (Acumed, Hillsboro, OR, USA)

4; The Acu-Loc Distal Radius Plate was inserted using 2.3-mm screws in the metaphysis and

3.5-mm screws in the diaphysis

Table 2 Characteristics of the plates and locking head screws with removal difficulty

Site	Plate	Plate number	Screw number
clavicle	LCP Reconstruction Plate 3.5	1	1
humerus	PHILOS	1	1
ulnar	LCP Metaphyseal Plate 3.5	2	2
	LCP Olecranon Plate	1	1
radius	LC-LCP 3.5	1	4
tibia	LCP Dital Tibia Plate	4	5
fibula	LCP Metaphyseal Plate 3.5	1	1

Table 3 Removal difficulty and screw diameter

Screw diameter (mm)	2.3-2.7	3.5	5.0
Number of screw with removal difficulty /	0/119 (09/)	15/209 (4 09/)	0/56 (0%)
Number of all screws	0/110 (0%)	15/300 (4.9%)	0/56 (0%)

Table 4 Characteristics of the difficult removal group (D group) and

the easy removal group (E group) in 3.5mm-diameter locking head screw

		D group	E group	P value	
Number of screws		15	293		
Age		32.1±17.2	45.6±17.8	0.010*	
Sex (male/female)		12/3	207/86	0.567	
Days from insertion to removal		529.2±143.2	389.2±190.5	0.002*	
Screw location diaphysis		10	166	0 505	
metaphysis		5	127	0.595	
				*P< 0.05	

table 5 Remaval difficulty and the time elapsed between insertion and removal in 3.5mm-diameter locking head screw

The time elapsed between	< 0.5	0.5 to 1	1 to 1 5	1.5 to 2.0	> 2
insertion and removal (year)	< 0.5	0.0 10 1	1 10 1.5		
Number of screw with removal	0/31	0/112	10/115	2/24	3/26
difficulty (Number of all corours	(00()	(0)()	(0.70/)	2/24	(11 - 50/)
difficulty / Number of all screws	(0%)	(0%)	(0.7%)	(0.3%)	(11.5%)

Locking head screw の抜去困難例の検討要旨 1200 文字【背景】

ロッキングプレートは、プレートと locking head screw (LHS)のロッキング機構により強 固な固定性が得られ、骨折治療に有用な内固定材料である。一方、LHS の抜去困難が生じ ることは稀ではなく、その場合長時間の手術や特殊な抜去器具が必要とされることがある。 本研究の目的は、LHS の抜去困難例の頻度、その危険因子について検討することである。

【対象と方法】

2006 年 4 月~2011 年 9 月の 5 年 6 か月間に、当院でロッキングプレートを抜去した症例 は 80 例 83 枚、LHS は 482 本であった。抜去した 482 本の LHS は、2.4~2.7mm 径 118 本、3.5mm 径 308 本、5.0mm 径 56 本であった。抜去困難例の頻度についてスクリュー径 ごとに調査した。また、3.5mm 径 LHS に限定し、抜去困難の危険因子の検討を行った。 3.5mm 径 LHS を抜去困難群(D 群)と抜去容易群(E 群)にわけ、スクリュー抜去時の 年齢、性別、抜去までの期間、スクリュー位置について検討を行った。また、抜去までの 期間を半年ごとにわけ、3.5mm 径 LHS の抜去困難の頻度を調査した。

【結果】

抜去した LHS 482 本のうち、抜去困難例は 15 本であった。抜去困難例の頻度は、2.4~ 2.7mm 径 LHS では 0%(0/118 本)、3.5mm 径 LHS では 4.9%(15/308 本)、5.0mm 径 LHS では 0%(0/56 本)であった。3.5mm 径 LHS を D 群 15 本、E 群 293 本にわけ、2 群間を比較した。スクリュー抜去時の平均年齢は D 群 32.1 歳、E 群 45.6 歳であり、抜去 までの平均期間は D 群 529.2 日、E 群 389.2 日であり、2 群間に有意差を認めた。性別、 スクリュー位置に関しては、2 群間に有意差を認めなかった。また、3.5mm 径 LHS の抜去 困難例の頻度は、抜去までの期間が 1 年未満では 0%(0/143 本)であり、1 年以上では 9.1% (15/165 本) であった。

(10/100 /) (α)

【結論】

本研究において、(1) 3.5mm 径 LHS の使用、が抜去困難の必要条件であり、(2) 抜去までの期間が長いこと、(3) 若年者への使用、が抜去困難の危険因子であると考えられた。3.5mm 径 LHS の抜去の際は、抜去用の器械を必ず準備し使用方法を熟知しておく必要がある。