

A 3-year Follow-up Study on the Alternating Use of Static Splints after Metacarpophalangeal Joint Arthroplasty in a Patient with Rheumatoid Arthritis

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Abstract: Burr et al. (2002) reported the results of a 19-month follow-up study on a static splinting regimen as an alternative to dynamic extension splinting after metacarpophalangeal (MCP) joint arthroplasty. However, the long-term results of static splinting therapy have not been reported. Therefore, we conducted a 3-year follow-up study on the use of alternating static splinting in extension and flexion after MCP joint arthroplasty. Active flexion and extension of the MCP joints and grip strength were evaluated before surgery and at 12 weeks and 3 years after surgery. The range of motion (ROM) of the MCP joints and grip strength improved at 12 weeks and 3 years postoperatively. The efficacy of dynamic extension splinting after MCP joint arthroplasty indicated no change in the ROM and grip strength. The findings in this case indicate the positive long-term results of a static splinting regimen.

Key words: rheumatoid arthritis, splint, range of motion

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Introduction

Common hand deformity in rheumatoid arthritis (RA) results from the destruction and dislocation of the metacarpophalangeal (MCP) joints and ulnar deviation of the finger (Chung, Kotsis & Kim, 2004).

Hand deformities caused by RA are often treated with surgery and rehabilitation to improve a patient's hand function-associated activities of daily living (ADLs) (Mannerfelt & Andersson, 1975; O'Brien, Jones, Mullis, Mulherin & Dziedzic, 2006).

MCP joint arthroplasty with implants has been adopted for treatment of RA patients since the 1960s (Swanson, 1972), because RA can damage the MCP joints resulting in flexion and ulnar deviation deformities. Surgical intervention via MCP joint arthroplasty using Swanson implants has been performed for improving hand function.

The use of a dynamic extension splint has been rec-

ommended after MCP joint arthroplasty (Swanson, 1972). A number of studies have reported that this method results in an increased extension MCP joint range of motion (ROM), but a decreased flexion (ROM), especially in the ulnar digits (Rothwell, Cragg & O'Neill, 1997; Moller, Sollerman, Geijer, Kopyylov & Tagil, 2005). Furthermore, Blair, Shurr & Buckwalter (1984), Bieber, Weiland & Volenec-Dowling (1986), and Delaney, Trail & Nuttall (2005) indicated that there were no changes in pre- or postoperative grip strength.

We have been carrying out dynamic splinting as therapy for patients undergoing MCP joint arthroplasty, and although MCP joint extension can be improved, our experience shows that MCP flexion and grip strength decrease after surgery. This finding is consistent with those of previous reports (Blair et al. 1984). Restricted MCP joint flexion and decreased grip strength may lead to increased difficulties in performing ADLs such as gripping a knife to cut food or squeezing a towel.

On the other hand, Burr, Pratt & Smith (2002) suggested the usefulness of alternating daily the application of static extension and flexion splints. Their study reported improved extension and flexion ROM. Furthermore, as compared to the results of the method recommended by Swanson (1972), the flexion ROM was much improved.

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Table 1. Postoperative MCP joint ROM with dynamic extension splinting

	Extension (degrees)				Flexion (degrees)			
	Index	Long	Ring	Small	Index	Long	Ring	Small
Our result	26	20	16	26	60	56	46	52
Mannerfelt et al.	8	12	10	4	51	55	50	39
Goldfarb et al.	23	27	24	16	60	60	60	49

Their study also highlighted the comfort, simple design, ease of production, and low cost as added advantages of the alternating splinting method. The purpose of this study was to investigate the 3-year follow-up results of alternating static splinting after MCP joint arthroplasty.

We adopted the alternating static splinting method after MCP joint arthroplasty rather than the dynamic splint because we believe that it is easier to both manipulate the splints after being discharged and flex the MCP joints while wearing the splints.

Case

The patient was a woman in her sixties whose condition had been diagnosed as RA 14 years previously. The patient had functional motion of the shoulder, elbow and wrist. However, because of the ulnar deviation and subluxation of the fingers at the MCP joints, the patient experienced weak palmar grip. Therefore, she was surgically treated. First, Swanson implants were inserted in 4 MCP joints of her right hand to correct the ulnar drift, and the palmar subluxation as well as to relieve pain. After the MCP joint arthroplasty, dynamic splinting was performed. At the 12th postoperative week, the results were nearly the same as those reported in other studies (Mannerfelt & Andersson, 1975; Goldfarb & Stern, 2003) (Table 1).

Nine months after the initial MCP joint arthroplasty, bridging calluses developed due to bone spurs near the MCP joints of the ulnar digits. Approximately 1 year after the initial MCP joint arthroplasty, the MCP joint ROM of the ulnar digits was diminished. Therefore, the bone spurs were surgically removed and the implants in all the MCP joints were replaced. After the second MCP joint arthroplasty, we employed an alternating static splinting method.

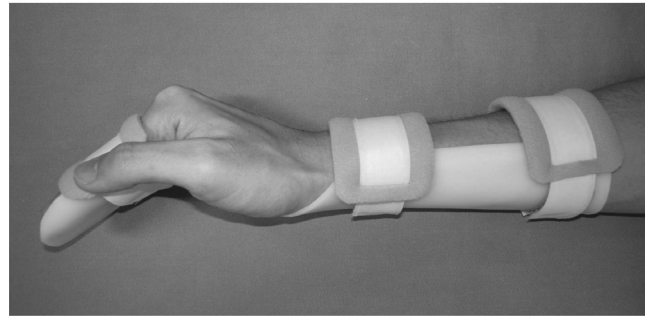
The patient was prescribed methotrexate (MTX) and prednisolone in the case of the dynamic extension splinting. However, tacrolimus hydrate and prednisolone were prescribed in the case of the alternating static splinting.

Progress and Rehabilitation Program

Evaluation

Although the postoperative rehabilitation program was completed 12 weeks after the second operation, a fol-

(a)



(b)



Fig. 1. Alternate splints of same type with splints the patient wore.

The wrist is extended at 30 degrees, the MP joints are flexed at 70 degrees, and IP joints are extended at 0 degrees (a). The wrist is extended at 30 degrees, and the MP and IP joints are extended at 0 degrees (b).

low-up rehabilitation program continued for 3 years. Objective measurements of active ROM of the MCP joints in flexion and extension were obtained with a small goniometer over the dorsum of the digital joints. The arc of active motion was determined by subtracting the active extension lag value from the active flexion value. Grip strength was measured using the JAMAR hand dynamometer.

Active flexion and extension of the MCP joints and grip strength were evaluated preoperatively (before the first and second operations) and at 12 weeks and 3 years after the second operation.

Alternating static splinting

Exercise and splinting were conducted according to the rehabilitation plan reported by Burr et al. (2002). Rehabilitation began on the third postoperative day. Static

Table 2. Rehabilitation after MCP joint arthroplasty

Time Frame	Therapeutic Intervention
3–4 wk postop	Active ROM initiated for MCP and IP joints every hour 2 splints used alternatively for 24 hours at a time Operated hand not used for ADLs at first 4 weeks
4–8 wk postop	Active ROM was continued 2 splints worn alternatively for protection and resting only Patient began to perform light activities at 4 postoperative weeks
8–12 wk postop	Active ROM was continued until 12 postoperative weeks 2 splints were worn alternatively only at night until 12 postoperative weeks The patient began using the operated hand for normal ADLs

extension and flexion splints were used for 12 weeks (Fig. 1).

With the static extension splints the MCP and interphalangeal (IP) joints were extended at 0 degrees. With the static flexion splints the MCP joints were flexed at 70 degrees, and the IP joints were extended at 0 degrees. With both splints, the wrist was extended at 30 degrees (Fig. 1). The basic aim of using the static extension splint was to maintain the MCP joints at maximum extension, whereas with the static flexion splint we aimed to achieve maximum flexion by extending the collateral ligament and articular capsule, and by excursing the extensor digitorum tendon distally.

The 2 splints were worn on alternate days for 24 hours at a time.

Postoperative rehabilitation program

The therapeutic intervention provided to the patient is shown in Table 2.

During the day, 2 types of exercises were performed. The MCP and IP joints together were actively extended and flexed, after which the MCP joints were actively flexed and extended; the IP joints were completely extended throughout. This sequence was performed 10 times every hour for 12 weeks after surgery.

The patient was advised to remove the splints every hour during the exercise during the first 4 postoperative weeks; moreover, she was instructed not to use the affected hand during these 4 weeks. After 4 postoperative weeks, the patient was allowed to use the affected hand for light ADLs such as fastening buttons and using a fork. At the 8th postoperative week, normal ADLs such as squeezing a towel and opening a tight jar were permitted. Thereafter, the patient was instructed to alternate between the 2 splints only at night until the 12th postoperative week. Therapy was completed by the end of the 12th postoperative week.

The patient was discharged three weeks after surgery, and the patient subsequently received regular outpatient treatment twice weekly for 3 months.

Results

Figure 2 shows the ROM and the grip strength of the 2 different splinting methods.

The ROM of the MCP joints before the first operation was 16 (–40/56) degrees in the index finger, 24 (–20/44) degrees in the middle finger, 12 (0/12) degrees in the ring finger, and 14 (–46/60) degrees in the little finger. The ROM of the MCP joints before the second operation was 24 (–40/64) degrees in the index finger, 40 (–26/66) degrees in the middle finger, 0 (–26/26) degrees in the ring finger, and 0 (–28/28) degrees in the little finger. The ROM at the 12th postoperative week with the use of alternating splinting was 24 (–40/64) degrees in the index finger, 46 (–20/66) degrees in the middle finger, 48 (–16/64) degrees in the ring finger, and 34 (–36/70) degrees in the little finger. The ROM three years after surgery was 32 (–40/72) degrees in the index finger, 48 (–22/70) degrees in the middle finger, 58 (0/58) degrees in the ring finger, and 32 (–40/72) degrees in the little finger (Fig. 3). The passive MCP joint extension at the 12th postoperative week for both operations was 0 degrees.

In addition, grip strengths before the first and second operations were 3.0 and 2.0 kg respectively. It increased to 6.0 kg after 12 weeks of therapy using alternating splinting, and 3 years after the second operation it increased to 8.0 kg.

Subjective patient comments indicated a preference for the alternating static splinting therapy. The patient judged dynamic extension splinting to be heavy on the hand and not easy to wear. The patient also found it difficult to flex the fingers. On the other hand, the patient judged the alternating static splinting to be lighter on the hand and easier to wear. The patient also reported increased facility in finger flexion.

Discussion

In general, dynamic splinting is implemented to maintain and increase the ROM of the MCP joints after MCP joint arthroplasty. Blair *et al.* (1984) reported that dynamic splinting increased active extension. However, it has been

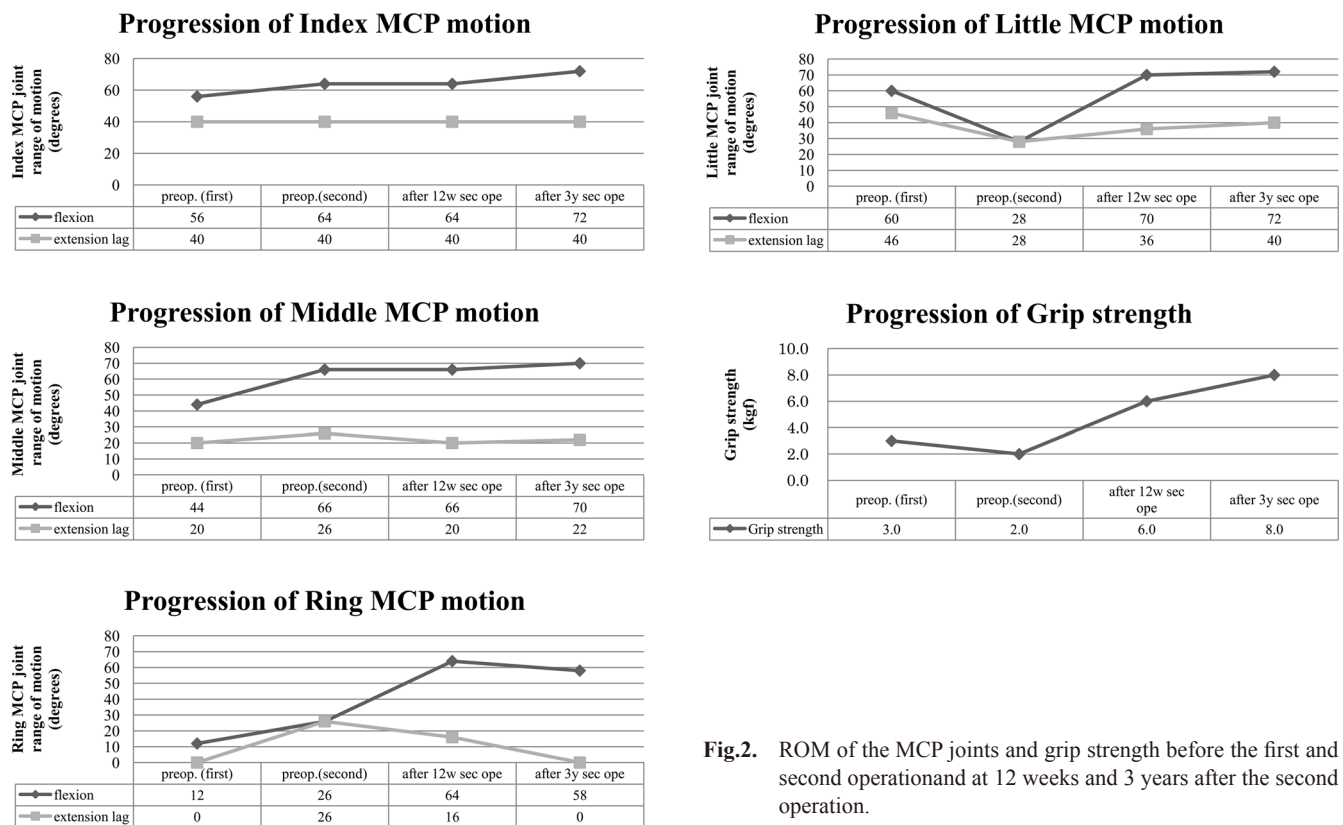


Fig. 2. ROM of the MCP joints and grip strength before the first and second operation and at 12 weeks and 3 years after the second operation.

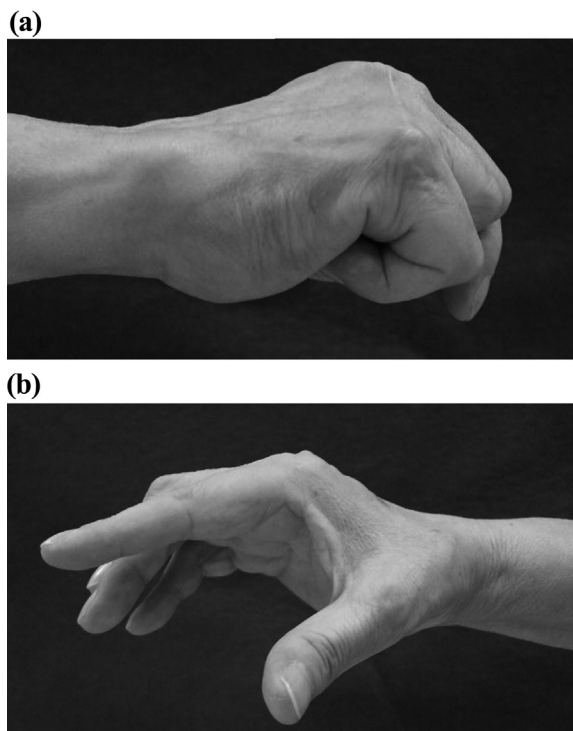


Fig. 3. Flexion (a) and extension (b) of the MCP joints three years after surgery.

reported that both active flexion of the MCP joints and grip strength using dynamic splinting decreased on average from 72 N to 62 N 54 months after surgery. O'Brien (1996) stated that there was no significant change in motion. However, our patient's motion and grip strength improved after 3 years as compared with the motion grip strength before the first and second operation, and those at 12 weeks after the second operation. el-Gammal & Blair (1993) reported that the best motion is during the first 2 years, but the ROM tends to decrease thereafter. However, our patient continued to show improved palmar grip after 3 years.

MCP joints are commonly known to be the most important joints for hand function; they contribute to 77% of the total arc of finger flexion (Moran & Berger, 2003) and are important for MCP joint flexion. However, flexing the MCP joint against the resistant forces of a dynamic splint can be very difficult for some patients (Burr et al., 2002). On the other hand, a static splint placed at MCP joint maintains the MCP joints at 70 degrees in a flexion position. Therefore, it is easy to increase the flexion angle of the MCP joint.

Active flexion ROM of the MCP joints and adequate grip strength is an important pre-requisite for various ADLs such as cutting vegetables with a kitchen knife, turning on the water tap, unscrewing the lid of a jar, or squeezing a towel. Alternating static splinting resulted in higher grip strength as compared to the grip strength

achieved with dynamic splinting after the first operation, and the grip strength further improved over 3 years.

Hume, Gellman, McKellop & Brumfield (1990) reported that the average functional ROM of the MCP joints should be 61 degrees to perform ADLs. Therefore, a flexion ROM of more than 60 degrees has to be achieved in the case of the MCP joints. In this patient, with the use of alternating static splinting, the flexion of the MCP joints was maintained at over 70 degrees for 3 postoperative years, except in the case of the ring finger. Thus, a functional ROM of the MCP joints was maintained in this patient. Three years after surgery, the increase in the ROM of the MCP joints as well as the increase in grip strength was due to fact that the patient used the affected hand frequently for ADLs 12 weeks after surgery, thus achieving MCP joint flexion.

The static splint is easy to put on and comfortable to wear; it is also aesthetically pleasing. Furthermore, this splint is not disturbed during ADLs as compared to the dynamic splint. In addition, when getting dressed or walking the outrigger of the dynamic splint sometimes damages clothes, but this does not occur with static splints.

However, the improvement in the extension ROM of the MCP joints was not as significant as that reported by Burr et al. (2002). This may be due to insufficient exercising of the affected hand.

The use of alternating static splints can be useful for the treatment of patients after MCP joint arthroplasty. The ROM of the MCP joints and grip strength achieved in the case of our patient suggests that alternating static splinting could be an effective postoperative therapy.

Conclusion

We investigated the 3-year progress of a patient with the use of alternating static splints after MCP joint arthroplasty for RA. Three years after surgery, MCP joint flexion and grip strength continued to improve. Therefore, alternating static splinting may be an effective postoperative therapy and could be used as a suitable alternative for dynamic MCP extension splinting.

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Application of Constraint-induced Movement Therapy for People with Severe Chronic Plegic Hand

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Abstract: Objective: To determine the efficacy of intense constraint-induced movement therapy (CIMT) for patients who cannot achieve finger extension due to a severe plegic hand after stroke. **Design:** Pre-post, pre-1 month follow-up, single-blinded, multi-baseline case. **Participants:** Fifteen participants who were all >12 months post-stroke. **Interventions:** Two weeks of CIMT including restraint of the nonparetic upper extremity and 6 hours of training each day. **Outcome:** There was a statistically significant effect of CIMT on upper extremity motor impairment assessed by the Fugl-Meyer Motor Assessment (FMA), the Motor Activity Log for low functioning patients (Grade 5 MAL) and Active Range of Motion (AROM). Post hoc analysis showed significant differences between pre- and post-treatment motor impairment scores, and the improvements in these scores were maintained at 1 month after completion of treatment. Improvements were mostly in the use of the involved upper extremity for bimanual activities. **Conclusions:** Intense CIMT conferred significant changes in objective measures in subjects with chronic severe plegic hand after stroke. Additional studies of the long-term benefits of this treatment on post-stroke motor impairments and related functional disabilities are warranted.

Key words: occupational therapy, hemiplegia, exercise training, rehabilitation, stroke

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Introduction

Constraint-induced movement therapy (CIMT) is used to improve motor function after stroke and to increase use of the affected hand in daily life (Taub et al., 2006; Taub, Uswatte & Pidikiti, 1999; Taub, Uswatte & Elbert, 2002; Morris & Taub, 2001). CIMT has been used for mild to moderate motor impairment (Taub et al., 2006; Taub et al., 1999; Taub et al., 1993; Winstein et al., 2003), and from moderate to “moderate to severe” (Bonifer, Anderson & Arciniegas, 2005b). The CI Therapy Research Team of the University of Alabama established the Constraint-Induced Therapy Criteria (UAB grade) (Bowman et al., 2006; Shaw et al., 2005) based on reported indication criteria for CIMT. This scale categorizes motor ability into five levels based on active range of motion, with

grade 1 indicating the highest motor ability and grade 5 the lowest, with no extension of the wrist, fingers or thumb. Most studies of CIMT have used the ability to extend the metacarpophalangeal (MP) and interphalangeal (IP) joints of each finger and thumb by at least 10° and to extend the wrist by at least 20° (UAB grade 1 or 2) as the indication for CIMT (Taub et al., 1993; Liepert et al., 1998; Liepert, Bauder, Miltner, Taub & Weiller, 2000; Kopp et al., 1999). Slightly broader criteria of extension of at least 10° at the wrist and IP joints of any two fingers, and to abduct the thumb at least 10° (UAB grade 3) have also been used (Bonifer et al., 2005a).

Based on these studies, patients with stroke must be able to extend at least 10° at the wrist and each finger and thumb to be eligible for CIMT (Bonifer et al., 2005a). Thus, many hemiplegic patients who wish to undergo CIMT have been excluded from this therapy. However, CIMT for severely affected hands without extension of fingers and thumbs: UAB grade 4 (Page & Levine, 2007), UAB grade 5 (Bowman et al., 2006; Page et al., 2007) has also been reported. Among these studies, a case report including detailed exercises showed that CIMT with up-

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per extremity braces and splints is effective for recovery of motor function and increasing use of the affected hands in daily life. Page et al. also reported CIMT combined with mental practice. These reports showed the general efficacy of CIMT, but included few subjects and did not prove that CIMT is effective for severely affected hands of UAB grade 4 or 5.

However, the outcomes suggested that CIMT for such hands can improve the ability of the patient to use household items through utilization of self-help devices and splints.

Further verification of CIMT for severely affected hands is important to enlarge the indication for CIMT, to improve motor function of more patients after stroke, and to increase use of a plegic hand in daily life. The objective of the present study was to examine the efficacy of CIMT with self-help devices/splints for severely affected hands with little or no extension of the wrist, fingers and thumb (UAB grade 4 or 5).

Methods

Participants

The participants were 15 patients with chronic hemiplegia after stroke who were admitted to the Rehabilitation Center of our hospital between November, 2009 and October, 2010. Participants (Table 1) had a mean age of 48.4 ± 9.6 years old and a mean interval after stroke of

48.6 ± 29.1 months. Thirteen had left hemiplegia. The participants submitted informed written consent to participate in this study after they received a full explanation of CIMT. The members of the rehabilitation team confirmed that each prospective participant met the following inclusion criteria: (1) at least a year after stroke, (2) UAB grade 4 or 5 (Table 2), (3) no severe speech disability (score of at least 4/6 on the Token Test), and (4) no severe dementia (score of at least 24/30 on the Mini Mental State Examination). The exclusion criteria were a history of injection for botulinum toxin for treatment of epilepsy, mental disorder (ICD-10), and spasticity.

Protocol

All participants underwent two weeks of intensive training for the affected side extremity, fingers and thumb on weekdays for six hours each day. In many reports, constraint of the non-affected hand is recommended for 90% of waking hours (Bonifer et al., 2005a; Bowman et al., 2006; Shaw et al., 2005), but since use of a severely affected hand in daily living is difficult, the constraint time needs to be reduced. Therefore, in the present study, the non-affected hand was immobilized in a padded mitt (NA-VIS Inc.) for 80% of waking hours. The time of use of the non-affected hand was recorded in a daily diary and checked by the occupational therapist (OTR) every week. The mitt was used in the action assignment to prevent the non-affected hand from seizing an object.

Apparatus

Participants who cannot extend the fingers and thumb cannot grasp and release items. Thus, we developed various splints that enable action assignments. The finger extension assisting splint (Fig. 1) utilizes the restoring force of a wire made of a shape-memory alloy to assist extension of the fingers with maintenance of the opposing extremity positions of the thumb and other fingers. The wire width may be changed in response to different levels of the active finger flexor force. The finger extension splint (Fig. 2) has Velcro tapes on the palm side of the main

Table 1. Participant characteristics

Item	Value
Age (years)	48.5 ± 9.6
Time poststroke (months)	48.6 ± 29.1
Sex (men/women)	15/0
Paralysis side (right/left)	2/13
Dominant hand affected	7
UAB grade 4 / 5	7 / 8
Motor Activity Log AOU	0.4 ± 0.7
QOM	0.5 ± 0.7

Values are shown as the mean \pm SD or n.

Table 2. UAB grade 4 or 5 active range of motion criteria

Impairment	Shoulder	Elbow	Wrist, Fingers, Thumb
Grade 4 Low MAL < 2.5			10° wrist extension at any arc of ROM, 10° extension or abduction of the thumb, extension of at least 2 additional fingers at any joint >0° and <10°
Grade 5 Low MAL < 2.5	At least <i>one</i> of the following: flexion $\geq 30^\circ$ abduction $\geq 30^\circ$ scaption $\geq 30^\circ$	Initiation*of both flexion and extension	Must be able to <i>either</i> initiate* extension of the wrist <i>or</i> initiate extension of one digit

Each movement must be repeated 3 times in 1 minute. Initiation is defined for the purposes of these criteria as minimal movement (i.e., below the level that can be measured reliably by a goniometer).

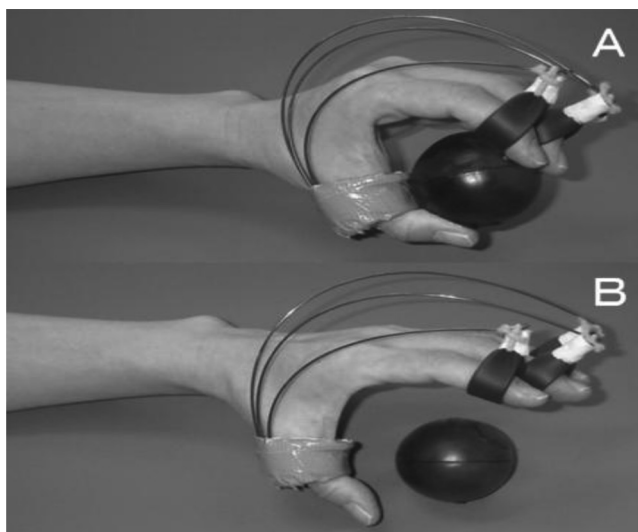


Fig. 1. A splint for assistance of finger extension. A: Motion of the participant in grasping an object. B: When the grasping force weakens, the force of the shape-memory alloy extends the fingers and the object can be released.

body, and a spoon and a pen holder may be affixed to the Velcro tapes. We also devised self-help devices on objects used in daily living to allow operation of these items with the affected hand. These devices include door knob turners, tap turners, drawer straps, terry cloth bath mitt, adaptive cups, and clothes with magnetic buttons.

Design and interventions

The study was designed as a single-blinded multi-baseline case series. Before starting training, each participant and the OTR selected three specific goals that the participant wanted to achieve in daily life after intense CIMT. For UAB Grade 4 participants, these goals were holding a rice bowl, opening and closing a refrigerator, typing on a keyboard of a personal computer, holding a telephone receiver, opening an umbrella, shooting with a rifle, putting on one's socks with both hands, putting on trousers with both hands, holding a cardboard box, holding on to a strap in an electric train, turning a tap on and off, using a knife and a fork, carrying a baby in one's arms, slipping into clothes and holding a cup. For UAB Grade 5 participants, the goals were holding a shopping bag, washing one's body, holding a form when filling it in, raising a flag for a karate referee, holding a wallet, holding a book, holding an umbrella, washing one's hands, swinging a golf club, holding a plastic bottle, drying oneself with a bath towel, holding a bag, opening and closing a door, unrolling a chart with both hands, and walking with a bag on one's arm.

Action assignments in the intensive training were performed with splints. The functional training included transferring a ball, pegging a board, building blocks, and

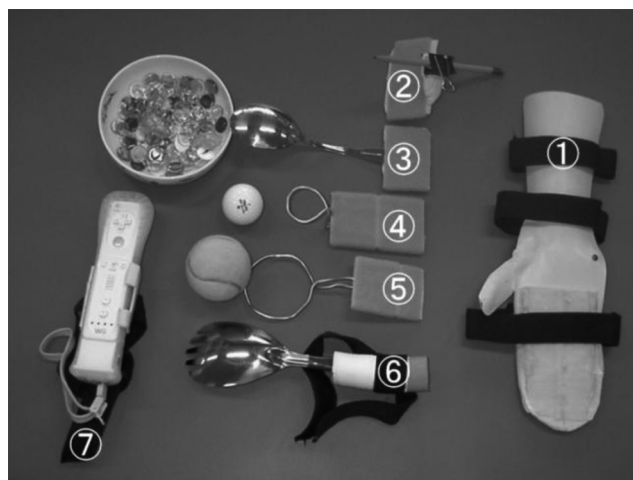


Fig. 2. Finger extension splint. (1) Main body, (2) Pen holder, (3) Spoon holder, (4) Golf ball holder, (5) Tennis ball holder, (6) Scoop holder, (7) Video-game controller holder.

shouldering an object; activity of daily living (ADL) and instrumental activity of daily living (IADL) training included dressing, washing one's body and turning a door knob; and applied behavior training included gardening, writing, drawing (painting), playing a video game, wiping a table and sweeping a floor. Participants underwent six hours of training daily under the supervision of OTRs with at least six years of involvement in CIMT and many years of experience. The same OTRs worked with the participants throughout the study.

The training content was set individually to match the affected level and character of the participant and the goals. In action assignments, "shaping" based on operant reward learning (Morris, Taub & Mark, 2006; Taub & Wolf, 1997) was used, with a gradual increase in difficulty and access. Linguistic feedback including "acclaim" was given only when the training was successful. In addition, exercise for general use of the affected hand in daily life (transfer package) (Morris *et al.*, 2006) was performed twice daily for 20 minutes in the morning and evening. Since the affected fingers could not be used practically, the non-affected hand was required for self care such as eating, going to the bathroom, bathing, dressing, and standing up, and the mitt was removed for these purposes. Additionally, since some of the participants required a walking stick or wheelchair for movement, the mitt was not used during movement due to safety considerations.

Assessments

Independent observers (OTRs not in charge of the CIMT) evaluated the participants on the day before the start of CIMT (pretreatment), one day after completion of CIMT (posttreatment), and one month after completion of CIMT (1-mo follow-up). Differences were determined

blindly by mixing of participants who received training other than intense CIMT. Fugl-Meyer assessment (FMA) (Fugl-Meyer et al., 1975) is a method for evaluation of recovery of motor function after stroke. This method is widely used (Bonifer et al., 2005a) and its test-retest reliability and validity have been verified (Gladstone, Danells & Black, 2002; Duncan, Propst & Nelson, 1983). In FMA, the degree and balance of range of motion, pain, sensation and damage to upper and lower extremities are measured. The upper and lower extremity subscales are scored on a 3-point scale from 0 to 2 (0 = cannot perform; 2 = can perform sufficiently). In the present study, only the upper extremity subscales (perfect score = 66) were used.

The modified Ashworth scale (MAS) (Bohannon & Smith, 1987) was used as a method with high reliability for quantitative evaluation of the degree of spasticity. The validity of the MAS has been confirmed specifically for the elbow (Gregson et al., 1999). With each patient in the supine position at rest, testing was conducted on the abductor of the shoulder on the plegic side, flexor of the elbow, flexor of the wrist, and flexor of the fingers by mobilizing the joint and recording the score based on the quality and degree of resistance. Each joint was scored on a 6-point scale from 0 (contraction around the joint and flexion/extension is impossible) to 5 (no increase in muscle tone). A perfect score in this test was 20.

The Active Range of Motion Test (AROM) is suitable for evaluation of active motor performance (Lin & Sabbahi, 1999). Evaluation was conducted based on the contents in the "Measurement of Joint Motion: A Guide to Goniometry" (Norkin & White, 2009). The active range of motion from a neutral position was measured for flexion and abduction of the shoulder joint on the plegic side, flexion and extension of the elbow joint, dorsal flexion of the wrist and extension of the MP and IP joints of each finger and thumb. For extension of the elbow, measurement was started from the 90° flexion extremity position.

The Motor Activity Log (MAL) includes evaluation of 30 common items in ADL and IADL, through scoring of the amount of use (AOU) and quality of movement (QOM) of the upper extremity on the plegic side based on a questionnaire (Uswatte, Taub, Morris, Vignolo & McCulloch, 2005; Van der Lee, Beckerman, Knol, de Vet & Bouter, 2004). The MAL has high test-retest reliability and validity. The MAL was modified based on a preceding study (Bowman et al., 2006) to allow evaluation of patients with low finger function of UAB Grade 4 or 5 (MAL grade 5) during CIT. In this modification, the 20 items of the standard MAL-30 that require good hand function were altered so that each action assignment required reduced motion skills.

Statistical analysis

Statistical analysis was performed to examine the hypothesis that significant effects of intense CIMT are indicated by FMA, MAS, and AROM evaluation of participants of UAB Grade 4 or 5. Differences among pretreatment, posttreatment, and 1-mo follow-up scores for the FMA, MAS, AROM, and Grade 5 MAL were tested. Since all test data were normally distributed, repeated-measures analysis of variance (ANOVA) was used, followed by multiple comparison using a Tukey post-hoc test. Calculations were performed in EXSAS ver. 7.5 for Windows and STATCEL ver. 2 for Windows Microsoft Excel add-in software.

Results

All participants underwent intense CIMT according to the predetermined protocol. The mean time of use of the mitt based on self-recorded diaries was 83% of waking hours. All pretreatment, posttreatment, and 1-mo follow-up scores are shown in Table 3. The FMA score for upper extremity motion showed significant improvement for participants in both Grades 4 and 5. Post hoc analysis indicated significant differences between pre- and posttreatment scores for both grades, and the mean FMA scores increased by 12.2 and 15.5 ($P < 0.01$, $P < 0.05$) for Grades 4 and 5, respectively. The effect was maintained for both grades at 1-mo follow-up (post vs. 1-mo follow-up: Grade 4, $P = 0.64$; Grade 5, $P = 0.94$). The MAS scores showed a significant attenuation effect on spasticity for Grades 4 and 5, with post hoc analysis revealing significant differences between pre- and posttreatment scores (Grade 4, $P < 0.01$; Grade 5, $P < 0.05$). The effect was also maintained at 1-mo follow-up (post vs. 1-mo follow-up: Grade 4, $P = 0.45$; Grade 5, $P = 0.92$).

There were significant differences between pre- and posttreatment and between pretreatment and 1-mo follow-up AROM scores for Grade 4 cases for shoulder flexion, elbow extension, wrist extension, and finger extension, but only small differences between posttreatment and 1-mo follow-up scores for these motions. For Grade 4, there were also only small differences among pretreatment, posttreatment, and 1-mo follow-up AROM scores for shoulder abductor and elbow flexion. For Grade 5 cases, there were significant differences between pre- and posttreatment and between pretreatment and 1-mo follow-up AROM scores for shoulder flexion and abductor, elbow flexion and extension, but only a small difference between posttreatment and 1-mo follow-up scores for these motions. There were only small differences among pretreatment, posttreatment, and 1-mo follow-up AROM scores for wrist extension and finger extension in Grade 5 cases. P values for the significant differences in AROM

Table 3. Summary of scores for outcome measures

Measures		Pretreatment	Posttreatment	1-mo Follow-up
FMA UE score	Grade 4	33.1 (6.9)	45.3 (2.5)**	43.6 (2.8)**
	Grade 5	11.5 (10.0)	27.0 (16.7)*	27.6 (17.5)*
MAS score	Grade 4	8.1 (2.0)	12.1 (1.8)**	11.3 (2.3)*
	Grade 5	7.8 (2.9)	11.2 (2.5)*	11.3 (2.7)*
AROM				
Shoulder flexion	Grade 4	112.9 (15.2)	139.3 (18.6)*	140.0 (18.3)*
	Grade 5	38.8 (27.2)	103.1 (37.5)**	103.1 (37.1)**
Shoulder abductor	Grade 4	96.4 (24.8)	120.7 (24.6)	120.7 (24.7)
	Grade 5	58.1 (12.2)	80.6 (11.2)**	80.6 (12.4)**
Elbow flexion	Grade 4	116.4 (19.9)	125.7 (20.1)	125.7 (18.4)
	Grade 5	21.9 (15.3)	48.8 (10.3)**	46.9 (11.6)**
Elbow extension	Grade 4	34.3 (11.3)	56.4 (15.7)*	57.1 (15.5)*
	Grade 5	8.8 (12.5)	40.0 (15.8)**	41.3 (11.9)**
Wrist extension	Grade 4	15.7 (3.5)	31.4 (6.9)**	31.4 (6.9)**
	Grade 5	8.1 (3.7)	12.5 (4.6)	13.8 (5.2)
Finger extension	Grade 4	24.3 (3.5)	54.3 (10.6)**	52.1 (12.2)**
	Grade 5	1.3 (2.3)	1.9 (3.7)	1.9 (3.7)
Grade 5 MAL AOU	Grade 4	0.6 (0.8)	2.0 (1.3)**	2.1 (1.4)**
	Grade 5	0.3 (0.5)	1.0 (1.2)**	1.1 (1.3)**
Grade 5 MAL QOM	Grade 4	0.7 (0.8)	2.0 (1.3)**	2.1 (1.4)**
	Grade 5	0.3 (0.6)	1.1 (1.3)**	1.2 (1.4)**

Values are shown as the mean \pm SD ; * $P < .05$. ** $P < .01$.

Table 4. Effect size (Cohen d) for each post hoc comparison

Measure		Pre vs. post	Pre vs. 1-mo	Post vs. 1-mo
FMA UE	Grade 4 Score	3.34	3.02	0.28
	Grade 5 Score	1.06	1.17	0.04
Grade 5 MAL AOU	Grade 4 Score	1.3	1.36	0.07
	Grade 5 Score	0.84	0.89	0.07
Grade 5 MAL QOM	Grade 4 Score	1.26	1.34	0.12
	Grade 5 Score	0.84	0.89	0.07

scores are given in Table 3.

In the Grade 5 MAL evaluation, the changes in mean AOU from pre- to posttreatment were 1.4 and 0.7 for Grades 4 and 5, respectively. Post hoc analysis revealed significant differences between pre- and posttreatment and between pretreatment and 1-mo follow-up for Grades 4 and 5 (both $P < 0.01$). There were only small differences between posttreatment and 1-mo follow-up scores for Grades 4 and 5, indicating that AOU was maintained at 1-mo follow-up (post vs. 1-mo follow-up: Grade 4, $P = 0.48$; Grade 5, $P = 0.46$). The MAL evaluation showed a significant effect of CIMT on QOM, with changes in mean values of QOM from pre- to posttreatment of 1.3 and 0.8 for Grades 4 and 5, respectively. Post hoc analysis showed significant differences between pre- and posttreatment and between pretreatment and 1-mo follow-up for Grades 4 and 5 (both $P < 0.01$). There were only small differences between posttreatment and 1-mo follow-up

scores for Grades 4 and 5 (post vs. 1-mo follow-up: Grade 4, $P = 0.24$; Grade 5, $P = 0.45$).

A Cohen d test (Cohen, 1988) was used for post hoc analysis of pre vs. post, pre vs. 1-mo follow-up, and post vs. 1-mo follow-up scores, and each effect size was calculated (Table 4). At least two specific goals established by the participant before starting intense CIT were attained. The specific goals included actions not requiring active finger extension.

Discussion

In this study, we verified the efficacy of intense CIMT for severely affected hands that did not meet the usual indication for CIMT. All participants had an interval of at least one year after stroke, and rehabilitation specialists had judged that motor dysfunction would be maintained. However, our results showed that intense CIMT

for severely affected hands of UAB Grades 4 and 5 is an effective regimen that can improve affected-side upper extremity functions in the chronic phase and increase the active use of paralyzed hands, with maintenance of these effects for at least a month after CIMT.

Functional outcome measures

The mean FMA score for the upper extremity in Grade 4 participants improved by 12.2 from pre- to post-treatment, and the effect size was 3.34. This result compares favorably with the effect sizes of 1.03 in Page et al. (Page, Levine & Hill, 2007), with UAB Grade 2 as the indicator, and of 0.62 in Bonifer et al. (Bonifer, Anderson & Arciniegas, 2005a), with UAB Grade 3 as the indicator. The mean FMA score in Grade 5 participants improved by 15.5 from pre- to post-treatment, and the effect size was 1.06, similar to that in Page (Page, Levine, Leonard, Szaflarski & Kissela, 2008).

The MAS results showed that intervention with intense CIMT significantly attenuated spasticity for Grades 4 and 5, and that the effect was maintained for at least one month. The mean pretreatment score for all participants was approximately *2/point*, equivalent to spasticity, and showed an increase in muscle tone for almost all ranges of motion. Intensive training with repeat grasping/releasing with an affected hand with strong spasticity and not allowing extension may strengthen spasticity. However, using a splint to assist extension of the fingers in intensive training may attenuate spasticity of the fingers and wrist.

The AROM results showed that intervention with intense CIMT significantly improved shoulder flexion, elbow extension, wrist extension and finger extension for Grade 4 cases, but did not improve shoulder abduction and elbow flexion. The combination of joint motions that showed improvement has a different pattern from that of the flexor cooperative motion of the upper extremity/hand of the affected side. Thus, it seems that the intervention subdivided motions in Grade 4 cases. In Grade 5 cases, improvement occurred only in the proximal parts of the upper extremity at the shoulder and elbow joints, while wrist extension and finger extension in the distal parts were not improved. This is important for determining indication criteria for therapy for finger and wrist extension, since the result suggest that UAB Grade 4 is the lower limit of the indication for intense CIMT to increase practical use of affected hands in daily life.

The results of Grade 5 MAL indicated that intense CIMT significantly improved the AOU and QOM of the affected hand in daily life for cases of Grades 4 and 5. In a study of CIMT in patients of UAB Grades 2–4 with traumatic brain injury in the chronic phase (Shaw et al., 2005), the effect size between pre- and post-treatment AOU was 1.4 for Grade 4 cases, which is almost the same

as the value of 1.3 in our Grade 4 participants. In Grade 5 MAL evaluation of CIMT, the effect size between pre- and post-treatment is considered to be significant and may be simpler and larger compared with that of standard MAL. The subjects who participated in CIMT had specific goals that might have motivated them to use their plegic hands. Placing devices on items for achieving specific goals to make them easier to use may also be beneficial for improving use of an affected hand in the real world.

Constraint of non-affected hands

Our recommended time for which non-affected hands were constrained with mitts was over 80% of waking hours. In general CIMT, constraint for 90% of waking hours is used for cases of Grades 1–3, but in intense CIMT in patients of Grades 4 and 5, eating and standing up are not possible with the affected hand, and 80% is the practical upper limit. Several reports (Taub et al., 1999; Taub & Wolf, 1997) have shown that constraint of non-affected hands is not important among the elements of CIMT. Therefore, we believe that the reduced constraint time in this study did not influence the effects of CIT.

Splints

Since participants with a severely affected hand with little or no extension of the fingers and thumb cannot grasp items, it was difficult for them to conduct the action assignments for intensive training for six hours each day. This may be one of the reasons why severely affected hands have previously been excluded from CIMT. However, in the present study, by using a splint to assist finger extension, the participants were able to fasten, pinch, grasp, rotate, and release items, and to draw, write, and strike in the same way as participants meeting the common indication criteria for CIMT. Therefore, they were considered to have undergone effective treatment for the affected extremity. Since these splints may be made easily and inexpensively, they can be widely used in a variety of rehabilitation settings.

Study Limitations

It is difficult for CIMT participants with little or no extension of the fingers and thumb to undergo intensive training involving repeated manipulation of items with the affected hand. Therefore, to make the intensive training effective for such participants, combined use of traditional rehabilitation techniques with a therapist's hands and therapy utilizing splints and self-help devices was performed. This is a disadvantage since it increases the cost of CIMT. Furthermore, since splints and self-help devices have their own therapeutic effects on affected hands, their use might bias the results of the tested effects

of CIT. In addition, the sample size in this study was relatively small and further investigation is needed to verify the findings in the general population.

Conclusion

The results of the study suggest that intense CIMT for severely affected hands with little or no extension of the fingers and thumbs improves the functions of the affected-side upper extremity, despite the hand not meeting the indication criteria for conventional CIMT. However, for a hand with no finger extension, the finger function was unchanged and functional recovery of the hand to the point that it could be used practically was not found, despite increased assistive use of the hand in daily life. We conclude that there is a need to develop CIMT further for severely affected hands and to enlarge the indication for CIMT.

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Community-based Interventional Programmes for Family Caregivers of Persons with Traumatic Brain Injury

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Abstract: The purpose of this study is to verify the effects of interventional programmes to reduce the psychological distress of family caregivers of persons with traumatic brain injury. An interventional programme was conducted over five sessions which were held for four hours and took place once a week, involving a total of 16 persons. The interventional programme mainly consisted of providing basic knowledge of traumatic brain injury, ways of treating cognitive dysfunction and training of communication skills applying assertiveness training. Evaluation criteria were GHQ-30, SDS, STAI, and RAS as assessment measures and were analysed before and after the intervention and at three month and six month follow-ups after the interventional programme. A considerable reduction of the mean score was statistically recognised compared with SDS at pre-intervention and after the six month follow-up, and STAI at pre-intervention and post-intervention in the analysis of variance of pre- and post-intervention and follow-ups.

Key words: traumatic brain injury, family interventions, communication skills training, assertiveness training for family

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Introduction

Cognitive dysfunction caused by traumatic brain injury affects the ability to respond to and process information, memory, attention, and stimulus of patients (Lezak, 2004). Among patients with traumatic brain injury, some exhibit neurobehavioral changes such as aggressiveness and self-centeredness and have difficulty performing daily living and social activities. Furthermore, aggressive language and behaviour are said to worsen, whereas other disability indexes improve over time (Brooks, Campsie, Symington, Beattie & McKinlay, 1987). Family members are confused by such changes in patients with traumatic brain injury and feel the burden of their care. Hall et al. (1994) indicate that the behavioural factors which cause family caregivers of persons with traumatic brain injury to experience the burden are those such as severe emotional outbursts, self-centeredness, slowness, forgetfulness

and aggressiveness. In addition, Kreutzer, Gervasio, and Camplair (1994a) report behaviour problems and emotional and personality disturbances as behavioural factors (Kreutzer, Marwitz & Kepler, 1992), while Brooks and McKinlay (1983) report personality change as a factor.

Moreover, evidence has been accumulated from recent decades of research that most family caregivers have psychological distress such as depression and anxiety caused by the neurobehavioral change of patients with traumatic brain injury (Perlesz, Kinsella & Crowe, 1999). Despite this evidence, both domestic and international, few intervention studies have been conducted to reduce the psychological distress of family caregivers of persons with traumatic brain injury (Boschen, Gargaro, Gan, Gerber & Brandys, 2007). Previous international studies have been trying to reduce the psychological distress of family caregivers through interventions such as information instruction on cognitive dysfunction (Sanguinetti & Catanzaro, 1987), behaviour management programmes (Carnevale, Anselmi, Busichio & Millis, 2002), stress management programmes (Singer et al., 1994) and problem-solving training (Rivera, Elliott, Berry & Grant, 2008). However, methodology problems have been reported, such as most of the preceding studies using as-

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assessment measures which are not effectively standardized, and information is lacking regarding the contents of the interventions (Sinnakaruppan, Downey & Morrison, 2005). On the other hand, the authors' prior study (Suzuki & Motomura, 2009) showed brain contusion patients' emotional and behavioural changes, such as Shouting out loudly with anger and Violent behaviour, were undermining the family caregivers' mental health. Also, the authors' clinical experience indicated that family caregivers are struggling with communication with patients who are experiencing emotional and behavioural changes due to the offensive behavior cannot be helped or the need to be quietly patient without saying anything because a warning might adversely promote anger. Kreutzer, Gervasio, and Camplair (1994b) in research using The Family Assessment Device (FAD) point out communication problems between primary caregivers and patients by referring to primary caregivers who could not frankly and clearly express their thoughts and feelings, and in some instances expressed anger and aggressiveness toward patients. Therefore, we conducted communication skills training applying assertiveness training as a communication method to express oneself without anxiety and tried to reduce the psychological distress of family caregivers. The concept of assertiveness originated in the USA and is a communication skill used to express oneself without anxiety based on maintaining one's own opinions while respecting the opinions of others (Alberti & Emmons, 2008). The assertiveness training method was originally established for persons with psychosocial problems (Riley & McCranie, 1990). Recent studies of occupations with high stress have been carried out (Johnson, 1993; Kilkus, 1993), and assertiveness training is used as part of interpersonal effectiveness training in Japan (Suzuki, Kanoya, Katsuki & Sato, 2007).

Aims

The purpose of this study is to verify the effect of an interventional programme which uses communication skills training as a core, applying assertiveness training in order to reduce psychological distress of family caregivers of persons with traumatic brain injury.

Method

Subjects

The participants were recruited from family members (240 related members) of persons with traumatic brain injury within the Kinki area of Japan. Preconditions for joining were: (1) a patient treated for traumatic brain injury; (2) a feeling of difficulty communicating with the patient; and (3) the ability to participate in the entire interventional programme schedule. Moreover, the number

of candidates was limited to 20 persons in total (10 persons at each meeting site) because the interventional programme consisted of communication skills training with role-playing. After a three-month period from the start of recruitment, we received 16 applicants and all of the 16 applicants fulfilled the preconditions. We randomly divided the 16 applicants in half, allocating them to Kobe and Osaka sites, and conducted the interventional programme. This study was approved by the ethics committee of Kobe University Graduate School of Health Science (Date of approval, December 8th, 2009).

Assessment measures

The following assessment measures were used for evaluation of the degree of psychological distress and assertiveness of family caregivers.

1. The General Health Questionnaire-30 (GHQ-30) (Goldberg, 1978)

This is an assessment measure consisting of 30 items in a self-administered questionnaire. It is a screening device for clarifying the mental health status of the respondent. Higher scores indicate lower mental health. The GHQ-30 Japanese version was used (Nakagawa & Obo, 1985).

2. Self-rating Depression Scale (SDS) (Zung, 1965)

This is an assessment measure consisting of 20 items in a self-administered questionnaire to examine depression in the respondent. Higher total scores indicate greater depression. SDS Japanese version was used (Fukuda & Kobayashi, 1983).

3. Stated-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch & Lushene, 1970)

This is an assessment measure consisting of 40 items in a self-administered questionnaire. 20 items pertain to Stated Anxiety, which examines how the patient feels at the moment moment' and 20 items pertain to Trait Anxiety, which inquires about the general feeling of the subject. Higher total scores indicate greater anxiety. STAI Japanese version was used (Mizuguchi, Shimonaka & Nakasato, 1991).

4. Rathus Assertiveness Schedule (RAS) (Rathus, 1973)

RAS is an assessment measure consisting of 30 items assessing assertiveness. In this study, we followed the RAS scoring method. Each item is scored from -3 to +3 excluding 0. +3 means very characteristic of me, or extremely descriptive and -3 means very uncharacteristic of me, or extremely non-descriptive. The scale ranges from -90 (least assertive) to +90 (most assertive). The higher the score the more assertive the respondent is. RAS is multipurpose and has been widely utilized including assertiveness training in adolescent character development enhancement programs for high school students (Kessler, Ibrahim & Kahn, 1986), the effect of assertiveness train-

ing for sociophobic patients (Cottraux, Mollard & Defayolle, 1982) and a study of anxiety and assertiveness in the relatives of alcoholics (Schuckit, 1982). It is possible to use RAS in the field of Health and Welfare. The reliability and validity of RAS has been verified by several researchers (Linehan & Walker, 1983; McCartan & Hargie, 1990). RAS Japanese version was used (Shimizu *et al.* 2003).

Procedure

The participants were explained the purpose and method of the study, and consent to participate in this study was granted. The descriptive information regarding the participants and the patients with traumatic brain injury was collected and confirmed, and we received answers to the assessment measures of GHQ-30, SDS, STAI, and RAS which was set as the pre-intervention variable. We conducted the interventional programme a total of five times, once weekly, for four hours each time. After the fifth session, we once again received answers to the assessment measures and set this as the post-intervention variable. At three months and six months after finishing the interventional programme, we mailed assessment measures to the participants as follow-up variables. After finishing the interventional programme at the Kobe site, we conducted an interventional programme of exactly the same content and frequency for the participants of the Osaka site. All of the participants participated in the entire interventional programme schedule and replied to all of the assessment measures.

Interventional programme

The interventional programme was mainly structured as Basic knowledge of traumatic brain injury, Methods for coping with cognitive dysfunction and Communication skills training. The operation of the interventional programme was directed by occupational therapists including the author who were schooled in assertiveness training and well-experienced in the rehabilitation of traumatic brain injury patients. Two occupational therapists assisted with the operation of the interventional programme during each session.

1. Basic knowledge of traumatic brain injury

We provided basic information regarding disturbance of attention, memory disturbance, dysexecutive behaviour, and emotional and behavioural changes.

2. Methods for coping with cognitive dysfunction

We provided various coping strategies to family caregivers for the above cognitive dysfunctions, including errorless learning for memory disturbance. Errorless learning allows patients to store information effectively, and immediately correct mistakes when the patient is learning. Memory aids adaptation. We explained how to both adapt memory aids to the needs of the patient, and

improve them according to the patients' conditions. With regard to emotional and behavioural changes, referring to "Assessment and management of behaviour problems associated with traumatic brain injury" by Ponsford, Sloan, and Snow (1995), a method of responding to problematic behavior of patients utilizing 6 factors was explained: Environmental arrangement, positive enhancement, time out, passive attitude, supportive attitude and records. Environmental arrangement acts to eliminate environmental factors which tend to induce problematic behaviour. Positive enhancement provides a bonus, encourages, praises, and notices when good behaviour is performed. Time-out has the participant ignore the problematic behaviour when it does not stop, leave the room, and isolate the patient. In Passive attitude criticising, blaming, and pushing or prodding must be absolutely avoided. In Supportive attitude always maintain support for the family member. (f) Regarding Records a record of problematic behaviour must be maintained in each case.

3. Communication skills training

Assertiveness training followed the standard guidelines and principles suggested by the authors on assertiveness (Alberti & Emmons, 2008). We explained the basis and information of assertiveness training by distributing written information on the subject. Role-playing of assertive behaviour was practiced through coaching and demonstration aids by the directors and other participants. The following roleplay method was suggested to family caregivers to convey their own wants to patients with behaviour problems stress free, while respecting the other person.

- (1) Identify the problem behaviour through explaining the situation which gives rise to the problem behaviour of the patients.
- (2) Present the request and suggestion which the participant carried out regarding the problem behaviour.
- (3) Assign participants to the roles of patient and caregiver. The participants provide information on the patient's expected response and way of speaking in order for the role playing member to act easily.
- (4) Encourage other participants to observe the roleplay and provide positive and negative feedback on the focused objectives of the request and suggestion, the ability to voice feelings, and intention to understand the patient.
- (5) Revise the request or suggestion based on the participants and leaders discussion of the contents of the feed-back.
- (6) Repeat the roleplay taking into account the revised request and suggestion methods.

Statistical analyses

SPSS (Statistical Package for Social Sciences v16 for Windows) was used for the statistical analyses. In order to

Table 1. Descriptive information of families and patients

Participants					Patients		
Sex	Age	The family relationship with the patients	Length of caregiving	No. of others in home	Sex	Age	Barthel Index
F	53y	Mother	5y	2	M	24y	90
F	57y	Mother	15y	2	F	29y	80
F	61y	Mother	15y	3	M	32y	60
F	59y	Mother	13y	3	M	30y	95
F	50y	Wife	8y	1	M	50y	80
F	49y	Mother	8y	2	M	26y	95
M	68y	Father	6y	4	F	34y	100
F	65y	Mother	11y	0	M	38y	85
F	44y	Mother	8y	2	M	20y	65
F	60y	Mother	5y	0	M	35y	100
F	75y	Mother	17y	0	M	46y	100
F	47y	Wife	6y	2	M	43y	90
M	60y	Father	11y	2	M	29y	100
F	75y	Mother	10y	2	F	41y	100
F	39y	Wife	3y	2	M	39y	60
F	66y	Mother	19y	2	M	34y	95

Note. M=Male; F=Female.

study the relationship between assertiveness and psychological distress, we conducted regression analysis based on setting the pre-intervention GHQ-30, SDS, and STAI each as dependent variables and RAS as an independent variable. We also conducted repeated measure analyses of variance in order to analyse the variance of variables from pre-intervention, post-intervention, and follow-ups (after three months and after six months) for verification of the effect of the interventional programme. If a significant difference in variance analyses was determined, *post-hoc analyses* were performed. Tukey's honestly significant difference test was used for multiple comparisons.

Results

Descriptive information of family participants and patients

Table 1 shows descriptive information of family participants and patients. Family participants consisted of two males and 14 females, between 39 and 75 years of age ($M=58$, $SD=10.5$), and 13 were parents and three were spouses. The duration of care giving was between 3 and 19 years ($M=10$, $SD=4.7$). The number of other persons living with each family participant and patient was between 0 and 4 persons ($M=1.8$, $SD=1.1$), while the numbers of patients living with persons other than the family participant was 13 males and three females. Their ages were between 20 and 50 years old ($M=34.4$, $SD=8.2$). The Barthel Index (Mahoney & Barthel, 1965) was used for the functional evaluation of daily living activities of the patients. This 10-item assessment tool evaluates physical dependence in daily living activities. The scoring range of

the Barthel Index is between 0 and 100 points and a higher score indicates a greater independence in daily living activities. The Barthel Index of the patients was between 60 and 100 points ($M=87.2$, $SD=14.4$).

The relationship between assertiveness and psychological distress

A regression equation called $SDS=46.5200.240xRAS$ was formulated. This regression equation was more significant at $p=0.043$ than the analysis of variance table, and the coefficient of regression was also significant at $p=0.043$. However, the coefficient of determination R^2 was small at 0.262 and too low for prediction accuracy. Although a multiple regression analysis was conducted using a forced entry method by entering factors, such as the length of caregiving and the Barthel Index, which were considered to be related ethically, there was no significance at $p=0.255$ in the analysis variance table, and a multiple regression equation, which could be significant, could not be formulated.

Verification of the effectiveness of the interventional programme

1) GHQ-30

The mean score for pre-intervention was 12.63 ($SD=8.38$), for post-intervention was 7.88 ($SD=7.27$), after the three-month follow-up was 10.81 ($SD=8.72$) and after the six-month follow-up was 8.56 ($SD=7.77$). Although the mean score for post-intervention decreased compared to pre-intervention, it increased again after the three-month follow-up and then again decreased after the six-month follow-up. There was no significant difference

Table 2. Means, SD, and comparison of means—GHQ-30, SDS, STAI, and RAS—pre- and post-intervention and follow-up

		<i>M</i>	<i>SD</i>	rep ANOVA		Tukey HSD	
				<i>F</i>	<i>p</i> value*	<i>p</i> value**	
GHQ-30	Pre	12.63	8.38	2.217	0.099		
	Post	7.88	7.27				
	Follow-up (3 M)	10.81	8.72				
	Follow-up (6 M)	8.56	7.77				
SDS	Pre	48.88	8.12	2.966	0.042	Pre—Follow-up (6 M)	0.045
	Post	44.63	7.26				
	Follow-up (3 M)	45.19	8.72				
	Follow-up (6 M)	44.00	9.95				
STAI (Stated anxiety)	Pre	52.88	12.18	3.538	0.042	Pre—Post	0.033
	Post	45.69	13.91				
	Follow-up (3 M)	49.56	14.62				
	Follow-up (6 M)	49.19	14.73				
STAI (Trait anxiety)	Pre	55.81	11.65	0.544	0.655		
	Post	52.94	12.11				
	Follow-up (3 M)	52.31	16.53				
	Follow-up (6 M)	53.06	15.40				
RAS	Pre	−10.88	22.86	2.450	0.076		
	Post	−7.13	27.26				
	Follow-up (3 M)	−0.56	35.14				
	Follow-up (6 M)	−8.38	25.65				

M=Mean; SD=Standard deviation. * repeated measure ANOVA, ** multiple comparison (Tukey HSD).

in the comparison of mean scores ($F=2.217$, $p=0.099$) at the time of measurement (Table 2).

2) SDS

The mean score for pre-intervention was 48.88 ($SD=8.12$), for post-intervention was 44.63 ($SD=7.26$), after the three-month follow-up was 45.19 ($SD=8.72$) and after the six-month follow-up was 44.00 ($SD=9.95$). Although the mean score at post-intervention decreased compared to pre-intervention, it again increased after the three-month follow-up and then again decreased after the six-month follow-up. At the time of measurement, there was a significant difference ($F=2.966$, $p=0.042$) when comparing the mean scores, and the result of post-hoc analysis shows that there was a statistically significant decrease ($p=0.045$) when comparing the mean scores of pre-intervention and after the six-month follow-up (Table 2).

3) STAI (Stated anxiety)

The mean score for pre-intervention was 52.88 ($SD=12.18$), for post-intervention was 45.69 ($SD=13.19$), after the three-month follow-up was 49.56 ($SD=14.62$) and after the six-month follow-up was 49.19 ($SD=14.73$). Although the mean score at post-intervention decreased compared to pre-intervention, it increased again after both follow-ups. There was a significant difference when comparing the mean scores ($F=3.538$, $p=0.042$) at the time of measurement, and the result of post-hoc analysis shows that there was a statistically significant decrease ($p=0.033$) comparing pre-intervention and post-intervention mean scores (Table 2).

4) STAI (Trait anxiety)

The mean score for pre-intervention was 55.81 ($SD=11.65$), for post-intervention was 52.94 ($SD=12.22$), after the three-month follow-up was 52.31 ($SD=16.53$), and after the six-month follow-up was 53.06 ($SD=15.40$). Although the mean scores through the time of evaluation after the three-month follow-up gradually decreased, it again increased after the six-month follow-up. There was no significant difference ($F=0.544$, $p=0.655$) comparing the mean scores at the time of measurement (Table 2).

5) RAS

The mean score for pre-intervention was −10.88 ($SD=22.86$), for post-intervention was −7.13 ($SD=27.26$), after the three-month follow up was −0.56 ($SD=35.14$), and after the six-month follow-up was −8.38 ($SD=25.65$). Although the mean scores through the time of evaluation after the three-month follow-up gradually decreased, it again increased after the six-months follow-up. There was no significant difference ($F=2.450$, $p=0.076$) comparing the mean scores at the time of measurement (Table 2).

Exemplification of the result of the interventional programme

In addition to verification of the effect by statistical analysis, we present here an example of the roleplay and protocol.

(1) Presentation of problematic behaviour: a female participant (Person A) experienced stress caused by the behaviour of the patient (the son) who insistently asks her

Table 3. Selected list of participants demands and suggestions used in role-playing

· Do not stay up late at night. Go to the bed earlier (between 11 pm and 12 pm).
· Fix your clothing by looking in a mirror after using the toilet.
· I want you to willingly go to see a doctor with no resistance.
· I want you to make sure to put things in their designated places because you forget where you put things.
· I want you to keep promised appointments.
· I want you to keep up a daily routine with regular hours. (I want you to make up a list of your daily schedule.)
· I want you not to get angry when I point out a mistake.
· Do not try to come along with me when I go out.
· I would like to refuse when you ask me to take you out. I want to say I cannot do it today.
· I want you not to shout in reaction to small noises around you.
· I want you to speak slowly and calmly.
· I want you to cut down the time you spend playing TV games by even just one hour.
· I want you to stop getting angry when you cannot get into a group circle.

to Listento what has happened today while she was busy cooking dinner.

(2) Presentation of request and suggestion: Person A requested that the son Not tell her what has happened during the day while she is cooking dinner.

(3) Role-play: we started the role-play by setting a scene such as cooking dinner.

The cast mate (acting as the son) performed the behaviour of insisting that Person A listen to him based on information such as the patient's manner of speaking and the patient's anticipated reaction when hearing Person A's request and suggestion, and acted out the part of not listening to Person A. The roleplay became stalled in a deadlocked situation.

(4) Feedback; other participants gave feed-back such as advising Person A to talk to the cast mate (acting as the son) in a calmer manner?, and encouraging Person A to be more honest and forthcoming about her son's behavior. The leader gave feedback to Person A regarding when Person A should make requests of her son that would meet his cognitive function level, such as "Can her son remember her request? " (As her son has memory impairment, there is a possibility that he might forget Person A's request.)

(5) Modification of request and suggestions; as a result of the discussion of the content of the feedback, Person A modified her request like this. "Until now, I have not had a chance to tell you that I was having a hard time when you begged me to listen to you while I was cooking dinner. Well, I will be able to listen to you after dinner, so please let me listen to you then when I can be relaxed."

(6) Re-role playing- although the cast mate (acting as the son) acted out accepting Person A's request, he added some improvised dialogue, such as "I am not confident that I can remember this until tomorrow," which took into consideration the son's memory impairment. Therefore, Person A added the suggestion "Shall we put a written promise note in the kitchen just in case you forget? " The cast mate (acting as the son) accepted her suggestion and the role-

play ended without them being aggressive to each other.

Person A gave the following feedback after finishing the roleplay: "Although until now I became emotional and often tended to talk aggressively, by performing the roleplay, I could understand what the other person thought after the way I had talked to him. I feel like I can actually present my requests and suggestions to my son, starting tomorrow, after this." The other participants also gave their feedback based on observing this roleplay. They indicated that they felt all this time, they had only been thinking about and speaking for themselves. And they got a tip on how to present demands and suggestions to a patient. Table 3 shows a selected list of the participants' demands and suggestions used in the roleplays.

Discussion

The purpose of this study was to verify the effectiveness of the interventional programme to reduce psychological distress of family caregivers for persons with traumatic brain injury. We focused on the problem of communication between family caregivers of persons with traumatic brain injury and patients with traumatic brain injury. In this study, the interventional programme consisted primarily of communication skills training through assertiveness training. As a result, after a six month follow-up, the mean scores of all psychological distress assessment measures were reduced compared to the pre-intervention mean scores. Through statistical analysis, both SDS, which compared the mean scores between pre-intervention and six months follow-up, and STAI (stated anxiety), which compared the mean scores between pre-intervention and post-intervention, recognised a statistically significant decrease in the mean scores. This indicates that the interventional programme relieved the psychological distress (especially depression and anxiety) of family caregivers of persons with traumatic brain injury. It is characteristic of the results that although the degree

of psychological stress decreased at post-intervention, it tended to increase again at follow-up. Therefore, the results suggest the necessity of continuous support even after finishing the intervention program. We conducted hearings for reference concerning impressions of the interventional programme, and the majority of the participants thought that the interventional programme would be beneficial for many other family caregivers of persons with traumatic brain injury. We also asked for continuous support focussing on each individual participant after finishing the interventional programme. Follow-up counselling for individual participants, including checking how the material learned from the interventional programme is being used in everyday communication with the patient, will enhance the effect of the interventional programme. As was indicated in the exemplification of the effect of the interventional programme, family caregivers who had experienced the interventional programme could objectively monitor their own past communication with the patient by recreating everyday communication exchanges between caregivers and patients through role-playing. This monitoring brought the realization that until now the requests and suggestions to the patient were one-sided and emotional. Furthermore, the monitoring not only improved making requests and suggestions through re-role-playing, it is also surmised that the biggest reason for reducing the psychological distress of family caregivers is that self-efficacy could be built up when necessary, and that one could make adjustments in behaviour and thinking. In this study, RAS was adopted to assess levels of assertiveness. As regression equations could be formulated for pre-intervention RAS and SDS, it is presumed there is a possibility of reducing depression symptoms through assertive communication. The evidence suggests the need for training communication skills, especially assertiveness training in order to reduce the psychological distress of family caregivers of persons with traumatic brain injury.

However, although the mean score of RAS increased until the three-month follow-up, there was no statistical significance at the time of measurement. This suggests that a different manner of intervention might be needed for behaviour modification of assertiveness. However, through RAS we see a degree of self-assertion or a trend in communication behaviour, and we believe it was meaningful to adapt the assessment measures in this study.

Study limitation

In the methodology of this study, we have adequately stated the information of the contents of the intervention by using widely acknowledged assessment measures. However, this study is limited due to the small sample size of only 16 persons. The reason the sample size was small was due to the fact that the interventional programme was

to be with participants of intended family caregivers in order to extract the frank opinions of the participants. That is to say, patients with traumatic brain injury often need to be watched by others on a daily basis. Therefore, there are many cases where the family caregivers cannot leave home. In order for family caregivers to participate in an interventional programme like the one in this study, family members other than the participant need to take over watching the patient. As a result, it was difficult for family caregivers to participate in the interventional programme. This suggests the necessity of developing human resources, aid agencies and social support services who can monitor the patients. An additional limitation was that due to ethical considerations, there was a lack of a control group. However, the inclusion of a control group would have led to a tendency for the group to only answer psychological assessment measures a total of four times, including the period of six months after the interventional programme, not only before and after the interventional programme. Several researchers have pointed out a lack of scientific validity for not setting a control group in this and previous studies (Boschen, Gargaro, Gan, Gerber & Brandys, 2007; Sinnakaruppan, Downey & Morrison, 2005). This is a common issue of intervention studies, not only studies of family caregivers of persons with traumatic brain injury.

Conclusion

This study suggests that an interventional programme focussing on communication skills training applying assertiveness training is effective in reducing the psychological distress of family caregivers of persons with traumatic brain injury. However, the results of this study suggest that further research taking into account the limitations mentioned previously is necessary.

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