# A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL OF MANUAL LYMPH DRAINAGE (MLD) FOR THE REDUCTION OF HAND OEDEMA AFTER DISTAL RADIUS FRACTURE.

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The effectiveness of MLD in reducing oedema of the hand after a traumatic injury was evaluated. Patients with gedema of the hand, which is defined as having a volume greater than 40ml compared to the uninjured hand, were chosen when the fixation period was completed after a fracture of the distal radius. Fractures were treated either with plaster or with an external fixator. A total of 51 patients were included in the study over a period of three years and were randomized into an experimental or control group. Therapy started on average three and a half days after mobilization. All patients received the same conventional treatment, including exercises, activities, pedema control and education. In addition, the experimental group received six treatments of MLD. Dedema of the injured hand was measured with a volumeter at 14 days and 60 days after commencement of treatment, and this was compared to the pre-treatment volume. There was a significantly greater reduction in gedema in the experimental group (median difference 30ml) compared to the control group (median difference 20ml) at the first measurement (p=0.005) taken at 14 days. These results indicate that MLD is a useful method for reducing post-traumatic oedema of the hand in the early phase.

INTRODUCTION

edema after hand trauma is a normal inflammatory tissue response, and early management is important as long-lasting oedema contributes to impaired motion and development of fibrotic tissue (Callins 1993, Morey and Watson 1986, Schuind and Burney 1997, Vasudevan and Melvin 1979). Inflammatory reactions include increased permeability of capillaries with release of plasma proteins into the interstitium, resulting in reduced oxygen transport due to the increased volume in tissue spaces. A certain amount of plasma proteins may be destroyed by macrophages in the region, but accumulation of plasma proteins in the damaged area may lead to chronic inflammation (Casley-Smith 1981 and 1988, LaStayo et al 2003, Schurmann et al 2001, Szczesny and Olszewski 2002 and 2003]. The lymphatic system plays an important role in the healing process, removing remaining excess proteins that cannot be reabsorbed by the venule portion of the capillaries due to their size. Therapy to reduce oedema has to

1997, Schurmann et al 2001, Szczesny and Olszewski 2002 and 2003, Vasudevan and Melvin 1979. Although many conventional treatment techniques are successful in resolving or decreasing acute oedema of the hand after trauma, some patients develop persistent oedema. Common therapies include elevation, active and resistive exercises, the application of cold packs and compression with elasticated gloves or wraps (Burkhart 1992, Collins 1993, Morey and Watson 1986, Vasudevan and Melvin 1979, Weinstock 1999). Patients are also encouraged to use the injured hand as much as possible in daily activities. Retrograde massage alone, or in combination with intermittent compression pump or string wrapping, has been reported to further reduce

oedema [Boiselle Howard 2001, Burkhart

1992, Carter 1996, Collins 1993, Mackin 1986,

focus on stimulating lymphatic uptake

of excess protein-rich fluid in the

traumatized area (Boardman 2003,

Boiselle Howard 2001, Casley-Smith 1981

and 1988, Casley-Smith et al 1985, Földi and

Clodius 1989, Ikomi et al 1996, International

Society of Lymphology 2003, Rockson 2001,

Sallustio et al 2000, Schuind and Burney

Michlovitz et al 2001, Morey and Watson 1986, Stockle et al 1997, Vasudevan and Melvin 1979, Weinstock 1999

A recent case report of a traumatic injury of the upper limb demonstrated that manual oedema mobilization is a useful method [Boiselle Howard 2001].

The role of the lymphatic system in maintaining tissue fluid balance and in establishing how to increase its capacity is important to further understand which techniques to use in clinical practice. As in veins, muscle contraction, elevation and compression are important for lymphatic flow, but lymph vessels can also be activated to pump themselves. MLD as described by Vodder (Kurz 1994, Kasseroller 1998, Wittlinger and Wittlinger 1996) is a technique that starts with increasing lymphomotoricity proximal to the injury before reaching the injured area. The massage starts at the left supraclavicular space, draining the lymph fluid into the axillary and subclavian veins (Boiselle Howard 2001, Földi and Clodius 1989, Kasseroller 1998, Kurz et al 1978, Rockson 2001]. The number of published studies is limited and they are based on oedema of the hand due to traumatic injuries of the upper limb. In our previous study we showed that, in addition to conventional treatment, MLD decreased oedema of the hand after fracture of the distal radius (Härén et al 2000). The aim of this study was to evaluate the effect of MLD, in addition to conventional treatment, on a larger number of patients with oedema of the hand after fractures of the distal radius. By giving fewer treatments and shorter sessions compared with our first study, we wanted to see if this method would be more cost-effective and suitable for routine clinical use.

# MATERIAL AND METHODS

This prospective randomized controlled study was carried out at Sundsvall County Hospital between February 2000 and June 2003. The Ethics Committee of Umea University approved the study.

### RECRUITMENT

Patients with oedema of the wrist and hand after a fracture of the distal radius, who were aged 45 years or older, were considered candidates for this study after their fixation period ended. Exclusion criteria were: infection, cancer, circulatory problems and rheumatoid arthritis, because MLD is partly contraindicated in all those cases. The fractures were treated either with plaster or with external fixator, and the Frykman classification system was used only to describe the fracture type (Carter 1996, Jaffe et al 1996, Flinkkila et al 1998]. When patients were referred for occupational therapy after removal of fixation 10 - 5 days), those who had visible oedema of the hand were asked back within an average of three days (range: 1-8), when the injured and uninjured hands were measured with a commercially available volumeter (Volumeters Unlimited, Idyllwild, CA, USA) (Curry et al 2003, Jaffe, Waylett-Rendall 1991]. The volumeter was filled with water and heated to room temperature until it overflowed. The patient was instructed to immerse the uninjured hand slowly into the volumeter until the stop rested in the web between the middle and ring fingers. The thumb was oriented towards the overflow spout. The water was poured from a beaker into a graduated cylinder. The same procedure was carried out on the injured hand and the difference in volume between the two hands was calculated. If the difference between hands was more than 40ml and the patients declared

Table 1: Comparability of the control group (n=26) and experimental group (n=25). Data are expressed as number of patients or mean (range).

	Control group	Experimenta group
Female/Male	21/5	21/4
Age (years )	63 (51-80)	62 (50-77)
Fractured hand: right/left	14/12	12/13
Fractured hand dominant	15/26	13/25
Frykman classification no 1-3	13	12
Frykman classification no 4-6	6	12
Frykman classification no 7-8	6	2
Plaster/External fixator	14/12	14/11
External fixation period (days)	43 (32-56)	47 (39-59)
Plaster fixation period [days]	32 (25-38)	33 (28-38)
Treatment start (days after removal of fixation)	3.4 (1-6)	3.5 (1-8)
Treatment start (days after fracture)	41 (28-58)	43 (33-62)
Treatment start, plaster (days after fracture)	36 (28-42)	36 (33-41)
Treatment start, external fixator idays after fracture)	47 [35-58]	52 (41-62)

themselves as healthy, the study protocol was discussed with the patient and informed consent was obtained. In total 55 patients were measured with the volumeter, two of whom decided not to participate. Two patients who initially volunteered and declared themselves healthy were subsequently excluded after checking their medical records. One had had breast surgery due to malignancy and the other had circulatory problems and a pin infection.

A total of 51 patients who met the inclusion criteria were enrolled into the study and were randomized by a computer program into either the experimental group or the control group. When describing the normal size of the injured hand before the trauma and when calculating the amount of the oedema compared to the normal size of the hand, differences due to hand dominance were considered. Patients were asked which hand was dominant. We measured the uninjured hand, estimating the dominant hand to be 3.43% larger than the non-dominant hand according to standard techniques, (van Velze et al 1991,

Vasiliauskas et al 1995]. All other oedema measurements were made on the injured hand and compared to the volume of the injured hand before treatment started (Curry et al 2003, Waylett-Rendall 1991). Both groups included patients with fractures that had been immobilised either with plaster or external fixator. Those who had plaster were immobilized for a shorter period - on average 13 days (immobilisation with plaster lasted on average 32.5 days, external fixation 45 days). The control group consisted of 26 patients and the experimental group consisted of 25 patients. We had based the sample size estimation on a difference of >12ml and a power of 90% indicating a target sample size of 82. which we expected to reach within two years. When the patients were included in the study, most had already received exercises to practise at home during the fixation period (control group n=21, experimental group n =20), but neither the patient nor the occupational therapist were informed about the study at that time. Details of both groups are shown in Table 1.

### INTERVENTION

All patients received the same conventional treatment, including elevation, active and resistive exercises for the hand and wrist, together with compression (Norco pedema glove, Össur Nordic AB, Uppsala, Sweden). Patients were instructed to use the oedema glove day and night until the first measurement. Verbal instructions and a written programme for active exercises at home were given and patients were encouraged to use the hand as much as possible in daily activities. In the experimental group, the first six treatments included 40 minutes of MLD, in addition to the conventional treatment, Treatment started immediately after inclusion in both groups.

# **OUTCOME MEASURES**

Both groups had six treatments over an average of 13 days [range 9-21] before the first treatment-related oedema measurement was performed on the injured hand. After the first measurement, both groups had an average of four conventional treatments [range 1-11], based, at this time, on the range of motion in the wrist, not the amount of oedema. The second oedema measurement on the injured hand was performed at two months (mean 58 days, range 32-71] after inclusion.

One therapist was responsible for all treatments and all measurements were carried out immediately after treatment by an occupational therapist who was not involved in the study.

The data were not normally distributed. Mann-Whitney U nonparametric tests were performed to compare the median differences in volume. The median difference was compared at the first and second measurements in each group and also between the experimental and

control groups. P-values of less than 0.05 were considered statistically significant. Confidence Intervals [CI] were used to describe the material in the text. The box and whisker plots show median values and first and third quartiles. Means and ranges were used only to describe the groups at baseline. The Statistical Package for the Social Sciences [SPSS, Sweden AB] was used for statistical analysis.

### RESULTS

As shown in Table 1, the two groups were comparable at baseline. Before treatment, oedema of the injured hand was measured and compared to the estimated volume of the hand before trauma. The calculated median normal size before trauma was 453ml (95% CI = 343 to 637) in the control and 454ml 195% CI = 372 to 595) in the experimental groups (figure 1). Figure 2 shows oedema of the injured hand compared to the estimated normal size before treatment started. Median was 62ml [95% CI = 30] to 183) in the control group and 63ml (95% CI = 33 to 115) in the experimental group. At the first measurement after commencement of treatment, the median decrease was 20ml [95% CI = -10 to 45] in the injured hands in the control group and 30ml (95% CI = 10 to 55) in the experimental group. At the second measurement, the median decrease in

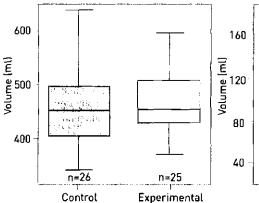
the injured hands was 35ml [95% CI = 15 to 80) in the control group and 40ml (95% CI=10 to 90) in the experimental group. The median oedema reduction of the injured hand at first and second measurements is shown in Figures 3 and 4 respectively. A statistically significant difference in oedema reduction, with a larger overall reduction in the experimental group, was observed at the first measurement (p= 0.005). At the second measurement, the experimental group still had a greater reduction in oedema than the control group, but the difference between the groups was not statistically significant.

When comparing the volume of injured hands with the estimated normal volume before the injury, at first measurement median oedema in the control group was 32ml (95% CI = 0 to 108) and in the experimental group, 20ml (95% CI = 3 to 55). There were no significant differences between groups at the second measurement when comparing the injured hand to its estimated normal size, as seen in Figure 5. When the control and the experimental groups were stratified according to type of fracture fixation at first measurement, oedema reduction was significant only in patients immobilized with external fixator (control group n=11, experimental group n=12, p=0.004], as shown in Figure 6.

### DISCUSSION

Table 2: Mean Irange) days after inclusion and number of treatments at first and second measuring point, manual lymph drainage (MLD) included at first measurement.

	Control group (n=26)	Experimental group (n=25)	
First measurement [days after inclusion]	14 [9-21]	13 (10-17)	
Number of treatments at first measurement	6	6	
Second measurement (days after inclusion)	56 (32-63)	60 (49-71)	
Number of treatments between first & second measurement	4 [1-11]	411-81	



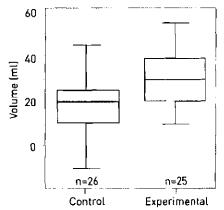
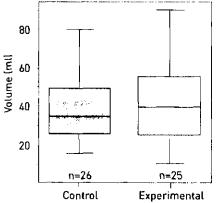
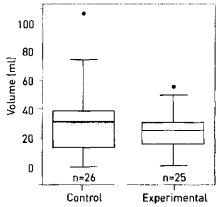


Fig. 1: Box and whisker plots showing estimated size of the injured hand (in ml) before the injury in the control and experimental groups. The boxes indicate median values, first and third quartile.

Fig.2: Box and whisker plots showing oedema of the injured hand before start of treatment in control and experimental groups. The boxes indicate median values, first and third quartiles (\* = extreme outlier).

Fig. 3: Box and whisker plots showing decrease in oedema (mtl of the injured hand at first measurement, a mean of 13 days after treatment started (6 treatments in total) in control and experimental groups.





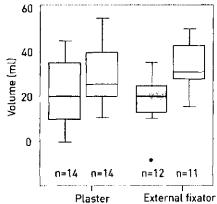


Fig.4: Box and whisker plots showing decrease in oedema (ml) of the injured hand from baseline to second measurement, a mean of 58 days after treatment started in control and experimental groups. The boxes indicate median values, first and third quartile. Between first and second measurements, both groups had only conventional treatment, a mean of 4 times (range: 1-11).

Fig.5: Box and whisker plots showing remaining oedema (mt) of the injured hand at second measurement, a mean of 58 days (range: 32-71) after inclusion in both control and experimental groups. The boxes indicate median values, first and third quartiles (\* = outlier).

Fig.6: Box and whisker plots showing decrease in oedema (mtl) of the injured hand at first measurement (after 6 treatments), according to type of fixation. The boxes indicate median values first and third quartiles (• = outtier).

Control
Experimental

The healing process after a traumatic injury is slowed when oedema is present, as the structure of the interstitium is altered and interferes with cellular metabolism, oxygen transportation and wound healing (Casley-Smith 1988, Morey and Watson 1986, Schurmann et al 1999). Early diagnosis and appropriate treatment of oedema in the hand is therefore important to stimulate healing and prevent complications (Schurmann et al 1999, Simons et al 1996]. The role of the lymphatic system is often not fully understood among hand therapists and hand surgeons, although many articles emphasise the necessity of lymphatic drainage of plasma proteins and fluid from the injured area (Casley-Smith 1981, Drake et al 1998, Ikomi et al 1996, Sallustio et al 2000, Szczesny and Olsweski 2002 and 2003]. Fluid transportation both in veins and lymphatics needs skeletal muscle contraction and the lymphatic system has, in addition, its own ability to pump and to increase its capacity several times (Boland and Adams 1999, Boris et al. 1994, Campisi et al 2001, Földi and Clodius 1989, Kurz et al 1978, Morey and Watson 1986, Rockson 2001, Sallustio et al 2000, Schmid-Schonbein 1990, Simons et al 1996. Szczesny and Olsweski 2002, 2003]. The MLD technique, according to Vodder, used in this study to reduce oedema was applied in the experimental group six times for 40 minutes over 13 days. The reason for the time chosen (40 minutes) was based on a previous investigation of this special technique, concluding that it takes quite a long time for the lymphatic system to get started (Wittlinger and Wittlinger 1996).

The study has some limitations. We based the sample size estimation on a difference of >12ml and a power of 90%, indicating a target sample of 82. After more than three years, 51 patients had been recruited into the study and our

judgement was that it would be difficult to go on for another one or two years. A new calculation based on a sample size of 51 was made by the statistician indicating a power level of 73%, which means that the findings need to be interpreted with caution. The tack of a statistical difference between groups at the last measurement may be due to the small sample size and therefore reduced power to detect a real difference, if one exists.

To highlight the importance of the lymphatic system in reducing oedema, we investigated patients with gedemaof the hand after a fracture of the distal radius fixated with either plaster or external fixation. Inclusion into the study occurred immediately after fixation was removed. Oedema was the only inclusion criterion and the patient's ability to move their wrist or use their hand were not considered. At first measurement, after six treatments a significantly greater oedema reduction was observed in the experimental group, which suggests that MLD is a useful method in reducing oedema in the early phase. After the first measurement, all patients had conventional treatment and as often as they required. At this time, the oedema was not a problem in either group. Range of motion in the wrist and ability to load and use the hand determined how many follow-up appointments the patient needed. Conventional treatment requirements between the first and second study measurements were not different between the experimental and control groups. When comparing oedema reduction in both groups, stratified by type of fixation, we continued to observe significant oedema reduction in the experimental group for patients who had an external fixator, but not for patients immobilized with plaster. Patients with a fracture immobilized

with external fixator had a longer fixation period, which probably leads to a more persistent oedema that is more difficult to reduce with conventional treatment (Boiselle Howard 2001, Casley-Smith 1981, Morey and Watson 1986, Vasudevan and Melvin 1979, Weinstock 1999|. For patients with fractures immobilised in plaster, the immobilization period was shorter and still more oedema reduction was observed in the experimental group, but the difference with the control group was not statistically significant.

All patients had oedema reduction during the treatment period and no one suffered from complications from the oedema. Although complications from oedema after fractures of the distal radius sometimes include fibrosis and loss of function, our study population was chosen to ensure the largest number of patients with oedema caused by the same traumatic injury. Our intention was not to establish this treatment on every patient with gedema of the hand after a radial fracture, but to investigate if this method had any effect on posttraumatic oedema in general. In this study, early treatment was initiated. When the second measurement was performed, two months after inclusion, there were no significant differences between groups. This could be explained by our assumption that both groups in this study would get almost complete oedema reduction and regain normal hand volume and function. However, we cannot entirely rule out that a continued use of MLD for a longer period would have demonstrated a more long-lasting and significant difference between the groups.

In our previous study | Härén et al 2000|, the experimental group had ten treatments of MLD, together with the conventional treatment. In the previous study, all oedema measurements

were comparisons between the injured and the non-injured hand because treatment started before the fixation period was completed and we were not able to measure the injured hand before treatment commenced. In the present study, we measured the volume before active oedema treatment was initiated to more accurately obtain a starting volume. In addition, we shortened the duration of each treatment by five minutes and also decreased the number of treatment sessions, in order to get a more cost-effective and clinically applicable method.

### CONCLUSIONS

The results support the use of MLD as complimentary to conventional therapy when there is excessive oedema of the hand after complicated traumatic hand injuries. The use of this additional modality to reduce oedema could be of crucial importance for these patients that otherwise would be delayed in their rehabilitation. MLD may also be beneficial for patients with less complicated injuries when problems with oedema persist after a period of conventional treatment.

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