**PROTOCOL OUTLINE**

# 1. Title

Feasibility of using silicone oil for hand exercises as a home based rehabilitation program following Dupuytrens contracture release surgery.

2. Short title:

Silicone oil: a medium for hand rehabilitation hand following Dupuytrens surgery.

**2. Investigators**

Principal Investigator (PI) Gail Donaldson, PhD Student University of Otago-(Wellington-based); Supervisors: Dr Gillian Johnson: Associate Professor, Centre for Health, Activity, and Rehabilitation Research (CHARR), School of Physiotherapy, University of Otago, Dunedin; Dr Meredith Perry. Lecturer, Centre for Health, Activity, and Rehabilitation Research (CHARR), School of Physiotherapy, University of Otago-Wellington.

**3. Specific Objectives**

To assess the feasibility of using silicone oil (SO) for hand exercises as a home based rehabilitation program following surgical release of Dupuytrens contracture as determined by evaluation of patient satisfaction levels and treatment fidelity.

**4. Relevance to Physiotherapy**

**The problem:**

The various approaches utilized in hand therapy rehabilitation by physiotherapists following Dupuytrens surgery have limited evidence to support their use and there is a clear need to evaluate exercise regimes with quality research [[1](#_ENREF_1)].

A recent survey of Australasian hand therapists (n=126) undertaken by the PI revealed that 45% of practitioner’s have at some point used SO as a medium for hand exercises and, of these therapists surveyed, 8.7% cited Dupuytrens rehabilitation as a reason for using SO [[2](#_ENREF_2)]. Of interest is that as many as 25% of therapists have used SO in practice, due to the belief that this medium assists with wound healing and regaining range of motion [[2](#_ENREF_2)]. Both pain and stress surrounding post-operative dressing changes are known to have a negative impact on wound healing [[3](#_ENREF_3), [4](#_ENREF_4)] thereby highlighting the diverse factors impacting on the rehabilitation process. The patient experience and associated levels of satisfaction in a post-operative rehabilitation program merits consideration and this element can be regarded as an important outcome in itself.

Establishing effective exercise protocols is essential to ensure patients regain function quickly while minimizing pain but, as yet, the efficacy of SO as an exercise medium has yet to be determined. If the use of SO can be shown to improve the overall post-operative experience from the patient perspective then a potential value can be attributed to SO. The knowledge gained from this investigation will provide the basis for future randomised controlled studies examining the effectiveness of this medium in the management of Dupuytren’s contracture.

**5. Background**

Dupuytrens disease (DD) is a common non-malignant disease affecting the palmar fascia of the hand. Fibroblast proliferation results in thickened nodules and tight bands appearing in the palm, leading to progressive and irreversible flexion deformities of the fingers [[5](#_ENREF_5)]. The condition of DD limits hand function and impacts on activities of everyday life with the ring and little fingers being the most commonly affected [[6](#_ENREF_6)]. Worldwide, the disorder of DD impacts on the lives of millions of people and costs of associated healthcare are huge [[7](#_ENREF_7)].

The incidence of DD varies with different population groups however the estimated global prevalence of DD is 2-42% [[6](#_ENREF_6)]. The prevalence is higher in specific groups, particularly Caucasian males of Northern European descent [[8](#_ENREF_8)]. New Zealand is classified as part of Oceania, where the prevalence for DD is estimated to be 23% [[8](#_ENREF_8)] but it is considered rare in non-Caucasian populations [[9](#_ENREF_9)]. The male to female ratio of DD is 5.9:1 [[8](#_ENREF_8)].

The optimal treatment for DD is unclear as studies have used a variety of surgical interventions and more recently collagenase injections to release the contracted palmar fascia [[10](#_ENREF_10), [11](#_ENREF_11)]. However, the aim after all interventions is to regain full finger extension as quickly and painlessly as possible with minimal complications.

Patients who have undergone surgery for DD usually have a skin deficit following release of the contracture and it is common practice for this open wound and skin surrounding the surgical incision (where there are skin deficits) to be left to heal naturally [[12](#_ENREF_12)]. However, the patient is still required to exercise their hand to regain full finger movement.

Silicone oil is a clear, oily liquid that is tasteless and odourless. Medical grade SO has a viscosity of 350 centistokes compared to that of water which has a viscosity of one centistoke. The chemical structure of dimethyl silicone fluid, (commonly referred to as SO) is quite different from all other fluids due to its backbone of silicone-oxygen linkages. These links are much stronger so they behave differently during oxidation, shear stress and heating. Due to this chemical composition, SO exhibits a profile of properties different to both water and air [[13](#_ENREF_13)].

Burns and plastic surgery units in England, New Zealand and Sweden have used medical grade SO since the 1980’s for the rehabilitation of burns and complex open hand injuries in the belief that early movement is gained with less pain [[14](#_ENREF_14), [15](#_ENREF_15)]. [Helal, Chapman [14]](#_ENREF_14) reported that in five cases with diverse hand pathology including DD release, daily exercises for 20 minutes in SO achieved full wound healing without further surgery. Furthermore four of the five cases achieved near full range of finger motion. However, despite common usage of SO by hand therapists in Australasia, there is a lack of data regarding its effectiveness and acceptability to patients.

**6. Significance of Study**

The significance of this study is to identify an intervention which could improve the overall patient post-operative experience after open hand surgery. A part of investigating a patient’s satisfaction when using SO is the relationship with self-rated pain levels while performing the exercises. It is thought that pain levels associated with finger motion may differ when SO is used [[17](#_ENREF_17)] and if there is better pain control this should lead to improved movement and a better outcome.

Treatment interventions that result in less pain while regaining motion, prompting the return of grip strength, will facilitate a timely return to work. Such interventions are of significant interest to patients, hand surgeons, hand therapists and funders of health care. At the completion of this study, the investigators aim to have determined the feasibility and efficacy of SO immersion as a medium for hand exercises. The home program must maintain acceptable treatment fidelity based upon the five elements of: treatment protocol design, provider training and delivery of treatment, receipt of treatment and enactment of treatment [[18](#_ENREF_18)] and furthermore, have a level of patient satisfaction that merits the use of SO as an intervention.

Operational definitions

For the purpose of this study the term treatment fidelity refers to the use of strategies that can monitor and enhance the accuracy and consistency of the SO intervention to ensure it is implemented as planned and that each component is delivered in a comparable manner to all study participants over time [[19](#_ENREF_19)].

Although the sample population of post-operative DD contracture release is a discrete study group, this current study is intended as a foundation upon which future research could be based with the potential for use with a wider population. Therefore, if a home based rehabilitation program using SO is shown to be feasible, has treatment fidelity and is acceptable to patients it could then be extended to future study to quantify its effectiveness.

**8. Experimental Protocol**

*8.1 Study design*

An RCT to investigate feasibility, treatment fidelity and patient satisfaction when SO is randomly assigned into a post-operative home based hand exercise program.

The null hypothesis states that there will be no differences between the two randomized exercise groups: Group I standard care and exercise, and Group II standard care and exercise using SO.

*8.2 Study setting*

The participants will be treated by one of three physiotherapists employed at the Wellington Hand Rehabilitation Centre (Wellhand) which is located in Wellington Central Business District. The physiotherapy clinic has good transport links and is beside the Wellington Railway Station and Central business hub (28 Waterloo, Pipitea, Wellington 6011). The participants will attend the clinic for all routine post-operative therapy appointments including the four visits where measurements for the study will be undertaken and accommodated as part of the patients’ standard rehabilitation program.

*8.3 Ethical considerations*

Māori Consultation has been undertaken with the University of Otago Ngāi Tahu Research Consultation Committee (Appendix 1). Ethical approval for this project will be sought from the Heath, Disability and Ethics Committee Central (HDEC-Central). Peer review will be undertaken as part of this process. Written informed consent will be sought from all participants prior to their commencement in the study in accordance with the University of Otago Human Ethical Committee guidelines.

*8.4 Target population*

Individuals from 20 years with a minimum of a 20 degree fixed flexion deformity of the metacarpal-phalangeal (MCP) joints of the fingers due to DD presenting to an orthopedic surgeon who undertakes a large proportion of private patients for DD surgical release within the wider Wellington region (A Thurston- Bowen Private Hospital). Participants will be restricted to patients attending Professor Thurston’s private hand surgery practice so that surgical technique is the same for all participants [[20](#_ENREF_20)]. Professor Thurston has approved the study design where patients who wish to participate in the study will be randomized into the two different post-operative care groups as detailed above.

*8.5 Recruitment*

Individuals presenting for primary contracture release surgery due to DD will be invited to participate in the study via an advertisement placed in the waiting rooms of A Thurston’s practice (Appendix 2). Participants who are interested in volunteering will register their interest with A Thurston’s practice manager and will be provided with an Information Sheet (Appendix 3) and their names and contact details will be forwarded to the PI.

*8.6 Participants*

Volunteers will be screened for eligibility before entering into the study. Screening involves identification of the inclusion and exclusion criteria for each volunteer.

*Inclusion criteria*

* Those individuals who have
1. Undergone surgical release of DD with or without associated proximal inter-phalangeal (PIP) joint contracture and, with no prior history of a DD intervention [[21](#_ENREF_21), [22](#_ENREF_22)].
2. An ability to understand English and complete the required forms associated with the study.

*Exclusion criteria*

* Those individuals with
1. Pre-existing finger injuries or conditions that affect range of motion (ROM), such as carpal tunnel syndrome, rheumatoid arthritis or other medical conditions that could confound the health related quality of life assessment.
2. Previous hand surgery, needling or injections for DD.
3. DD surgery requiring skin grafts.

*8.7 Sample size considerations*

Recent data from 12 trials within the UK and USA found that 39% of people presenting for DD release were presenting for surgery for the first time [[21](#_ENREF_21)]. No statistics on the presentation rate for DD undergoing primary surgical intervention in New Zealand are available. However A. Thurston’s practice records show that approximately 30 new DD patients present for the first time each year. This study will aim to recruit 10-12 patients into each arm of the study over 18 months of data collection.

*8.8 Method*

Participants will provide written informed consent (Appendix 4) prior to completing baseline information at the pre-operative assessment (Appendix 5) in accordance with HDEC guidelines. The assessments will be conducted at the physiotherapy clinic in the week prior to the patients scheduled surgery.

*Randomization*

Allocation to the two groups - Group I (usual care-without SO) or Group II ( usual care with SO) will be carried out by an independent person whereby sequentially numbered sealed envelopes which have been generated from Randomisation.com [[23](#_ENREF_23)] will determine which arm of the study the participant enters into. The physiotherapy practice receptionist will randomly allocate participants to either Group I or Group II when they phone to book their first appointment. This will ensure the allocation is concealed from the PI [[24](#_ENREF_24)]. Patients will be allocated to one of three physiotherapists using the criteria of next available appointment at a time which is convenient to the patient.

*Treatment Intervention Groups*

The treatment intervention for both groups requires all post-operative dressings to be removed daily for the exercise session. Both groups, usual treatment (Group I) and the SO group (Group II), will exercise their operated hand for 20 minutes daily for a period of two weeks. All participants will be taught their exercises program in a 45 minute one-to-one education session by their assigned physiotherapist and then continue their daily exercises independently as a home exercise program according to their group allocation.

Group I: Usual treatment group - Standard care of exercises (Appendix 6). Participants assigned to the usual treatment group will be required to perform the 20 minute home exercise program when they change their dressings. Exercises are continued until full finger movement is restored.

Group II: Silicone treatment. Participants will perform the same exercises as the usual treatment group but with their operated hand immersed in silicone oil as illustrated in Figure 1. Participants assigned to the SO treatment group will be provided with a 500ml container of SO and thereafter perform their home exercises with their hand submerged in this medium.



**Figure 1: A** **small container of silicone oil for hand exercises for Group II**

All participants will return 14 days post-operatively for re-assessment and termination of the use of SO as an exercise medium. Scar care will be offered equally to both groups at this point as required. The study end-point will be three months post-operatively (see Figure 2).



Figure 2 Overview of Study Method

*Primary outcome measures*:

The feasibility of this study will be assessed from two approaches, the therapists and the participants.

"Therapists" includes an evaluation of the enactment of the therapeutic intervention by means of an independent video recording. The participant evaluation examines inclusion/exclusion criteria, the speed of recruitment, retention rates and the acceptability of the intervention to the participants using a survey and focus group. The evaluation of the treatment fidelity of the SO intervention administered as a home program will be performed utilizing three different approaches: physiotherapy delivery, patient receipt and enactment, patient acceptability as summarized in Figure 3.

**Part A)**

**1: Physiotherapy delivery.**

Three different physiotherapists will be involved in the treatment of the patients in both arms of the study. There is a possibility is that their instructions may vary as they train the patient in the use of SO. Therefore a video will be made of the physiotherapists delivering all of the first therapy sessions where the patient is taught the home program, and this will be reviewed using the SEGUE framework which is used to assess the communication of medical practitioners and physiotherapy students in America [25]. It evaluates whether or not critical communication tasks have been accomplished during an interaction, and in particular when a new treatment plan is implemented, that the instructions are provided clearly without the use of jargon and the patient’s ability to follow the plan is discussed [[25](#_ENREF_25)]. The SEGUE tool has been shown to have acceptable concurrent and construct validity and very high intra-rater reliability when coding videotaped encounters (*Kn*=0.99) [[26](#_ENREF_26)]. A numerical score will be assigned to rate the completeness of physiotherapy delivery in each initial patient training session (Appendix 7).

**2: Treatment Fidelity**

A video of the participants independently performing the exercise program at home will be recorded by a research assistant during the first two weeks post operatively. Neither the PI nor the participant’s treating physiotherapist will be present during this assessment. This independent strategy will enable the PI to identify the level of difficulty the patient experiences completing the home program, and compare it to the patient self-rated scores for difficulty and pain. Treatment enactment will be assessed by comparing the actual patient enacted treatment recorded at home on video compared to the written protocol if the intervention was delivered as intended. In particular, the daily immersion period in the SO and the number of finger flexion and extensions performed during the treatment session will be examined. This is a novel method to evaluate the enactment of a physiotherapy treatment program, and if shown to be feasible it could be utilized in future studies.

**Part B)**

**1: Patient receipt and enactment of SO intervention.**

The treatment protocol requires the patient to have a good understanding of the program of exercises to be undertaken and be able to replicate the intervention with relative ease at home. Enactment will be self-recorded daily by the patient in their treatment dairy (Appendix 8). Two variables, pain and the perceived level of difficulty the participant has completing the intervention including application of dressings, will be recorded. The numerical pain rating scale (NPRS) rates zero as “no pain” through to ten as the “worst possible pain” [[27](#_ENREF_27)] and has acceptable validity for responsiveness to changes in pain [[28](#_ENREF_28)]. A one point change in NPRS score reflects a minimally clinically important difference and two points equates to “much better” [[29](#_ENREF_29)] which may be important when using SO. In order to rate the patients perceived level of difficulty while completing the exercise program and subsequent dressings, a Likert scale will be used. The anchor point at zero equates to the patient completing the intervention independently with ease, five is 'required some help', ten suggests that they needed assistance from another person throughout the intervention.

**2: Patient Satisfaction**

Patient feedback of the intervention approaches will be determined using the client satisfaction questionnaire (CSQ-8). This questionnaire was developed and tested by Attkisson [[30](#_ENREF_30)] and has been shown to have construct validity, reliability and high internal consistency (α = 0.93) [[31](#_ENREF_31)]. The CSQ-8 has recently been used to assess patient satisfaction in maternity services [[32](#_ENREF_32)], plastic surgery [[33](#_ENREF_33)] and podiatry in Australia [[34](#_ENREF_34)]. The CSQ-8 questionnaire will be administered at the final assessment three months post-surgery (Appendix 9). Patients will be invited to add further information in response to the open ended question “Do you have any comments or thoughts about the use of SO?" At the completion of the data collection, all participants assigned to Group II SO users will be invited to a focus group to share their experiences and thoughts on the use of silicone oil.



**Figure 3 Algorithm of the three phases examining treatment fidelity**

*Secondary outcome measures:*

For this feasibility study two health related quality of life questionnaires will be administered to the patients at baseline and the final outcome phase at twelve weeks following surgery to determine if they can detect a clinically meaningful change in this study group. The Michigan Hand Outcome Questionnaire (MHOQ) is region specific and has been shown to identify significant change after DD [[35](#_ENREF_35)]. MHOQ comprises six domains: overall hand function, activities of daily living, pain, work performance, aesthetics, and satisfaction [[36](#_ENREF_36)] (Appendix 10). It has high test-retest reliability and reliable internal consistency (α = 0.90) and high construct and content validity [[37](#_ENREF_37)]. In addition, a new health-related quality of life questionnaire which has excellent test-retest reliability (α = 0.97) and acceptable construct validity (r=0.61) [[38](#_ENREF_38)] entitled the Unite Rhumatologique des Affections de la Main (URAM) will also be used. The URAM has been developed for specific use in Dupuytrens assessment, but, as yet, no published studies have used it. (Appendix 11).

Objective outcomes measures of range of movement (degrees of motion) and will be recorded at four occasions: baseline (1 week pre-operatively) with repeated measures taken at three and fourteen days post-operatively, and the final outcome at twelve weeks after surgery. Motion at the MCP and PIP joints of the involved fingers will be measured using standardized goniometry[[39](#_ENREF_39)]. Fixed flexion deformities of the MCP and PIP (if present) will be recorded at baseline. Hand grip strength will be measured using a Jamar dynamometer (kilograms of force) at baseline and at the final assessment at 3 months. The study endpoint, twelve weeks post-operatively, will document the residual extension deficit. This outcome is widely used as the primary outcome measure in DD surgery research [[22](#_ENREF_22), [40](#_ENREF_40)].

*Study success criteria*

* That 70% of eligible patients can be recruited and retained in the study
* Retention rate to 12 week assessment is 95% and the reasons for dropouts are clearly identified.
* That the SO intervention is acceptable to participants
* That SO is shown to have acceptable treatment fidelity for patient use as part of a home exercise program after DD surgery
* There are no adverse events attributable to SO usage

*Researcher Roles*

The PI will undertake all treatment measurements at the baseline and final outcome phases of the study for all participants. The PI will not provide any treatment interventions and will be blinded to the allocation of SO. All treatment will be provided by clinicians at Wellhand physiotherapy, all of whom have postgraduate training in hand rehabilitation. An independent research assistant will be employed solely for the purpose of undertaking the video of the patient carrying out their home-based hand exercise program and will not be involved in the rehabilitation of the patient in any way.

*Data analysis*

Base line demographics and characteristics of participants will be analyzed with descriptive statistics.

Completeness of physiotherapy delivery is reflected by the SEGUE score. The mean scores will be compared between the study Group I and Group II to evaluate the degree of uniformity in delivery of both interventions using independent t-tests.

How receptive the patient is to the intervention (patient receipt) will be assessed using the numerical rating scale for pain, and the Likert scale for level of difficulty. A comparison between the intervention groups I and II will be made using independent t-tests to identify if the SO intervention was thought to be significantly more difficult, or painful, from the patient perspective. Enactment will be measured by comparing patient diaries with the protocol for daily exercises and number of minutes spent in oil for variances from the protocol. The number of finger flexion and extensions will be counts from video footage compared to the number specified in the protocol and will be analyzed using a t-test.

Acceptability of Intervention from the patient perspective will be determined by the satisfaction survey CSQ-8. Independent t tests between the 2 study groups will be performed to identify if a significant difference exists. Free text from the open ended questions will be analyzed by grouping the data into clusters and themes then classified by frequencies. Qualitative data collected from the focus group will be analyzed using the same method. Quality of life questionnaires (MHOQ and URAM) will be analyzed using t tests.

*Data Storage*

All data that identifies a patient will be stored in the Wellington Hand Rehabilitation Centre’s Gensolve Medical Records System. Specific study data that will not identify patients in any way will be stored in an Excel spreadsheet with password protection known only to the principal researcher. Supervisors will also have access to this data for analysis and writing up purposes.

**10. Budget**

Participants will be compensated for travel only in relation to the four visits relevant to the study. All participants will pay for their physiotherapy treatment costs with the therapists as usual, and they will be able to schedule more visits as required.

The budget costs are based on 30 participants being involved with the study.

1. Petrol vouchers for participants: (4 X $20) x 30 = $2,400.00
2. Silicone oil: (15 X $55) = $ 825.00
3. Containers (15 X $10) = $ 150.00
4. Printing and stationery costs = $ 600.00
5. Research assistant for video recording (50 hours at $20/hour) = $ 1000.00

30 approximately1hour home visits plus 30 minutes travel time TOTAL = $4,975.00

Applications for funding will be made to the Wellington Regional Physiotherapy Research Group and the New Zealand Association of Hand Therapists Research Fund. Administration costs will be covered by the Physiotherapy School PhD internal research account (maximum $1000 per annum).

**11. Study time line**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Research tasks | May2015 | June - December 2015-2016 | January -October 2017 | November 2017 |
| Peer reviewEthics approval |  |  |  |  |
| Data collectionWriting |  |  |  |  |
| Data analysisWriting |  |  |  |  |
| Revision of thesisSubmission of thesis |  |  |  |  |

**13. Safety and adverse events**

Rehabilitation will be provided according to evidence based medicine and best practice principles [[41](#_ENREF_41)]. Patients are able to have as many treatments as they require in consultation with their therapists, regardless of the group they are assigned to. The number of treatments required will be documented. Any adverse events that are considered part of the DD post-operative period e.g. wound infection and sensory deficits, will be managed by immediate referral back to the surgeon in charge and documented for reporting [[10](#_ENREF_10), [12](#_ENREF_12), [21](#_ENREF_21)]. Research has shown no adverse effects attributable to SO use in 47 previous hand rehabilitation interventions [[42](#_ENREF_42)].

**14. Study termination criteria**

Should inflammation, granuloma formation or abnormal scar formation occur that the therapist in charge of the patient believes is specific to SO use, the patient will be removed from the SO arm of the study. If this should occur in 30% of participants the study will be terminated.

**15. Dissemination of Research findings**

The insights gained from this study will be disseminated primarily via article submission to a relevant peer reviewed hand rehabilitation scientific journal for publication. The results will also be presented at New Zealand Hand Therapy/Hand Surgery Meetings. The entire study and results will be presented in their entirety as a thesis for a Doctor of Philosophy at University of Otago. All participants will receive by post a simple summary of the findings of the study at its conclusion.

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