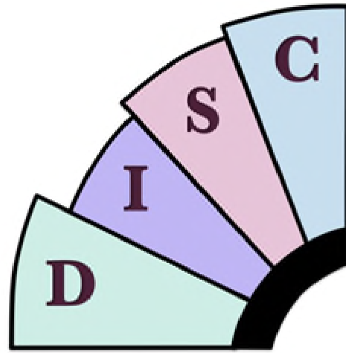

Dupuytren's Interventions Surgery vs Collagenase

Treatment Delivery - Case Report Form

FOR STUDY INVESTIGATOR COMPLETION

Site ID: ☐☐

Participant Study Number: ☐☐☐☐

Participant Initials: ☐☐☐

Visit date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

This project was funded by the National Institute for Health Research Health Technology Assessment Programme (project number 15/102/04).

Instructions for this Case Report Form

Note: This Case Report Form (CRF) may be completed by the principal investigator or a delegated member of staff listed on the DISC trial Delegation Log.

The Screening Number pre-printed on the DISC Trial Screening for Eligibility Summary form should be entered as the Participant Study Number on the cover page of this CRF.

Please complete all sections of this CRF using the spaces provided, and sign off when complete:

Time point	CRF Sections to be completed
Pre-treatment - *If assigned treatment will not be completed as planned*	A
Pre-treatment - *If assigned treatment is to be completed as planned*	A, B, C
During treatment	D, E
Post treatment	F, G, H

When complete, please remove the staple and take a photocopy of the completed CRF for site records.

Please do not re-staple original. Place the unstapled original in a “DISC trial business reply envelope” and send via post to York Trials Unit.

Participant Study Number: ☐☐☐☐

Section A: Pre-treatment confirmation

1. **Please confirm the participant's hand, digit and joint that are designated as reference for this study.**
Please cross one box only.

Left Hand			Right Hand		
Thumb	☐ MCP	☐ PIP	Thumb	☐ MCP	☐ PIP
Index	☐ MCP	☐ PIP	Index	☐ MCP	☐ PIP
Middle	☐ MCP	☐ PIP	Middle	☐ MCP	☐ PIP
Ring	☐ MCP	☐ PIP	Ring	☐ MCP	☐ PIP
Little	☐ MCP	☐ PIP	Little	☐ MCP	☐ PIP

2. **Please confirm the treatment the participant was randomised to receive**

☐ Collagenase injection ☐ Limited fasciectomy surgery

3. **Is the assigned treatment going ahead today?** ☐ Yes ☐ No

If Yes, please proceed to Section B

If No, please state why

☐ Patient has received tetracycline antibiotics within the previous 14 days

☐ Patient is currently pregnant or breastfeeding

☐ Surgery cancelled or postponed

☐ Patient did not attend

☐ Patient received other treatment for Dupuytren's Contracture since Baseline (please specify) ________

☐ Other (please specify) ________

4. **Will the treatment delivery be rescheduled?** ☐ Yes* ☐ No*

***If Yes, please note to complete a *new* Treatment Delivery CRF when delivering the rescheduled treatment. If No, please note to complete a Change of Status from if relevant.**

Proceed to the end of the CRF to complete Section H (Case Report Form Sign off).

Signature of person completing page: ________ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Participant Study Number: ☐☐☐☐

Section B: Pre-treatment Joint measurements

Part 1 – Active Movement (Extension)

Please take one measurement of extension for the **reference digit.**

Please enter measurements below
(key: MCP = metacarpophalangeal, PIP = proximal interphalangeal, DIP = distal interphalangeal)

MEASUREMENT 1	MCP	PIP	DIP
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
Extension and Flexion = maximal reading **Tick negative if hyperextension present**			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

If unable to obtain a measurement, please tick for which joint(s)

☐ **MCP** ☐ **PIP** ☐ **DIP**

Part 2 – Extension Deficit (Passive Extension)

Please take one measurement of extension for the **reference digit.**

Please enter measurements below
(key: MCP = metacarpophalangeal, PIP = proximal interphalangeal, DIP = distal interphalangeal).

MEASUREMENT 1	MCP	PIP	DIP
Extension	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees	☐ Tick if negative ☐☐☐ degrees
Extension and Flexion = maximal reading **Tick negative if hyperextension present**			Not applicable ☐ (only to be ticked if the reference digit is the thumb)

If unable to obtain a measurement, please tick for which joint(s)

☐ **MCP** ☐ **PIP** ☐ **DIP**

Proceed to Section C

Signature of person completing page: ☐

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Section C – Pre-Treatment Photographs

A photograph has been taken of the reference hand in extension (from the side of the hand with little finger closest to the camera) ☐ Yes ☐ No

A photograph has been taken of the reference hand in flexion making a tight fist (from the side of the hand with the little finger closest to the camera) ☐ Yes ☐ No

A photograph has been taken of the reference hand in extension (camera directly above the hand) ☐ Yes ☐ No

If 'No', please indicate why photographs have not been completed

☐

Proceed to Section D

Signature of person completing page: ☐

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Participant Study Number: ☐☐☐☐

Section D – Collagenase Administration

Cross here if the participant was not allocated to collagenase and proceed to Section E ☐

Date of collagenase administration	☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)
Joints treated	**Left Hand** Thumb ☐ MCP ☐ PIP Index ☐ MCP ☐ PIP Middle ☐ MCP ☐ PIP Ring ☐ MCP ☐ PIP Little ☐ MCP ☐ PIP **Right Hand** Thumb ☐ MCP ☐ PIP Index ☐ MCP ☐ PIP Middle ☐ MCP ☐ PIP Ring ☐ MCP ☐ PIP Little ☐ MCP ☐ PIP
Volume of drug administered	**Carton 1** Batch Number ☐☐☐☐☐☐☐☐ Expiry Date ☐☐ / ☐☐ (m m / y y) ☐ 0.20ml (one PIP joint treated) ☐ 0.25ml (one MCP joint treated) ☐ Other volume (please specify) ☐.☐☐ ml **Carton 2** Batch Number ☐☐☐☐☐☐☐☐ Expiry Date ☐☐ / ☐☐ (m m / y y) ☐ 0.20ml (one PIP joint treated) ☐ 0.25ml (one MCP joint treated) ☐ Other volume (please specify) ☐.☐☐ ml
Were any of the following limitations identified; no cord, tight skin, pain, anxiety?	☐ Yes ☐ No If 'Yes', please indicate those which apply: ☐ No cord ☐ Tight skin Pain: ☐ mild ☐ moderate ☐ severe ☐ Anxiety

Signature of person completing page: ____________

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Was any additional medication prescribed to treat the limitations?	☐ Yes ☐ No If 'Yes', please specify type of medication: ☐
Staff in clinic during procedure	*Please complete number of staff for each type, or enter '00' if not applicable.* Consultant Number ☐☐ Trainee surgeon - ST Number ☐☐ Nurse Number ☐☐ Band ☐☐ Health Care Assistant Number ☐☐ Band ☐☐ Operating Department Practioner Number ☐☐ Band ☐☐ Other Please specify ☐ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ☐ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ☐ Number ☐☐ Band (if Agenda for Change) ☐☐
Did the patient need unplanned admission as an inpatient following the procedure?	☐ Yes ☐ No If 'Yes', please complete the Adverse Event Number ☐☐

Proceed to Section E

Signature of person completing page: ☐

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Participant Study Number: ☐☐☐☐

Section E – Limited Fasciectomy Procedure

Tick here if the participant was not allocated to limited fasciectomy and ensure Section D is completed before proceeding to Section F ☐

Date of Limited Fasciectomy Surgery	☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)
Time entered anaesthetic room (24 hr)	☐☐ : ☐☐ (hh:mm)
Time entered operating theatre (24 hr)	☐☐ : ☐☐ (hh:mm)
Time of "knife to skin" (24 hr)	☐☐ : ☐☐ (hh:mm)
Time operation finished (24 hr)	☐☐ : ☐☐ (hh:mm)
Time out of theatre (24 hr)	☐☐ : ☐☐ (hh:mm)
Was the surgery performed as	☐ Day case ☐ Inpatient admission If inpatient admission, please record date and time of patient discharge DD/MM/YYYY Hh:mm (24 hr) ☐☐ / ☐☐ / ☐☐☐☐ ☐☐ : ☐☐ (d d / m m / y y y y h h : m m)
Did the patient need unplanned admission as an inpatient following the procedure?	☐ Yes ☐ No If Yes, please complete the Adverse Event Number ☐☐
Anaesthetic:	Type of anaesthetic used: ☐ None ☐ Forearm block ☐ Axillary or brachial plexus block ☐ General anaesthetic ☐ Other (please specify) ________ ☐ Local Anaesthetic (please provide details below) Name of local anaesthetic administered: ________ Concentration administered: ☐☐ % Volume administered: ☐☐ . ☐☐ ml

Signature of person completing page: ________ Date (dd/mm/yyyy): ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

	Staff involved in anaesthesia: *Please complete number of staff for each type, or enter '00' if not applicable.* Consultant Anaesthetist Number [ ][ ] Trainee Anaesthetist – ST Number [ ][ ] Other Please specify [ ] Number [ ][ ] Band (if Agenda for Change) [ ][ ] Other Please specify [ ] Number [ ][ ] Band (if Agenda for Change) [ ][ ]
Joints treated	see below

Left Hand

Thumb	☐ MCP	☐ PIP
Index	☐ MCP	☐ PIP
Middle	☐ MCP	☐ PIP
Ring	☐ MCP	☐ PIP
Little	☐ MCP	☐ PIP

Right Hand

Thumb	☐ MCP	☐ PIP
Index	☐ MCP	☐ PIP
Middle	☐ MCP	☐ PIP
Ring	☐ MCP	☐ PIP
Little	☐ MCP	☐ PIP

Signature of person completing page: [ ]

Date *(dd/mm/yyyy)*: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Assessor ID: [ ][ ]

Staff in theatre during procedure	*Please complete number of staff for each type, or enter '00' if not applicable.* Consultant — Number [ ][ ] Trainee surgeon - ST — Number [ ][ ] Nurse — Number [ ][ ] — Band [ ][ ] Health Care Assistant — Number [ ][ ] — Band [ ][ ] Operating Department Practioner — Number [ ][ ] — Band [ ][ ] Other Please specify [ ] — Number [ ][ ] — Band (if Agenda for Change) [ ][ ] Other Please specify [ ] — Number [ ][ ] — Band (if Agenda for Change) [ ][ ] Other Please specify [ ] — Number [ ][ ] — Band (if Agenda for Change) [ ][ ] Did the Anaesthetic team stay in the operating room during the procedure? [ ] Yes [ ] No
Antibiotics used	Were antibiotics used? [ ] Yes [ ] No If Yes, please complete the following:

Name of antibiotic	**Dosing**		
1. Cephalosporin	[ ] None	[ ] Single dose	[ ] Multiple dose
2. Teicoplanin	[ ] None	[ ] Single dose	[ ] Multiple dose
3. Erythromycin	[ ] None	[ ] Single dose	[ ] Multiple dose
4. Augmentin	[ ] None	[ ] Single dose	[ ] Multiple dose
5. Vancomycin	[ ] None	[ ] Single dose	[ ] Multiple dose
6. Other, please specify:	[ ] None	[ ] Single dose	[ ] Multiple dose

Signature of person completing page: [ ]

Date *(dd/mm/yyyy)*: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Assessor ID: [ ][ ]

How was the wound managed?	☐ Z plasty ☐ Wound left open ☐ Other (please specify): [ ] ☐ Skin graft If skin graft, which type of graft was used? ☐ Full thickness ☐ Partial thickness
Were any of the following limitations identified; no cord, tight skin, pain, anxiety?	☐ Yes ☐ No If Yes, please indicate those which apply: ☐ No cord ☐ Tight skin Pain: ☐ mild ☐ moderate ☐ severe ☐ Anxiety
Was any additional medication prescribed to treat the limitations?	☐ Yes ☐ No If Yes, please specify type of medication: [ ]
Degree of Correction to reference digit	☐ Full ☐ Almost Full ☐ Partial ☐ None

Proceed to Section F

Signature of person completing page: [ ]

Date *(dd/mm/yyyy)*: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Assessor ID: [ ][ ]

Participant Study Number: ☐☐☐☐

Section F – Joint Manipulation

Tick here if the participant was not allocated to collagenase and proceed to Section G ☐

Date of manipulation	☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)
Was there spontaneous correction?	☐ Yes ☐ No If Yes, please indicate those which apply: ☐ Partial spontaneous correction ☐ Complete spontaneous correction
Will manipulation proceed as planned?	☐ Yes ☐ No If No, please provide the reason:
Time manipulation commenced (24 hr)	☐☐ : ☐☐ *(hh:mm)*
Time manipulation completed (24 hr)	☐☐ : ☐☐ *(hh:mm)*
Was local anaesthesia used?	☐ Yes ☐ No If Yes, please provide details below: Name of local anaesthetic administered: Concentration administered: ☐☐ % Volume administered: ☐☐ . ☐☐ ml
Staff in clinic during manipulation	*Please complete number of staff for each type, or enter '00' if not applicable.* Consultant Number ☐☐ Trainee surgeon - ST Number ☐☐ Nurse Number ☐☐ Band ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐

Signature of person completing page: ____ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Was the manipulation completed as planned?	☐ Yes ☐ No If No, please provide the reason why manipulation was not completed as planned: ☐ Unable to manipulate cord/cord did not snap during manipulation ☐ Other (please specify):
Degree of correction in the reference digit	☐ Full ☐ Almost Full ☐ Partial ☐ None Joint angle: ☐☐☐ degrees

Proceed to Section G

Signature of person completing page:

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐

Section G – Wound Clinic Appointment (to be completed following Limited Fasciectomy Surgery only)

Tick here if the participant was not allocated to limited fasciectomy and ensure Section F is completed before proceeding to Section H ☐

Time appointment commenced (24 hr)	☐☐:☐☐ *(hh:mm)*
Time appointment completed (24 hr)	☐☐:☐☐ *(hh:mm)*
Staff in clinic	*Please complete number of staff for each type, or enter '00' if not applicable.* Consultant Number ☐☐ Trainee surgeon - ST Number ☐☐ Nurse Number ☐☐ Band ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐ Other Please specify ____ Number ☐☐ Band (if Agenda for Change) ☐☐
What is the degree of correction in the reference digit?	☐ Full ☐ Almost Full ☐ Partial ☐ None Joint angle: ☐☐☐ degrees

Proceed to Section H

Signature of person completing page: ____________ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

Section H – Case Report Form Sign Off

1. All sections of the Treatment Delivery CRF have been completed ☐ Yes ☐ No

2. Participant has been provided with their 2 week and 6 week questionnaires ☐ Yes ☐ No

3. A copy of all photographs taken have been sent to YTU ☐ Yes ☐ No

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CRF Sign Off (To be completed by assessor (clinician or research nurse) who has reviewed all data in the CRF)

Name: ____________________

Signature: ____________________

Assessor ID: ☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Signature of person completing page: ____________________

Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐

Assessor ID: ☐☐