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The effectiveness and clinical outcomes of the Minerva cervical thoracic jacket in patients with type II odontoid fractures

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Background/aim: The objective of this study was to carry out a detailed analysis and assess the outcomes for the Minerva cervical thoracic jacket (CTJ) in patients with type II odontoid fractures who could not be surgically treated.

Materials and methods: Twenty-six patients for whom the Minerva CTJ was used rather than surgery for different reasons were included in the study. All patients were fitted with the Minerva CTJ within the first 24 h following diagnosis. The patients were followed 4 weeks after hospital discharge and then at 2-week intervals. Results were considered significant at $P < 0.05$ and a 95% confidence interval was calculated.

Results: Of the 26 patients, 17 were male and 9 were female. The mean age was 49.03 years old (range: 16–86 years old). Fusion occurred in 25 of the 26 patients ($P = 0.004$), and the mean time to fusion was 6.8 weeks ($P = 0.002$). The mean length of hospital stay was 4 days and the mean follow-up period was 7.3 weeks. None of the patients had any complications due to the Minerva CTJ and the mortality rate was 0%.

Conclusions: The Minerva CTJ application was a safe and cheap technique in the management of type II odontoid fractures. It had a high fusion rate and no complications.

Key words: Odontoid, Minerva jacket, halo, fracture, fusion, type II

1. Introduction

Odontoid fractures account for 15% of all cervical spine fracture and have been classified by Anderson and D'Alonzo as types I, II, and III (1,2). Type II fractures account for 60% of all odontoid fractures, and these are unstable at the level of the odontoid base (3).

The optimal treatment for odontoid fractures remains controversial, especially in elderly patients who typically have an increased risk of operative complications when treated surgically and an increased risk of nonunion and prolonged treatment duration for medical treatment.

Both surgical and conservative methods for the management and treatment of type II odontoid fractures have been reported in the literature. However, because the treatment of all types of odontoid fractures is controversial, no single method of management is universally accepted (4–6). In recent years, many types of medical products for nonsurgical treatment, such as the conventional halo vest (CH), cervical thoracic orthosis (CTO), cervical thoracic jacket (CTJ), and other types of semirigid immobilizers, have become popular. The CH has never been proven to show superiority over surgical techniques, although many publications have positively reported on its effectiveness as a treatment option (6,7).

There are very few reports in the literature regarding the effectiveness and feasibility of the Minerva CTJ (Aspen Medical Europe Ltd., Redditch, UK), a noninvasive technique, in type II odontoid fractures. The aim of this study was to carry out a detailed analysis and assess outcomes for the Minerva CTJ in patients who, for various reasons, could not be surgically treated.

2. Materials and methods

Between 2011 and 2015, 39 patients diagnosed with type II odontoid fractures were prospectively examined in our institution. The study protocol was approved by the institutional review board, and consent was obtained from all patients. Thirteen patients were treated surgically with a posterior approach, and for 26 patients the Minerva CTJ was used rather than surgery, either because of high ASA scores (13 patients with ASA III and 7 patients with ASA IV) and/or because they had refused surgical treatment

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(6/26 patients) for different reasons such as religious beliefs or psychological problems.

Characteristics including age, sex, neurological deficit, etiology of the fracture, additional spinal injury, existence of metabolic diseases, smoking, outcomes of fusion or nonfusion, duration of fusion, length of stay, mean follow-up period, and complications related to the treatment were evaluated. After initial diagnosis, cervical magnetic resonance imaging (MRI) was performed to check for possible ruptured or injured ligaments. In addition, displacement and/or diastase of the odontoid process were evaluated by cervical computed tomography (CT) (Figure 1).

All patients were fitted with the Minerva CTJ within the first 24 h following diagnosis (Figure 2). The patients were followed 4 weeks after hospital discharge and then at 2-week intervals. In addition to the clinical examination, cervical X-ray or cervical CT was used to evaluate fusion during follow-up visits.

Statistical analysis was performed using SPSS 22.0 for Windows (IBM Corp., Armonk, NY, USA) with the assistance of senior statisticians. The Mann–Whitney U test was used to examine nonparametric data and ANOVA was used for parametric data. Results were considered significant at $P < 0.05$, and a 95% confidence interval (CI) was calculated.

3. Results

Of the 26 patients, 17 (65.3%) were male and 9 (34.7%) were female. The mean age was 49.03 years old (range: 16–86 years old). Type II odontoid fractures were detected in 12 patients (a mean age of 33.1 years old) after high-energy trauma and in 12 patients (a mean age of 70.1 years old) after low-energy trauma (falls) ($P = 0.039$), while the remaining two patients had sustained the fractures by diving into the shallow end of a swimming pool (Table).

Neurological deficit was found in only one patient following neurological examination at admission. Posterior displacement of the odontoid process was observed in 15 patients and anterior displacement was seen in eight patients. Three patients had no displacement in any direction ($P < 0.05$). The mean posterior displacement was 2.46 mm and the mean anterior displacement was 1.88 mm ($P = 0.044$).

Fusion occurred in 25 (96%) of the 26 patients ($P = 0.004$), and the mean time to fusion was 6.8 weeks ($P = 0.002$) (Figures 3 and 4). This varied depending on the number of fractures, the size and direction of displacement, patient age, and the presence of metabolic disease. The mean time to fusion was 5.9 weeks in patients with isolated type II fractures, but it was 10 weeks in patients with other accompanying cervical spine fractures ($P = 0.037$).

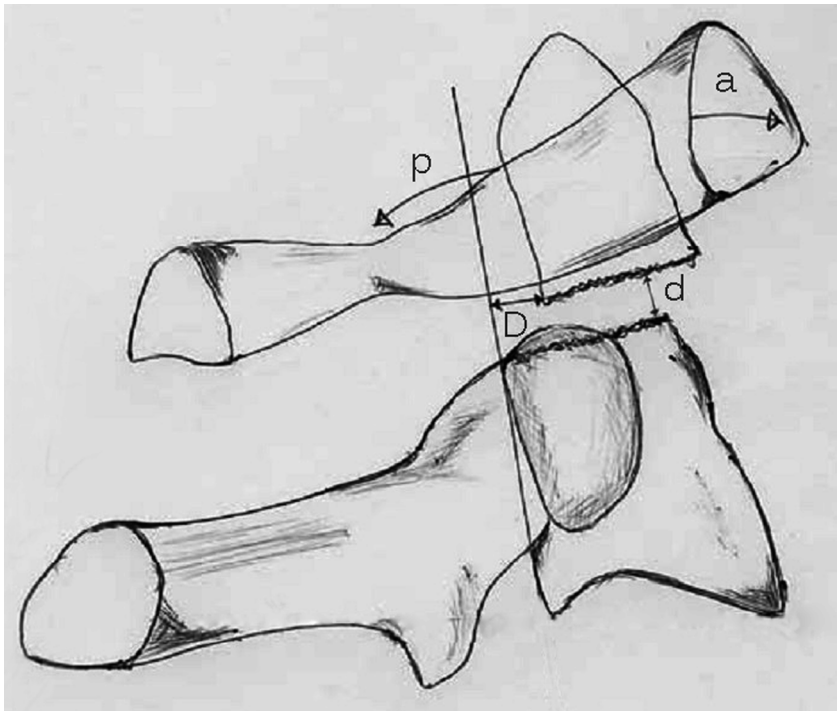

Figure 1. Sagittal illustration of C1 (atlas) and C2 (axis): a: anterior direction of displacement, p: posterior direction of displacement, D: displacement of the odontoid (mm), d: diastasis of the odontoid (mm).

Figure 2. The Minerva cervical thoracic jacket; anterior (right) and posterior view (left).

The mean time to fusion according to size, independent of the direction of displacement, was 8.5 weeks in cases with displacement of ³3 mm and 6.4 weeks in cases with displacement of £2 mm (P = 0.045). The mean time to fusion according to direction but independent of the size of displacement was 7 weeks (P = 0.034) with posterior displacement and 7.5 weeks (P = 0.039) with anterior displacement. The mean time to fusion was 10.5 weeks for patients aged ³65 years old, 6 weeks for patients between 50 and 64 years old and for those between 30 and 49 years old, and only 5 weeks for patients aged ≤29 years old (P = 0.001). The mean time to fusion was 11 weeks in patients with metabolic diseases and 5.8 weeks in patients without metabolic diseases, regardless of age (P = 0.033). The mean time to fusion in three patients with fractures associated with ligament injury was 6.6 weeks (P = 0.028).

Diastasis was seen in eight patients and was between 1 and 2 mm in size. The relationship between fracture etiology and diastase was not statistically significant (P > 0.05). In addition, the mean time to fusion in these patients was 6 weeks, which was similar to overall mean time to fusion (P = 0.031).

The mean length of hospital stay was 4 days, and the mean follow-up period was 7.3 weeks (a range of 4–20 weeks). None of the patients had any adverse events or complications due to Minerva CTJ treatment, and the mortality rate was 0%.

In the 13 surgically treated patients, the mean age was 34.09 (a range of 21–43 years old), and fusion was achieved in all patients. The mean time to fusion was 6.2 weeks. The mean length of hospital stay was 9 days, and the mean follow-up period was 7.1 weeks. One of the patients had

Table. Subject characteristics with initial and follow-up findings.

Patients	Age (years)	Sex	Etiology	Direction of displacement	Diastasis	Smoker	Neurologic status at admission	Length of stay (days)	Fusion & time (weeks)	Associated-spinal injury	Metabolic disease	Ligaments
1	81	F	Fall	Posterior - 2 mm	-	-	No impairment	8	Yes - 12	C1 anterior arc fracture	OP	-
2	25	M	High-energy trauma	Posterior - 1 mm	-	+	No impairment	2	Yes - 6	None	None	-
3	31	M	High-energy trauma	-	1 mm	+	No impairment	2	Yes - 12	None	None	-
4	55	F	Fall	Anterior - 2 mm	-	-	No impairment	4	Yes - 8	None	Osteopenia	-
5	66	F	Fall	Anterior - 3 mm	-	-	No impairment	4	Yes - 14	None	OP	-
6	19	M	Diving	Posterior - 4 mm	-	-	No impairment	7	Yes - 6	C3 spinous process fracture	None	Ruptured ALL
7	56	M	High-energy trauma	-	-	+	No impairment	1	Yes - 6	None	None	-
8	75	F	Fall	Anterior - 3 mm	-	-	No impairment	6	Yes - 16	C1 posterior arc fracture	OP + DM	-
9	40	M	High-energy trauma	Posterior - 2 mm	-	-	No impairment	2	Yes - 4	None	None	-
10	78	F	Fall	Posterior - 2 mm	1 mm	-	No impairment	7	Yes - 8	C1 anterior arc fracture	None	-
11	28	M	High-energy trauma	Anterior - 3 mm	-	-	No impairment	2	Yes - 4	None	None	-
12	16	M	Diving	Posterior - 1 mm	-	-	No impairment	1	Yes - 4	None	None	Ruptured C3-4-5 ISL
13	18	M	High-energy trauma	Posterior - 3 mm	1 mm	-	No impairment	4	Yes - 4	None	None	-
14	24	M	High-energy trauma	Posterior - 2 mm	2 mm	-	No impairment	5	Yes - 6	None	None	-
15	65	F	Fall	Posterior - 1 mm	-	-	No impairment	3	Yes - 8	None	DM	-
16	38	M	High-energy trauma	-	-	+	No impairment	1	Yes - 4	None	None	-
17	67	F	Fall	Anterior - 2 mm	1 mm	-	No impairment	5	Yes - 6	None	None	-

Table. (Continued).

18	72	M	Fall	Posterior - 5 mm	2 mm	+	Anterior cord syndrome	13	Not achieved	Jefferson fracture	DM	Ruptured TL + PLL
19	62	F	Fall	Posterior - 4 mm	1 mm	-	No impairment	5	Yes - 10	None	Osteopenia	Ruptured ALL
20	44	M	High-energy trauma	Posterior - 3 mm	-	+	No impairment	3	Yes - 4	None	None	-
21	43	M	High-energy trauma	Anterior - 1 mm	-	+	No impairment	1	Yes - 4	None	None	-
22	86	M	Fall	Posterior - 2 mm	-	-	No impairment	8	Yes - 10	C1 anterior arc fracture	OP + DM	-
23	57	M	Fall	Anterior - 2 mm	-	+	No impairment	2	Yes - 4	None	None	-
24	78	F	Fall	Posterior - 4 mm	-	-	No impairment	7	Yes - 10	None	Osteopenia	-
25	25	M	High-energy trauma	Anterior - 1 mm	-	+	No impairment	1	Yes - 4	None	None	-
26	26	M	High-energy trauma	Posterior - 1 mm	1 mm	+	No impairment	3	Yes - 6	None	None	-

ALL: Anterior longitudinal ligament, DM: diabetes mellitus, ISL: interspinous ligaments, OP: osteoporosis, PLL: posterior longitudinal ligament, TL: transverse ligament.

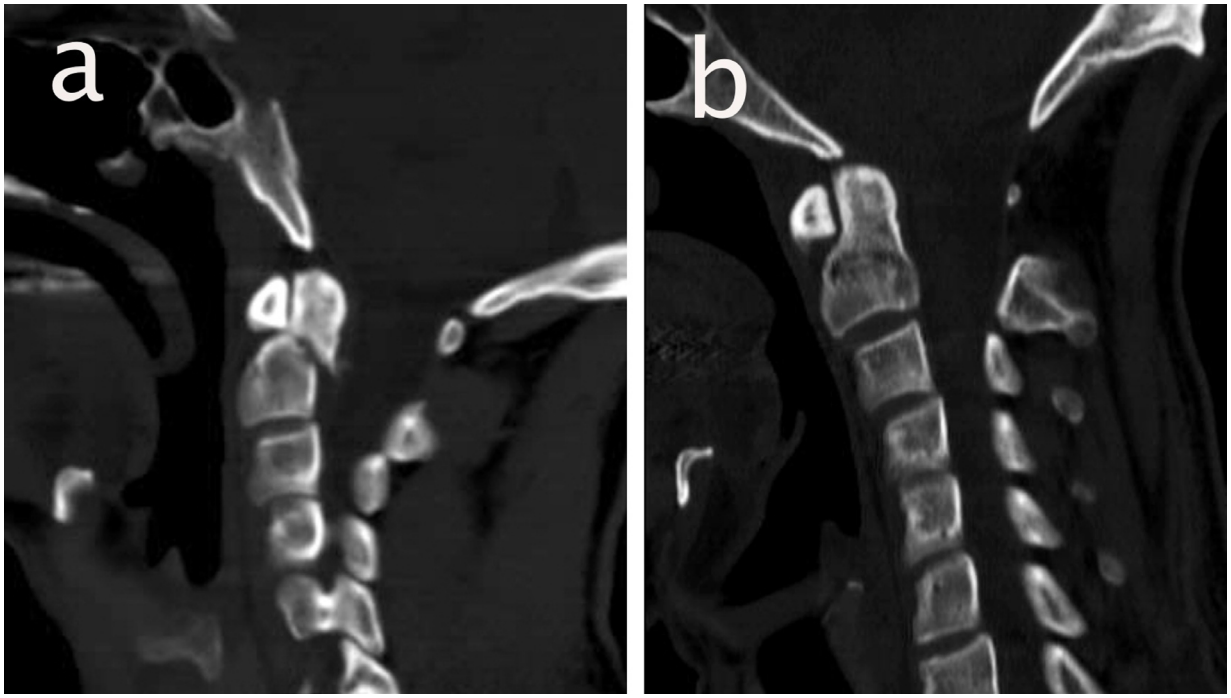

Figure 3. a) Posteriorly displaced type II odontoid fracture on sagittal cervical CT scan, b) CT sagittal view shows odontoid union at 8 weeks after Minerva CTJ application.

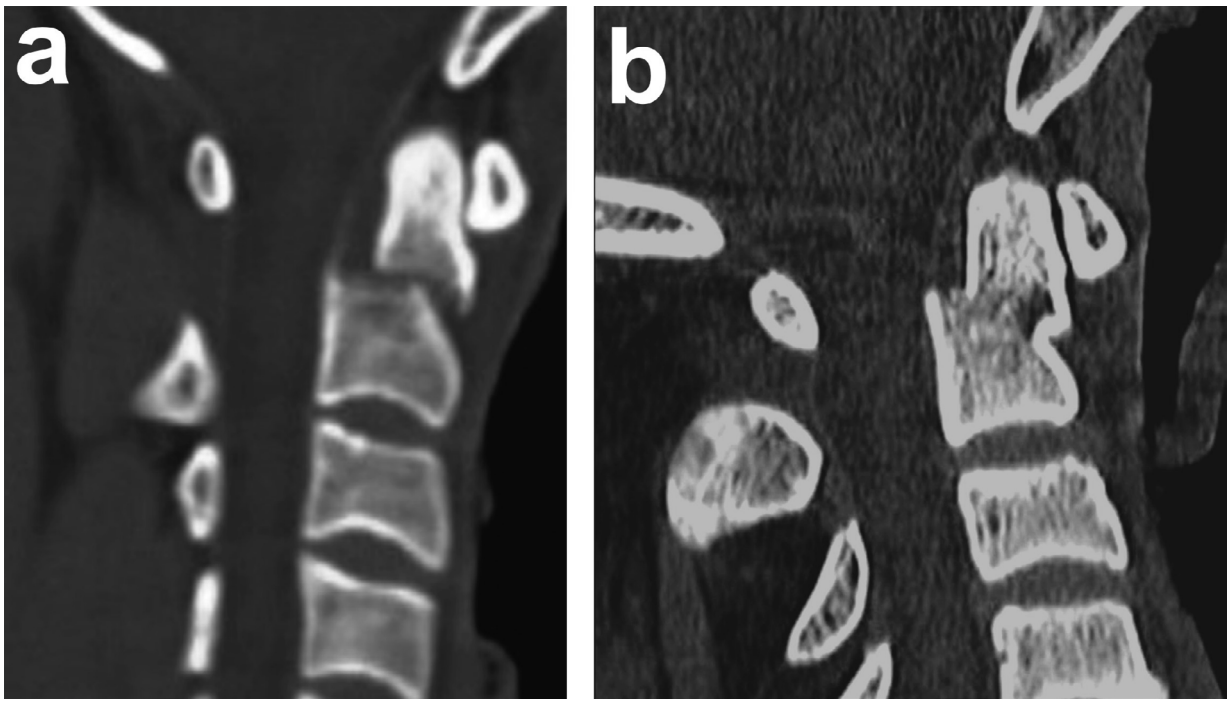

Figure 4. a) Anteriorly displaced type II odontoid fracture on a sagittal cervical CT scan, b) CT sagittal view shows odontoid union at 7 weeks after Minerva CTJ application.

a complication, a surgical-site infection only. A mortality rate of 0% was seen in these patients.

4. Discussion

The original halo vest system was developed by Perry and Nickel in 1959 to treat cervical instability due to poliomyelitis (8), and the first and extended usage of it in the treatment of cervical spine fractures was reported by Thompson (9). The main aim of this system is to provide cervical immobilization.

Biomechanical studies of the CH in cadavers with or without cervical instability revealed that the vest provides limited flexion and extension from 1.0° to 3.4°, and it appears to immobilize the spine against axial rotation (10). Unfortunately, usage of the CH is associated with a high rate of complications, mainly pin and ring loosening, which occur in up to 60% of patients, and pin infection, which occurs in 20%. (11,12) Other complications of CH use include dysphagia and pressure ulcers, which occur in up to 11% of patients (12). Facial scarring at the site of pin insertion is another distressing problem. Glover et al. reported penetrative skull and dural injuries, epilepsy, and pneumocephalus due to the overtightening of the halo pins by the patient (13). Therefore, CH usage needs proper patient education and close monitoring. For this reason, the ideal orthosis for cervical immobilization should provide adequate and effective stabilization for the healing of fractures without these risks and without additional neurologic or cosmetic damage to patients.

In the current study, we did not observe any complications related to the Minerva CTJ; in addition, the fusion rate was 96.1%. The cost-effectiveness of the Minerva CTJ is another advantage, as it is less than 70% of the cost of a CH (the Minerva CTJ costs $150, the CH is $970, transoral screwing is $2050, and posterior occipitocervical fusion costs $2850). The CTJ has been manufactured using the best design features of past proven systems with upgraded materials. Features include MRI-safe pieces, designed for comfort and ease of wear. Sawers et al. carried out biomechanical studies of orthoses and reported that cadaveric specimens with C1–C2 instability had significantly less flexion–extension and lateral-bending motion during treatment with the noninvasive halo compared with the CH (14). In addition, there is no need for anesthesia during application of the CTJ, which is another important advantage. As a result, we prefer the CTJ to the CH for our patients.

The Minerva CTJ does have a disadvantage in that the design makes it possible for the patient to dislodge or loosen it, often resulting in a requirement for more follow-up visits and adjustments. However, this appears to be the only disadvantage of the orthosis.

All patients in this report were of adult stature, so the pediatric CTJ was not used; the pediatric version is a differently designed orthosis, which should be assessed for risks and benefits independently of this report.

Lewis et al. reported a mortality rate in elderly patients with type II fractures of 4.5% when treated with the CH and 9% when treated with a collar (15). In the current study, patients treated with the CTJ had a 0% mortality rate.

Cervical spine surgeries may lead to deterioration in the condition of the patient and carries significant risks, especially for the elderly. However, CTJ treatment is a safe and cheap technique in the management of type II odontoid fractures without any complications. Kim et al. reported 20 weeks for time to fusion in surgically treated patients and 17.6 weeks in patients treated with the CH; that is, they concluded that surgical patients had a shorter bone-healing time than patients who received a CH (16). The mean bone-healing time was 7.2 weeks in the present study (a range of 4–16 weeks).

We therefore conclude that patients treated nonsurgically with the Minerva CTJ experience an overall favorable outcome without any mortality, and that this applies both to younger and older patients.

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