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B R U G M A N N

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At the attention of the EMA

Brussels, 27/07/2021

To whom it may concern,

EudraCT clinical trial result – partial results

Sponsor	Centre Hospitalier Universitaire Brugmann		
Trial Title	Randomized controlled prospective study on the injection of corticoids for the treatment of acute sprains of the proximal interphalangeal joints of the finger (thumbs excluded).		
EUDRACT	2016-003875-22	**Sponsor reference**	CHUB-Diprophos-IPP

I hereby notify you that the clinical trial identified above was closed on 31/07/2017 without reaching its recruitment goal, due to the nature of the study (graduation work of a master level student in Medicine, limited amount of time to perform the study).

The clinical study summary report, based on the results presented in the graduation work of Dr Laura Place (ULB, Faculty of Medicine, Academic Year 2016-2017) is annexed to this letter.

I remain at your disposition for further information on this trial.

C.H.U. BRUGMANN BRUXELLES
UNITÉ DE RECHERCHE CLINIQUE
DR BESSE H. TATIANA
1-84145-58-001

Kind regards,
Dr T. Besse-Hammer

CHU UVC BRUGMANN

Clinical Study Summary Report

Trial Title	Randomized controlled prospective study on the injection of corticoids for the treatment of acute sprains of the proximal interphalangeal joints of the finger (thumbs excluded).
Sponsor	Centre Hospitalier Universitaire Brugmann (CHU Brugmann)
Sponsor address	4 Place A. Van Gehuchten, 1020 Brussels, Belgium
Principal Investigator	Dr Albert De Mey (Co-investigator : Dr Laura Place)
Protocol Identifier	CHUB-Diprophos-IPP
EudraCT number	2016-003875-22
Name of IMPs	Diprophos (Dipropionate of betamethasone + disodic phosphate of betamethasone), delivered by MSD Belgium BVBA/SPRL
	Marcaine (bupivacaine chlorhydrate), delivered by NV AstraZeneca SA/Aspen Pharma Trading Limited
Trial objective	Assess the effect of corticoids in the acute treatment of the sprain of the proximal interphalangeal joints of the fingers. The long term aim is to assess if corticoids can be used as first choice treatment, instead of a long immobilization or a careful precocious mobilization.
Endpoints	Primary endpoint: flessum The flexum is defined as present when there is a deficit of extension. Secondary endpoints: PPI extension and flexion, girth, edema, grip strength, VAS, Quick-DASH, and MHQ
Study population	Adults over 18 years old, with a sprain of the proximal interphalangeal joint of the fingers: type I and II and III of the Eaton classification (except if fracture/luxation with more than 50% of the articular surface injured). Trauma of one articulation only, consultation within 2 weeks of trauma.
Exclusion criteria	Sprain of the thumb, articular hyperlaxity, trauma>2 months, unstable PPI, surgical sprains: non-reducible dislocation, unstable dislocation-fracture, nerve or tendon damage, contraindications to injectable corticosteroids: allergy to corticosteroids, infection at the injection site, PPI prosthesis.
Trial design	Multicentric (CHU Brugmann + Leopold Park Clinic), controlled, open-label, prospective.
Trial start date	08/12/2016
Trial end date	31/07/2017
Target number of subjects for whole trial	60
Subjects analyzed in this report	32
Countries concerned by this trial	Belgium
Ethical approval date	16/11/2016 (Ethics committee CHU Brugmann)
Competent authorities approval date	08/12/2016 (FAGG)
Report date	22/07/2021

IMP information

Diprophos	
Marketing authorization holder	MSD Belgium BVBA/SPRL
MA number	BE110801
Date of first marketing authorization approval	01/07/1978
Approved indications	Corticoids are used as adjuvant therapy. For intra-articular administrations: as adjuvant treatment for a short period of time to help patients overcome an acute episode or an exacerbation in osteoarthritis or rheumatoid polyarthritis.
Dosage and route of administration	Suspension for injection, 0.5ml (5mg + 2 mg/1ml), 1 injection only, periarticular use
Mode of action	Betamethasone is a synthetic glucocorticoid. It has a strong anti-inflammatory, anti-allergic and immunosuppressive activity. Glucocorticoids diffuse through cell membranes and form complexes with specific cytoplasmic receptors. These complexes then enter the cell nucleus , bind to chromatin and stimulate transcription of messenger RNA and protein synthesis of various enzymes. This action would ultimately be responsible for the effects observed during the systemic use of glucocorticoids.

Marcaine	
Marketing authorization holder	NV AstraZeneca SA - Aspen Pharma Trading Limited
MA number	BE078251
Date of first marketing authorization approval	16/11/1970
Approved indications	Surgical anesthesia and management of acute pain.
Dosage and route of administration	Solution for injection, 0.5ml (0.5% solution), 1 injection only, periarticular use
Mode of action	Bupivacaine hydrochloride is a long-acting amide local anesthetic with anesthetic and analgesic effects. It reversibly blocks the propagation of a stimulus along the nerve fibers by inhibiting the influx of sodium ions through the cell membrane of nerve cells. The sodium channel of the nerve cell is considered a receptor for local anesthetics.

Diprophos is the corticoid used in our study. In the form of a syringe in injectable suspension, it is composed of 5mg / 1ml of betamethasone dipropionate and 2mg / 1ml of betamethasone sodium phosphate. In total, 1 ml is injected including 0.5 ml of Diprophos diluted with 0.5 ml of marcaine without adrenaline 0.5%. The infiltration is administered para-articularly, by lateral ulnar and radial approach. The time between trauma and infiltration should be at least 1 week.

1. List of abbreviations

PPI - proximal interphalangeal joint
PP - palmar plate
DASH: questionnaire of the disabilities of the arm, shoulder and hand
EVA: visual analogical scale
Group A: infiltration
Group B: no infiltration
ITT: Temporary work interruption
MHQ: Michigan hand questionnaire

2. Introduction

The proximal interphalangeal joint (PPI) is a trochlear joint, only capable of flexion and extension. Its stability is possible thanks to the capsule-ligamentary structures that surround it: the palmar plate (PP) which limits its hyperextension and the collateral ligaments (main and accessory).

PPI hyperextension lesions are among the most common ligament injuries of the hand. Harmless in appearance, they are nevertheless a source of significant morbidity: pain and edema persist for 3 to 6 months. The swelling of the PPI sometimes becomes a persistent sequel (the edema is replaced by a thicker ligament scar). These strains are sometimes underestimated by the patient and the primary care practitioner. Unnecessarily prolonged immobilization treatment leads to permanent rigidity of the PPI, which affects the function of the hand.

Currently, there is no consensus as to an optimal conservative management for a stable sprain of PPI. Uncertainty persists regarding the type of immersion (splint, syndactyly or immediate mobilization) and its duration (sometimes up to 6 weeks). However, despite early mobilization, the most common complication is an extension deficit with permanent flessum. In this case, a dynamic extension splint and physiotherapy are prescribed. PPI sprains therefore require treatment for several months, sometimes even arthrolysis in extreme cases.

The main aim of this study is to compare the results of corticosteroid infiltration (new therapeutic approach) in patients with a stable sprain of PPI versus the usual treatment (early mobilization by splint and/or syndactyly). The infiltration of corticosteroids is a procedure already carried out in current practice in the centers involved in this study. This study aims to objectify the field findings (acceleration of the clinical course, better functional result).

3. Methodology

3.1 Participants

Of the 45 patients identified, six patients were excluded (exclusion criteria), three were lost to follow-up and four had an incomplete file. Two patients had two PPI sprains. Two non-infiltrated patients, without improvement after 1 month, were infiltrated. A total of 36 long fingers for 32 patients with a stable PPI sprain were included in the study. Half received corticosteroid infiltration (group A, n = 18) while the other half, the control group (group B, n = 18) received the usual treatment, namely a rest splint and / or syndactyly. Pain relievers were prescribed on demand. If necessary, physiotherapy or a nocturnal extension splint was prescribed.

3.2 Diagnostic procedure

The severity spectrum of hyperextension PPI injury ranges from incomplete soft tissue rupture to unstable dislocation fractures. The diagnosis is based mainly on the history of the trauma

(with or without dislocation) and on the clinical evaluation of the patient (pain, swelling, bruising on the palmar face and reduction in the articular amplitude).

X-rays can classify these lesions into three stages (Eaton's classification): hyperextension (type I), dorsal dislocation (type II) and fracture-dislocation (type III). For type III lesions, when the avulsed fragment exceeds 30% of the joint surface, the reduction is unstable and surgical treatment may be necessary. Note that a small bone tear from the base of P2, regardless of the type of sprain, does not modify the conservative treatment.

3.3 Data collection

The assessment started at the first consultation (D1). The patients were seen again 1 week (D7) and 1 month later (D30). On D1, a standard x-ray (face, profile and three-quarter) of the injured finger was taken in all patients. At the physical examination (D1-D7-D30) four measurements (in comparison with the contralateral side) were systematically taken: flexion, extension, perimeter, grip strength. Three questionnaires were completed by the patients: the VAS and the quick DASH (on D1-D7-D30) and the MHQ (on D7-D30). The EVA makes it possible to assess the pain on active mobilization. The Quick-Dash assesses the return to daily activities and sports. The MHQ is made up of 6 subgroups assessing overall hand function, daily activities, work, pain, aesthetics and patient satisfaction. The demographic parameters were recorded on D1: age, sex, origin, dominant hand, injured hand and finger, accident circumstance, patient status, smoker, daily intake of analgesics. At D7 and D30, it was recorded whether there has been use of analgesics, physiotherapy, extension splint or ITT.

3.5 Treatment

Diprophos is the corticoid used in our study. In the form of a syringe in injectable suspension, it is composed of 5mg / 1ml of betamethasone dipropionate and 2mg / 1ml of betamethasone sodium phosphate. In total, 1 ml is injected including 0.5 ml of Diprophos diluted with 0.5 ml of marcaine without adrenaline 0.5%. The infiltration is administered para-articularly, by lateral ulnar and radial approach. The time between trauma and infiltration should be at least 1 week.

3.6 Variables

The primary outcome is the flessum. The secondary outcomes are: PPI extension and flexion, girth, edema, grip strength, VAS, Quick-DASH, and MHQ. The flexum is said to be present when there is a deficit of extension. Edema is said to be present when the perimeter of the injured PPI is greater than 102% of the contralateral PPI. The results are processed according to a scoring and grading system.

Score	EVA	Movement loss	Strength	Perimeter
25			>100%	<100%
25-0	0/10-10/10	0°- 40°	100% - 0%	100% -150%
0		>40°		>150%

Total score is an addition of the scores given for each compound (EVA – Movement loss – Strength – Perimeter). Total score ranges from 0 to 100.

Results gradation (total score)	
Excellent	75-100
Good	50-74
Intermediate	25-49
Bad	0-24

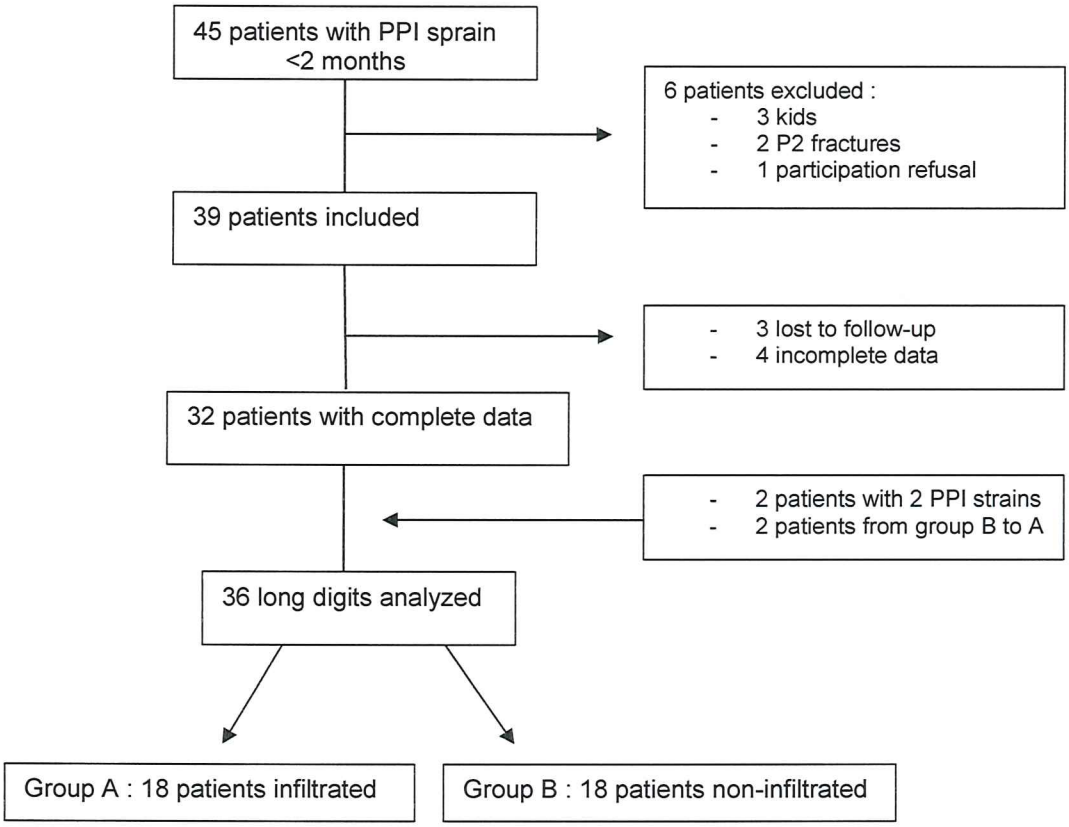
3.7 Statistical analysis

Data were analyzed using SPSS version 20 statistical software. Descriptive analysis was performed for the sample and for each treatment group. The evolution of the quantitative measures was evaluated over time (within-subject variable) and between treatment groups (between-subject variable) using repeated measures analysis (ANOVA) with Bonferroni correction and t tests for independent samples. To assess the presence of flessum, edema or an 'excellent' result, non-parametric tests (Cochran's Q and Chi-square) were performed. Selected p-value: $p < 0,05$

4. Results

4.1 Descriptive analysis of the sample

Out of a total of 36 long fingers for 32 participants with a stable PPI sprain, all were Caucasian and half were male. The average age was 38 years (range: 14-74 years). There were 34 type I sprains according to Eaton (94%) and 2 type II (6%). In total, 17 patients (47%) presented within 2 weeks after the trauma compared to 19 (53%) within 2 weeks to 2 months; 50% of patients had already been treated previously. The dominant hand was injured in 53% of cases. The fingers involved were in order of frequency: ring fingers (33%), middle fingers (31%), little fingers (19%) and index fingers (17%). Of the 36 sprains, 64% occurred during a sporting activity, 6% at work and 31% in another situation. Within the sample, 58% of patients were employees, 14% self-employed, 1% under mutual insurance, 17% students and 8% retirees. Only 3 patients smoked.



	Total population
N patients	36
Treatment -Infiltration (group A) -No infiltration (group B)	 18 (50%) 18 (50%)
Age - Average - Minimum - Maximum	 38 14 74
Sex - Men - Women	 18 (50%) 18 (50%)
Origin Caucasian	 36 (100%)
Eaton Classification -Type I -Type II -Type III	 34 (94%) 2 (6%) 0 (0%)
Elapsed time - < 2 weeks - 2 weeks – 2 months	 17 (47%) 19 (53 %)
Treatment before the 1st consultation	18 (50%)
Dominant hand injured	19 (53%)
Injured finger - Index finger - Middle finger - Ring finger - Little finger	 6 (17%) 11 (31%) 12 (33%) 7 (19%)
Type of accident - Sports - Work related - Other	 23 (64%) 2 (6%) 11 (31%)
Patient status - Employee - Independant - Student - Retired - Under mutual insurance	 21 (58%) 5 (14%) 6 (17%) 3 (8%) 1 (3%)
Smoker	3 (8%)

4.2 Descriptive analysis of each group

The two groups are similar in terms of age (t-test = - 1,299, p = 0,203), sex (Chi square =0, p=1,000) and Eaton classification (Chi square =0, p =1,000) but not in terms of the time elapsed between the trauma and the first consultation (Chi square =9,028, p =0,003).

	Group A	Group B	Chi square/t test	P value	<0.05 = *
N patients	18	18			
Age - Mean - Minimum - Maximum	 42 17 74	 35 14 74	 -1,299	 0,203	
Sex - Men - Women	 9 (50%) 9 (50%)	 9 (50%) 9 (50%)	 0	 1,000	

Origin - Caucasian	18 (100%)	18 (100%)	/	/	
Eaton Classification - Type I - Type II	17 (94%) 1 (6%)	17 (94%) 1 (6%)	0	1,000	
Elapsed time - <2 weeks - 2 weeks – 2 months	4 (22%) 14 (78%)	13 (72%) 5 (28%)	9,028	0,003	*
Treatment prior to the 1st consultation	11 (61%)	7 (39%)			
Dominant hand injured	11 (61%)	8 (44%)			
Injured finger - Index finger - Middle finger - Ring finger - Little finger	3 (17%) 6 (33%) 5 (28%) 4 (22%)	3 (17%) 5 (28%) 7 (39%) 3 (17%)			
Type of accident - Sports - Work related - Other	10 (56%) 1 (6%) 7 (39%)	13 (72%) 1 (6%) 4 (22%)			
Patient status - Employee - Independant - Student - Retired Under mutual insurance	12 (67%) 1 (6%) 2 (11%) 2 (11%) 1 (6%)	9 (50%) 4 (22%) 4 (22%) 1 (6%) 0 (0%)			
Smoker	2 (11%)	1 (6%)			

4.3 Analysis of the quantitative measures

Repeated measures ANOVA shows a major time effect ($p < 0.005$) indicating a significant improvement in each measurement (extension, flexion, girth, EVA, Quick-DASH and MHQ) at D7 and D30 except for strength where the improvement is not significant between D7-D30 ($p = 0,071$).

For strength and pain there is an effect of the treatment. On D30, in the infiltrated group, the mean force is significantly bigger (t test = -2,404, $p = 0,022$) and the pain is significantly lower (t test = 2,219, $p = 0,036$).

For overall function and satisfaction, there is also a treatment effect. On D30, in the infiltrated group, the overall function is significantly bigger (t test = -2,474, $p = 0,019$) and satisfaction too (t test = -2,314, $p = 0,027$). However, for satisfaction, it is already significantly bigger on D7 (t test = -2,433, $p = 0,020$). For the other measures, the treatment effect is not significant ($p < 0,05$).

A time/treatment interaction is observed for pain ($F = 3,237$, $p = 0,050$) and for extension deficit ($F = 7,016$, $p = 0,004$). The infiltrated group presents a more serious clinical picture in terms of pain and extension deficit, but these two measures improve much more rapidly with infiltration.

ANOVA for repeated measures of the 4 measurements and 2 questionnaires (J1-J7-J30)

		Group	n	$\bar{x}$	Effects -Intra-subject -Inter-subject -Interaction	F	p-value	<0.05 = *
Extension	D1	A	18	-14,67	Time	28,762	0,000	*
		B	18	-9,94				
	D7	A	18	-4,22	Treatment	0,088	0,768	

		B	18	-7,28				
	D30	A	18	-0,56	Time*treatment	7,016	0,004	*
		B	18	-4,78				
Flexion	D1	A	18	68,06	Time	28,395	0,000	*
		B	18	74,94				
	D7	A	18	83,33	Treatment	0,175	0,678	
		B	18	83,17				
	D30	A	18	94,22	Time*treatment	1,010	0,363	
		B	18	93,56				
Perimeter	D1	A	18	61,11	Time	72,768	0,000	*
		B	18	62,89				
	D7	A	18	56,28	Treatment	1,416	0,242	
		B	18	60,33				
	D30	A	18	55,00	Time*treatment	3,043	0,061	
		B	18	58,06				
Strength	D1	A	18	18,17	Time	25,404	0,000	*
		B	18	13,72				
	D7	A	18	26,33	Treatment	4,869	0,034	*
		B	18	19,44				
	D30	A	18	29,67	Time*treatment	1,390	0,256	
		B	18	20,72				
EVA	D1	A	18	4,11	Time	51,152	0,000	*
		B	18	3,67				
	D7	A	18	1,67	Treatment	0,634	0,432	
		B	18	2,22				
	D30	A	18	0,78	Time*treatment	3,237	0,050	*
		B	18	1,67				
Quick Dash	D1	A	18	38,12	Time	83,892	0,000	*
		B	18	37,89				
	D7	A	18	22,35	Treatment	0,761	0,389	
		B	18	27,52				
	D30	A	18	9,34	Time*treatment	1,964	0,148	
		B	18	16,57				

Multiple comparisons for the intra-subject effect (=time) of the 4 measures and 2 questionnaires

	Time		$\bar{x}$ difference	P value	<0.05=*
Extension	D1	D7	-6,556	0,000	*
	D7	D30	-3,083	0,003	*
	D1	D30	-9,639	0,000	*
Flexion	D1	D7	-11,750	0,001	*
	D7	D30	-10,639	0,000	*
	D1	D30	-22,389	0,000	*
Perimeter	D1	D7	3,694	0,000	*
	D7	D30	1,778	0,000	*
	D1	D30	5,472	0,000	*
Strength	D1	D7	-6,944	0,000	*
	D7	D30	-2,306	0,071	
	D1	D30	-9,250	0,000	*
EVA	D1	D7	1,944	0,000	*
	D7	D30	0,722	0,005	*
	D1	D30	2,667	0,000	*
Quick-Dash	D1	D7	13,069	0,000	*
	D7	D30	11,997	0,000	*
	D1	D30	25,067	0,000	*

Multiple comparisons for the inter-subject effect (=treatment) of the 4 measures and 2 questionnaires

		Group	$\bar{x}$	t-test	p-value	<0.05 = *
Extension	D1	A	-14,67	1,243	0,222	
		B	-9,94			
	D7	A	-4,22	-0,953	0,347	
		B	-7,28			
	D30	A	-0,56	-1,638	0,111	
		B	-4,78			
Flexion	D1	A	68,06	0,862	0,396	
		B	74,94			
	D7	A	83,33	-0,029	0,977	
		B	83,17			
	D30	A	94,22	-0,250	0,804	
		B	93,56			
Perimeter	D1	A	61,11	0,688	0,496	
		B	62,89			
	D7	A	56,28	1,588	0,122	
		B	60,33			
	D30	A	55,00	1,221	0,231	
		B	58,06			
Strength	D1	A	18,17	-1,506	0,141	
		B	13,72			
	D7	A	26,33	-1,918	0,064	
		B	19,44			
	D30	A	29,67	-2,404	0,022	*
		B	20,72			
EVA	D1	A	4,11	-0,705	0,486	
		B	3,67			
	D7	A	1,67	1,079	0,288	
		B	2,22			
	D30	A	0,78	2,219	0,036	*
		B	1,67			
Quick Dash	D1	A	38,12	-0,043	0,966	
		B	37,89			
	D7	A	22,35	0,914	0,367	
		B	37,52			
	D30	A	9,34	1,592	0,121	
		B	16,57			

ANOVA with repeated measures on the MHQ questionnaire (J7-J30)

		Groups	N	$\bar{x}$	Effects -Intra-subject -Inter-subject -Interaction	F	P value	<0.05=*
MHQ- total	D7	A	18	79,311	Time	30,322	0,000	*
		B	18	71,589				
	D30	A	18	89,983	Treatment	2,872	0,099	
		B	18	81,633	Time*treatment	0,028	0,868	
MHQ- global function	D7	A	18	76,389	Time	32,897	0,000	*
		B	18	68,056				
	D30	A	18	88,333	Treatment	4,284	0,046	*

		B	18	75,833	Time*treatment	1,468	0,234	
MHQ-daily life activities	D7	A	18	84,311	Time	49,411	0,000	*
		B	18	76,689				
	D30	A	18	92,467	Treatment	1,898	0,177	
		B	18	88,206	Time*treatment	1,442	0,238	
MHQ- work	D7	A	18	82,222	Time	8,174	0,007	*
		B	18	71,667				
	D30	A	18	92,778	Treatment	1,731	0,197	
		B	18	83,611	Time*treatment	0,031	0,861	
MHQ-pain	D7	A	18	27,222	Time	31,735	0,000	*
		B	18	31,389				
	D30	A	18	15,278	Treatment	0,221	0,641	
		B	18	17,778	Time*treatment	0,135	0,716	
MHQ-esthetics	D7	A	18	73,972	Time	4,251	0,047	*
		B	18	81,961				
	D30	A	18	87,167	Treatment	0,149	0,702	
		B	18	84,739	Time*treatment	1,808	0,188	
MHQ-satisfaction	D7	A	18	78,933	Time	19,001	0,000	*
		B	18	63,428				
	D30	A	18	88,894	Treatment	6,750	0,014	*
		B	18	75,228	Time*treatment	0,136	0,715	

Multiple comparisons for the inter-subject effect (=treatment) of the questionnaire MHQ(J7-J30)

		Groups	$\bar{x}$	t-test	P value	<0.05=*
MHQ- total	D7	A	79,311	-1,442	0,159	
		B	71,589			
	D30	A	89,983	-1,728	0,093	
		B	81,633			
MHQ-global function	D7	A	76,389	-1,496	0,144	
		B	68,056			
	D30	A	88,333	-2,474	0,019	*
		B	75,833			
MHQ-daily life activities	D7	A	84,311	-1,554	0,129	
		B	76,689			
	D30	A	92,467	-1,032	0,309	
		B	88,206			
MHQ- work	D7	A	82,222	-1,091	0,283	
		B	71,667			
	D30	A	92,778	-1,301	0,202	
		B	83,611			
MHQ-pain	D7	A	27,222	0,548	0,588	
		B	31,389			
	D30	A	15,278	0,344	0,733	
		B	17,778			
MHQ-esthetics	D7	A	73,972	0,881	0,386	
		B	81,961			
	D30	A	87,167	-0,338	0,737	
		B	84,739			
MHQ-satisfaction	D7	A	78,933	-2,433	0,020	*
		B	63,428			
	D30	A	88,894	-2,314	0,027	*
		B	75,228			

4.4 Analysis of the qualitative measures

Flessum

In group A, the number of flessum decreases significantly over time (p = 0,001) but not in group B (p = 0,165). At D7 (Chi-square = 4,500, p = 0.034) and At D30 (Chi-square = 7,200, p = 0,007), the number of flessum is significantly lower than in the infiltrated group. We therefore conclude that the infiltration allows a faster and bigger disappearance of the number of flessum from the first week.

Q Cochran test for repeated measures of the flessum during time for each group

		N	Yes (%)	Cochran Q	P value	<0.05=*
Group A	Flessum D1	18	14 (77,8)	15,000	0,001	*
	Flessum D7	18	9 (50,0)			
	Flessum D30	18	4 (22,2)			
Group B	Flessum D1	18	15 (83,3)	3,600	0,165	
	Flessum D7	18	15 (83,3)			
	Flessum D30	18	12 (66,7)			

Multiple comparisons of the intra-subject effect (=time) for flessum for each group with the Q Cochran test

		Temps		Cochran Q	P value	<0.05=*
Group A	Flessum	D1	D7	5,000	0,025	*
		D7	D30	5,000	0,025	*
		D1	D30	10,000	0,002	*
Group B	Flessum	D1	D7	0,000	1,000	
		D7	D30	3,000	0,083	
		D1	D30	1,800	0,180	

Chi square test for group comparison (flessum) at each timepoint

Indicators	Groups	N	Yes (%)	Chi square	P value	<0.05=*
Flessum J1	A	18	14 (77,8)	1,770	0,674	
	B	18	15 (83,3)			
Flessum J7	A	18	9 (50,0)	4,500	0,034	*
	B	18	15 (83,3)			
Flessum J30	A	18	4 (22,2)	7,200	0,007	*
	B	18	12 (66,7)			

Edema

In both groups, the number of edemas decreases significantly over time (p <0.05) except in group B between D1-D7 where p = 0,157. On D7 (Chi square = 9,753, p = 0,002) and at D30 (Chi square = 11,688, p = 0,001), the number of edemas is significantly lower in the infiltrated group. It is therefore concluded that the infiltration allows a faster and greater reduction in the number of edemas from the first week.

Q Cochran test for repeated measures of the edema during time for each group

		N	Yes (%)	Cochran Q	P value	<0.05=*
Group A	Edema J1	18	18 (100,0)	25,125	0,000	*
	Edema J7	18	7 (38,9)			
	Edema J30	18	2 (11,1)			

Group B	Edema J1	18	18 (100,0)	9,333	0,009	*
	Edema J7	18	16 (88,9)			
	Edema J30	18	12 (66,7)			

Multiple comparisons of the intra-subject effect (=time) for edema for each group with the Q Cochran test

		Time		Cochran Q	P value	<0.05=*
Group A	Edema	D1	D7	11,000	0,001	*
		D7	D30	5,000	0,025	*
		D1	D30	16,000	0,000	*
Group B	Edema	D1	D7	2,000	0,157	
		D7	D30	4,000	0,046	*
		D1	D30	6,000	0,014	*

Chi square test for group comparison (edema) at each timepoint

Indicators	Groups	N	Yes (%)	Chi square	P value	<0.05=*
Edema D1	A	18	18 (100,0)	/	/	
	B	18	18 (100,0)			
Edema D7	A	18	7 (38,9)	9,753	0,002	*
	B	18	16 (88,9)			
Edema D30	A	18	2 (11,1)	11,688	0,001	*
	B	18	12 (66,7)			

4.5 Analysis of the scoring system and grading of results

In both groups, the number of excellent results decreases significantly over time ($p < 0.05$) except in group B between D1-D7 where $p = 0,157$. On D7 (Chi square = 6,415, $p = 0,011$) and on D30 (Chi square = 12,500, $p < 0.001$), the number of excellent results is significantly higher in the infiltrated group. It is therefore concluded that the infiltration allows a faster and greater increase in the rate of excellent results from the first week.

Results gradation for each group at each time point

	Excellent			Good			Medium			Bad
	D1	D7	D30	D1	D7	D30	D1	D7	D30	D1-D7-D30
Group A	0/18 (0%)	9/18 (50%)	17/18 (94%)	8/18 (44%)	9/18 (50%)	1/18 (6%)	10/18 (56%)	0/18 (0%)	0/18 (0%)	0/18 (0%)
Group B	0/18 (0%)	2/18 (11%)	7/18 (39%)	7/18 (39%)	14/18 (78%)	10/18 (56%)	11/18 (61%)	2/18 (11%)	1/18 (6%)	0/18 (0%)

Chi square test for the comparison of the 'excellent' grade between the two groups at each time point

Indicators	Groups	N	Yes (%)	Chi-square	P value	<0.05=*
Excellent D1	A	18	0 (100)	/	/	
	B	18	0 (100)			
Excellent D7	A	18	9 (50)	6,415	0,011	*
	B	18	2 (11)			
Excellent D30	A	18	17 (94)	12,500	0,000	*
	B	18	7 (39)			

Q Cochran test for repeated measures on the 'excellent' grade inside the 2 groups

		N	Yes (%)	Cochran Q	P value	<0.05=*
Group A	Excellent D1	15	0 (0,0)	25,529	0,000	*
	Excellent D7	15	9 (50,0)			
	Excellent D30	15	17 (94,4)			
Group B	Excellent D1	15	0 (0,0)	11,143	0,004	*
	Excellent D7	15	2 (11,1)			
	Excellent D30	15	7 (38,9)			

Multiple comparisons of the intra-subject effect (=time) for the 'excellent' grade within each group with Q Cochran test

		Time		Cochran Q	P value	<0.05=*
Group A	Excellent	D1	D7	9,000	0,003	*
		D7	D30	8,000	0,005	*
		D1	D30	17,000	0,000	*
Group B	Excellent	D1	D7	2,000	0,157	
		D7	D30	5,000	0,025	*
		D1	D30	7,000	0,008	*

4.6 Analysis of the need for additional treatment or ITT

Infiltration decreases the risk of having to wear a rest pad and/or syndactyly between D1-D7 (Chi-square = 16,831, p <0,001) and between D7-D30 (Chi-square = 4,433, p = 0,035). On the other hand, for additional treatments (nocturnal extension splints, physiotherapy and analgesics), despite a lesser need at 1 month in the infiltrated group, the difference is not significant. The same goes for the ITT.

Chi-square test to compare the need between the two groups of an additional treatment or an ITT

Indicators	Groups	N	Yes (%)	Chi-square	P value	<0.05=*
Rest splint / syndactyly between D1-D7	A	18	1 (6)	16,831	0,000	*
	B	18	13 (72)			
Rest splint / syndactyly between D7-D30	A	18	1 (6)	4,433	0,035	*
	B	18	6 (33)			
Extension splint between D1-D7	A	18	2 (11)	0,800	0,371	
	B	18	4 (22)			
Extension splint between D1-D30	A	18	6 (33)	2,786	0,095	
	B	18	11 (61)			
Physiotherapy between D1-D7	A	18	2 (11)	0,364	0,546	
	B	18	1 (6)			
Physiotherapy between D1-D7	A	18	4 (22)	0,148	0,700	
	B	18	5 (28)			
Analgesics between D1-D7	A	18	11 (61)	0,450	0,502	
	B	18	9 (50)			
Analgesics between D7-D30	A	18	4 (22)	0,148	0,700	
	B	18	5 (28)			
Temporary work incapacity between D1-D7	A	18	1 (6)	1,125	0,289	
	B	18	3 (17)			

Temporary work incapacity between D7-D30	A	18	0 (0)	3,273	0,070	
	B	18	3(17)			

5. Conclusion

The infiltration of corticosteroids has its place in the treatment of stable PPI sprains of long fingers since it improves the prognosis and is well tolerated. It allows for a much earlier and bigger resolution of pain and the strength in the hand is also recovered more quickly. It also decreases the risk of edema and flessum more rapidly. In addition, patients say they are satisfied from the first week on and recover a significantly bigger overall function at one month. An excellent result is obtained much earlier in the event of infiltration. Through this study, we recommend infiltrating patients with a stable sprain of PPI of a long finger who still present with significant flessum, swelling or pain one week after the trauma.