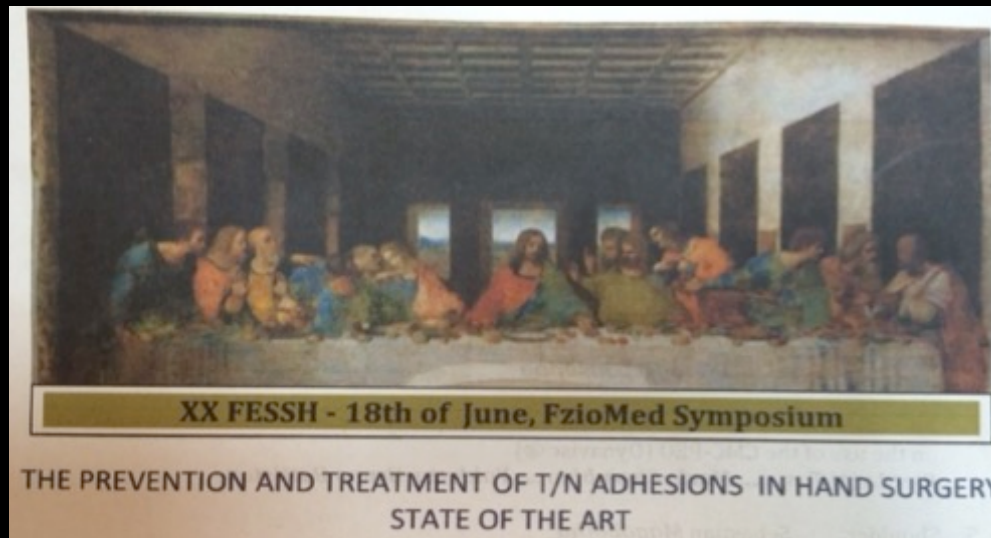


Preliminary results of the SICM study about the use of Carboxy-methyl-cellulose and Poly-ethylene-oxide (Dynavisc®) in tenolysis in zone II of flexor tendon of the hand

G. Caruso, C. Novelli



Tendon adhesions

Adhesions reducing tendon gliding are one of the most common problem following flexor tendon repair reducing final AROM (Active Range of Motion) and preventing good results in terms of fast recovery

Tenolysis is OFTEN a valuable choice to improve tendon primary surgery results

Appropriate rehabilitation reduces but cannot prevent the formation of **adhesion** or their **recurrence** following tenolysis

Dynavisc: Adhesion barrier gel

DYNAVISC is a clear, absorbable gel acts as a temporary, protective barrier to effectively **separate tissues** and **reduce fibrosis** after various surgical procedures, without interfering with normal healing.

DYNAVISC is composed of (Carboxymethylcellulose (CMC), Poly-Ethylene Oxide (PEO), NaCl and CaCl based gel)

- Visco-elastic, "cohesive" properties
- Used not only for the prevention of fibrosis, but also for the reduction of inflammatory post-surgical syndrome.
- It is reabsorbed gradually, with hydrolytic natural process, followed by macrophage activity

Multicentre Clinical Trial on Efficacy of Dynavic in Tendon Adhesion Surgery



S.I.C.M. Società Italiana di Chirurgia della Mano

Rationale

- Study:
 - Multicentric (17 hand surgery services in Italy)
 - Controlled
 - Randomized
- Method:
 - Tenolysis procedure using/ non-using Dynavisc+ immediate rehabilitative program
- Goal:
 - Evaluation of results in patient Dynavisc+ vs Dynavisc- (TAM-VAS)



**Dr. M. CHERUBINO
/VALDATTA**
Varese

Prof. G. PAJARDI
Milano – S. Giuseppe/MultiMedica

Dr. DE MAS
Pordenone

Dr R. ADANI
Verona

Prof. F. BASSETTO
Padova

Prof. A. LANDI
Modena

Prof. M. RICCIO
Ancona

Prof. M. COLONNA

Prof. U. PASSARETTI
Napoli

Dr J. MESSINA
Milano - Istituto G. Pini

Dr. P. GHIGGIO
Ivrea

Dr. B. BATTISTON
Torino

Prof. I. ROSSELLO
Savona

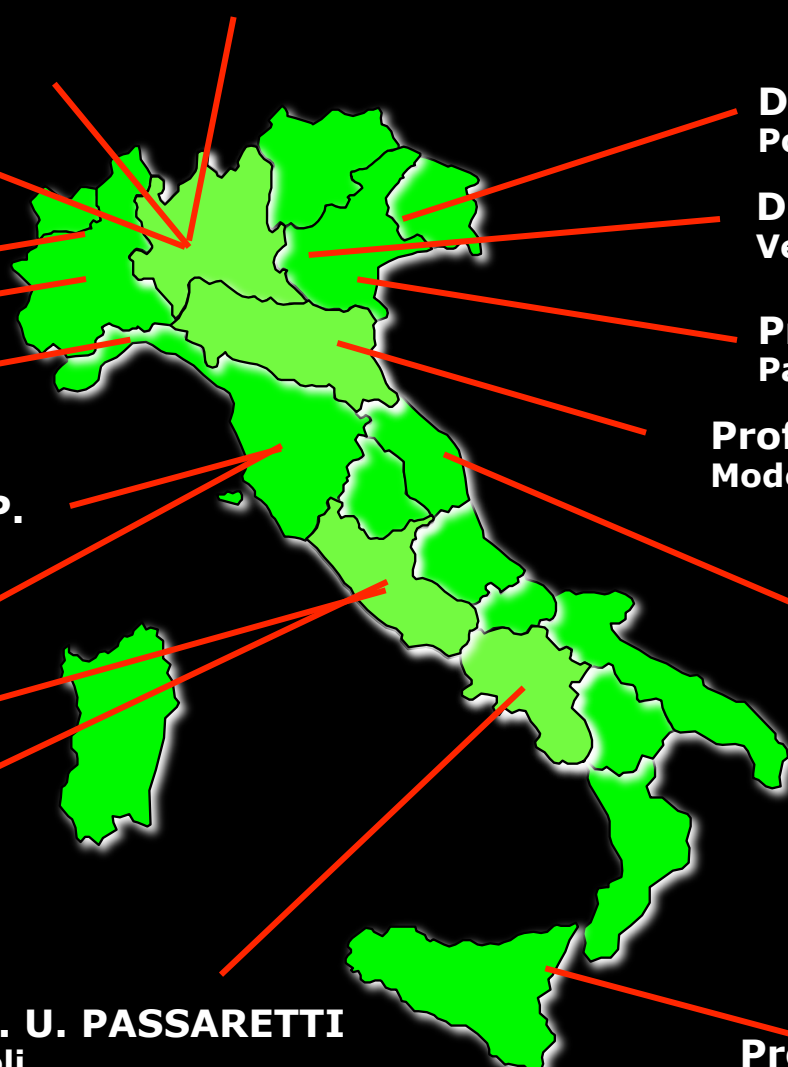
**Dr. M. CERUSO/P.
BIGAZZI**
Firenze - Careggi

Dr. A.VITALI/G. CARUSO
Firenze – IOT Palagi

Dr. N. FELICI
Roma – San Camillo

Dr. A. SPAGNOLI
Roma – Sapienza

Dr. L. CARA
Cagliari



Project

- INCLUSION CRITERIA
 - Adhesion of flexor tendon in zone II, in long finger without injuries of other tissue (bone-nerve-soft tissue loss)
 - Monodigital adhesion
 - Adhesion subsequent to lesion of at least 3 months ago
 - Both male and female and age included among 18-65
 - Informed consensus on surgical treatment

Project

- EXCLUSION CRITERIA

- Adhesion in flexor tendon zone I, III, IV and V
- Thumb adhesions
- Uncontrolled diabete mellitus, collagenopaties, Auto immunological conditions, Neoplasia, ematopoietic disorders, psicolagical diseases
- Pregnancy

Informed consensus

CONSENSO INFORMATO

Io sottoscritto/a dichiaro di essere stato/a informato/a in modo a me comprensibile dal Dott.

- Di essere affetto/a da rigidità secondaria a lesione tendinea

Sulla necessità di essere sottoposto/a all'intervento chirurgico di tenolisi flessori con possibile uso di gel antiaderenziale (Dynavisc- materiale bio-compatibile")

- Sulle eventuali alternative di terapia e sulle conseguenze di un mancato trattamento della mia malattia
- Sulle caratteristiche dell'intervento proposto, sui benefici attesi, sulle conseguenze previste ed anche sui rischi e complicanze che devono comunque essere considerati in relazione all'intervento previsto, in modo particolare, tra le altre, sulla possibilità della risoluzione non completa della rigidità

Confermo pertanto di aver recepito consapevolmente quanto sopra e di aver potuto esprimere domande ed aver ottenuto i relativi chiarimenti.

Per questi motivi, ACCONSENTO al trattamento proposto.

Circa il trattamento dei dati riguardanti la mia salute, AUTORIZZO i Medici della U.O. ad informare il Medico Curante Dott.

Sede e data,

Firma del Medico

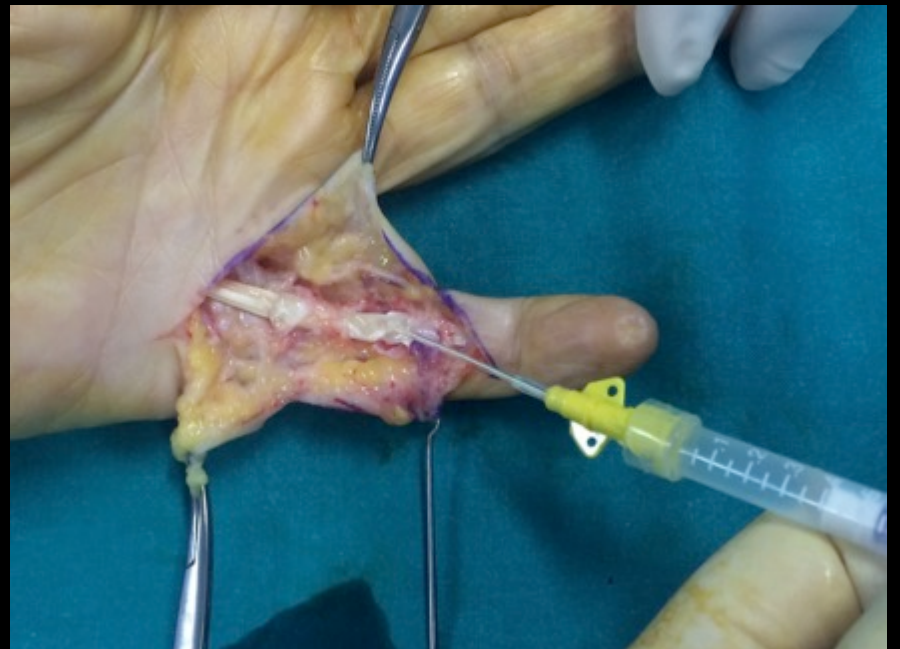
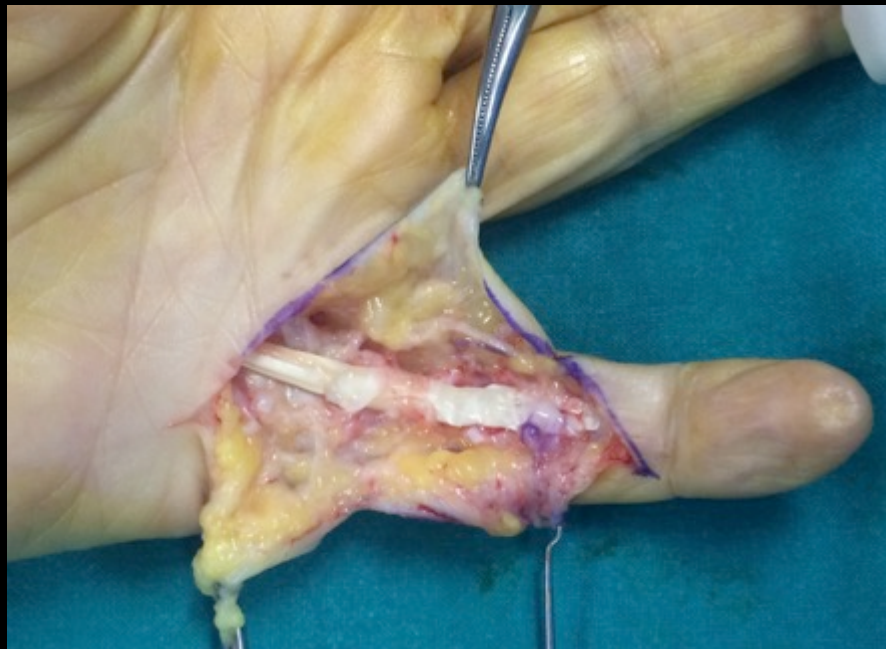
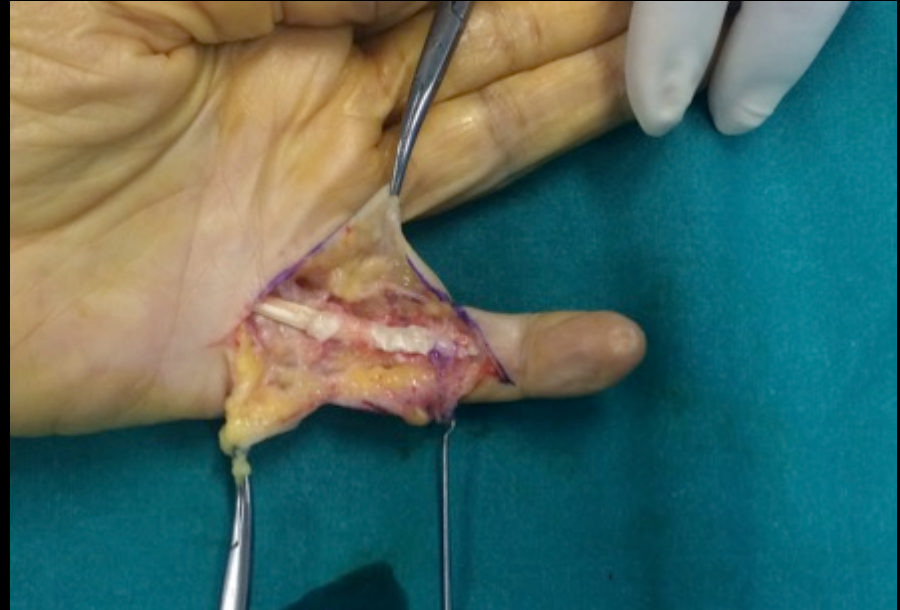
Firma del paziente

FIRMA DELL'EV. TESTIMONE

Clinical trial

- Anesthesia: Brachial plexus
- Tenolysis: standardized surgical technique
- Physio-kinesitherapy: immediate rehabilitation – within 48 hours – performed by dedicated hand physiotherapist
- Evaluation:
 - TAM
 - VAS

Procedure



Rehabilitation Protocol

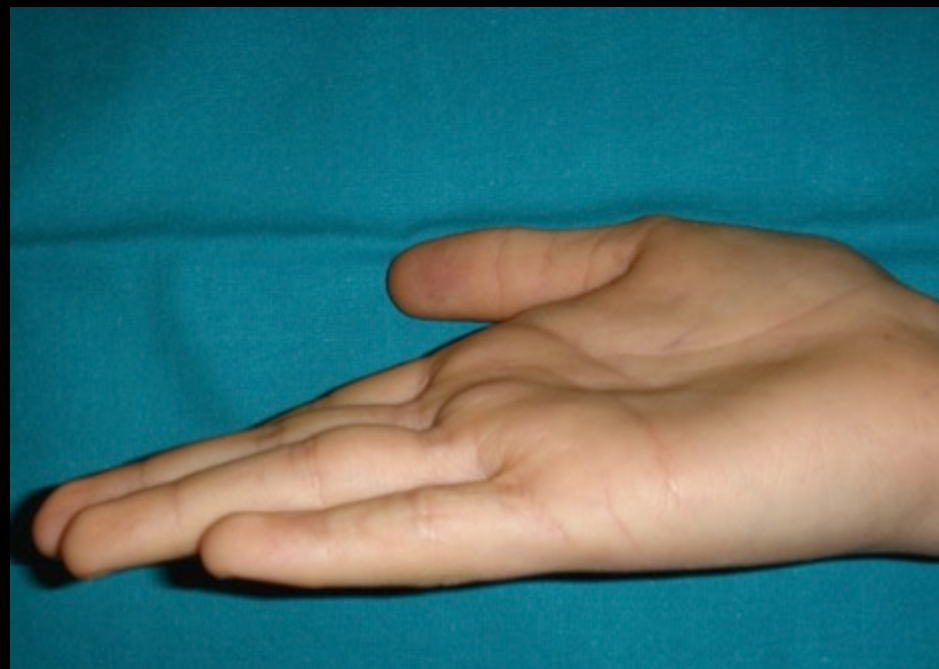
- Rehabilitation protocol starts immediately after surgery (if possible the same afternoon!!)
- From 1° dpo to 15°: once a day seance with the therapist + 5/6 session of exercises at home + 1-2 awake in the night + dynamic splints day and night
- From 15° dpo to 30°: once a day seance with the therapist + 5/6 session of exercises at home + dynamic splints day and night
- From 30° dpo to 60°: twice or trice a week seance with the therapist + 4/5 session of exercises at home+ dynamic splints day and night
- Dynamic splints untill 90° dpo (even later when needed)



Rehabilitation Protocol

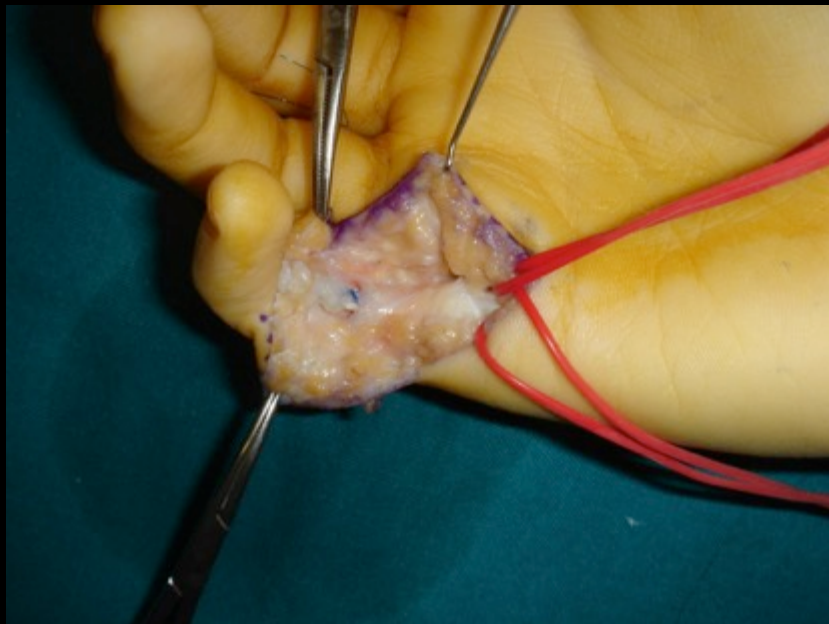
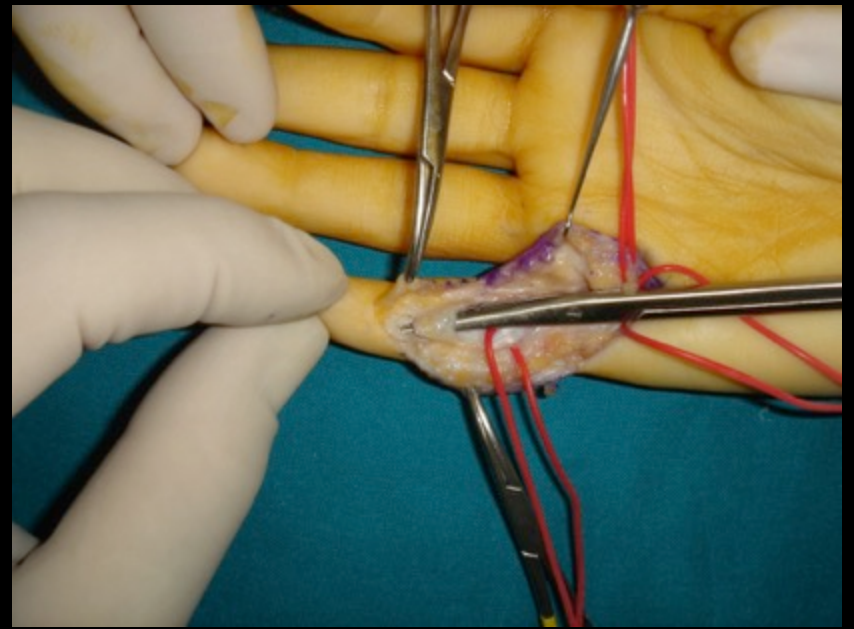
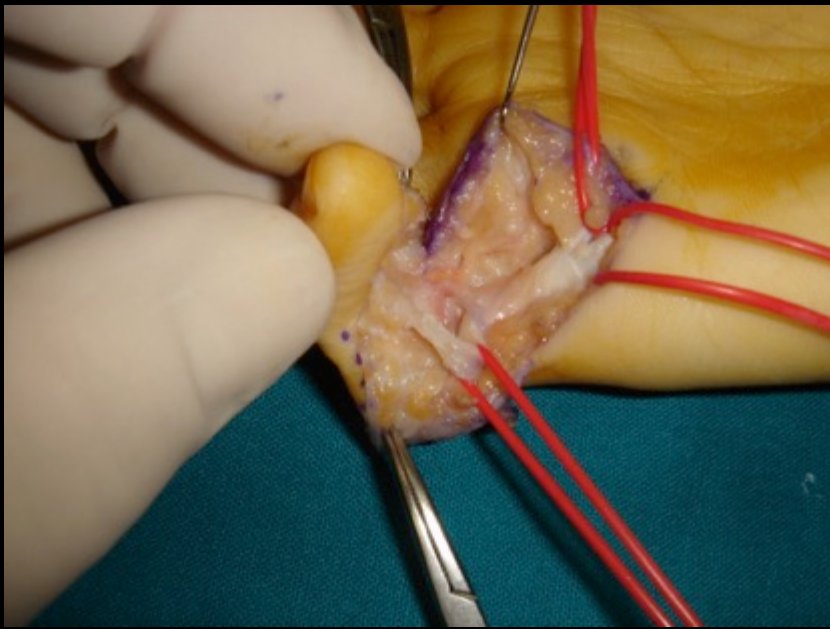


Dynamic splints in flexion and in extension, worn several hours per day (switching flexion and extension) and even during the night



CASE 1 – fdp 5°

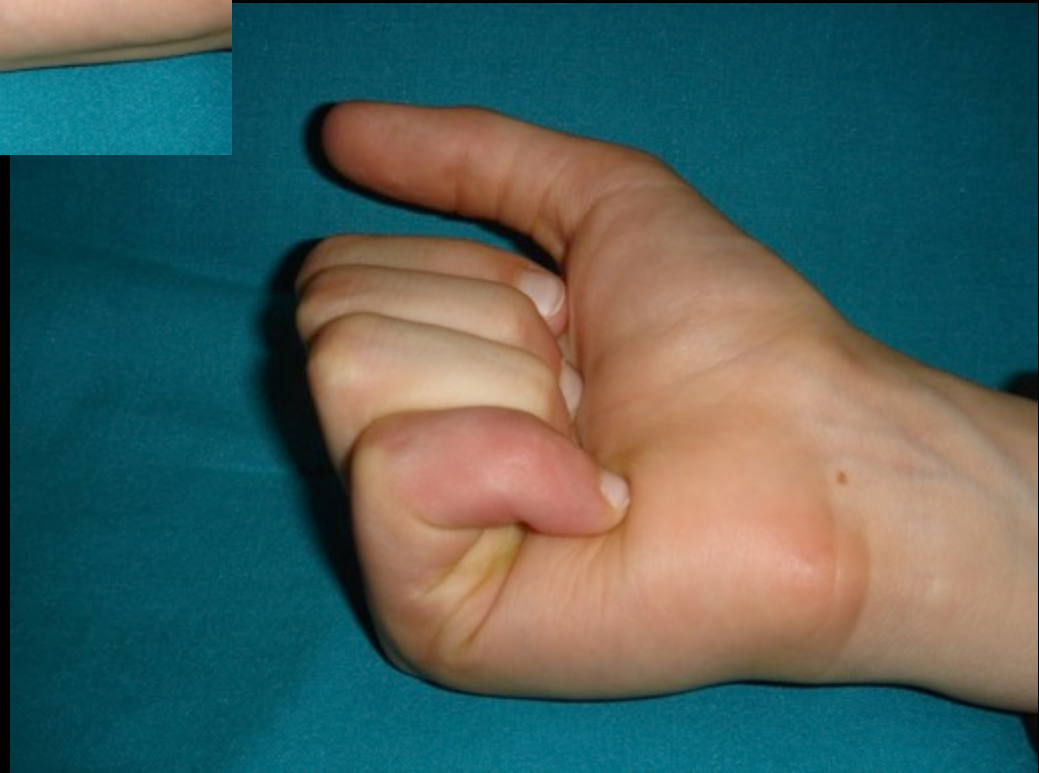




CASE 1 – fdp 5°



CASE 1 – fdp 5°





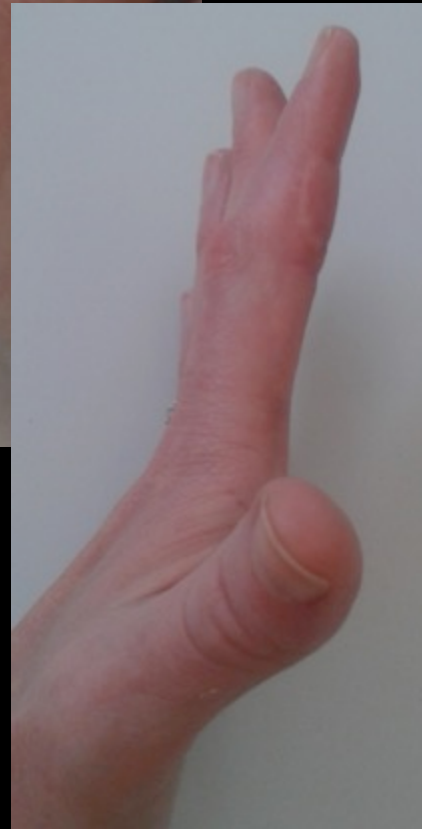
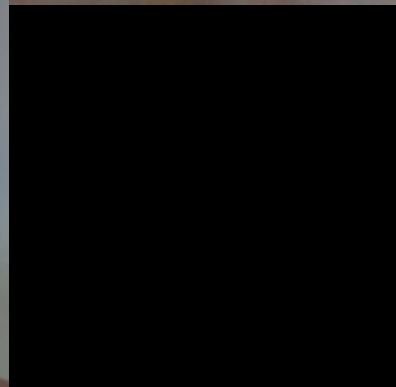
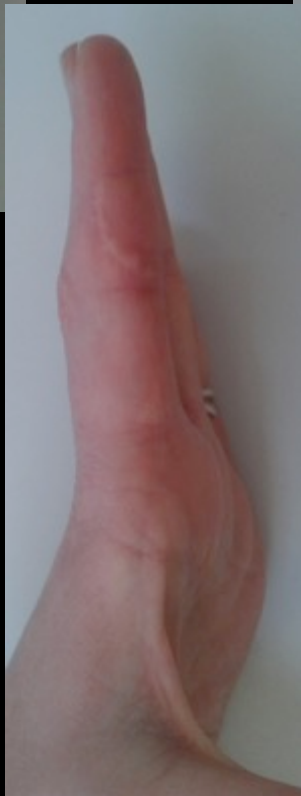
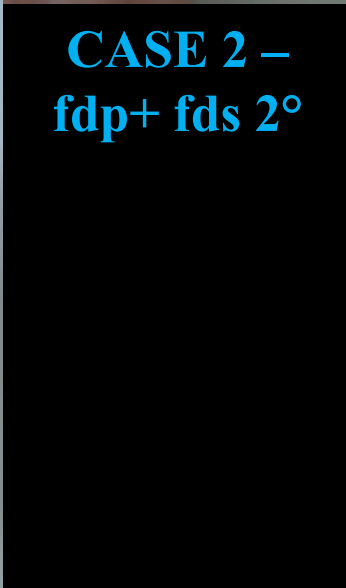
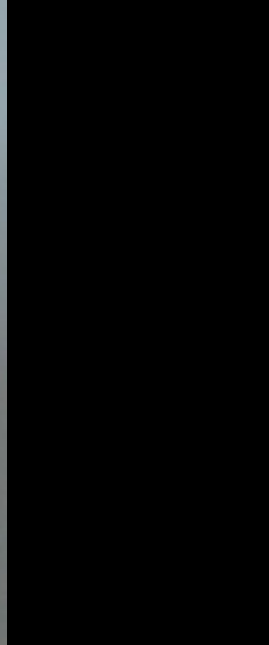
CASE 2 – fdp+ fds 2°





CASE 2 – fdp+ fds 2°



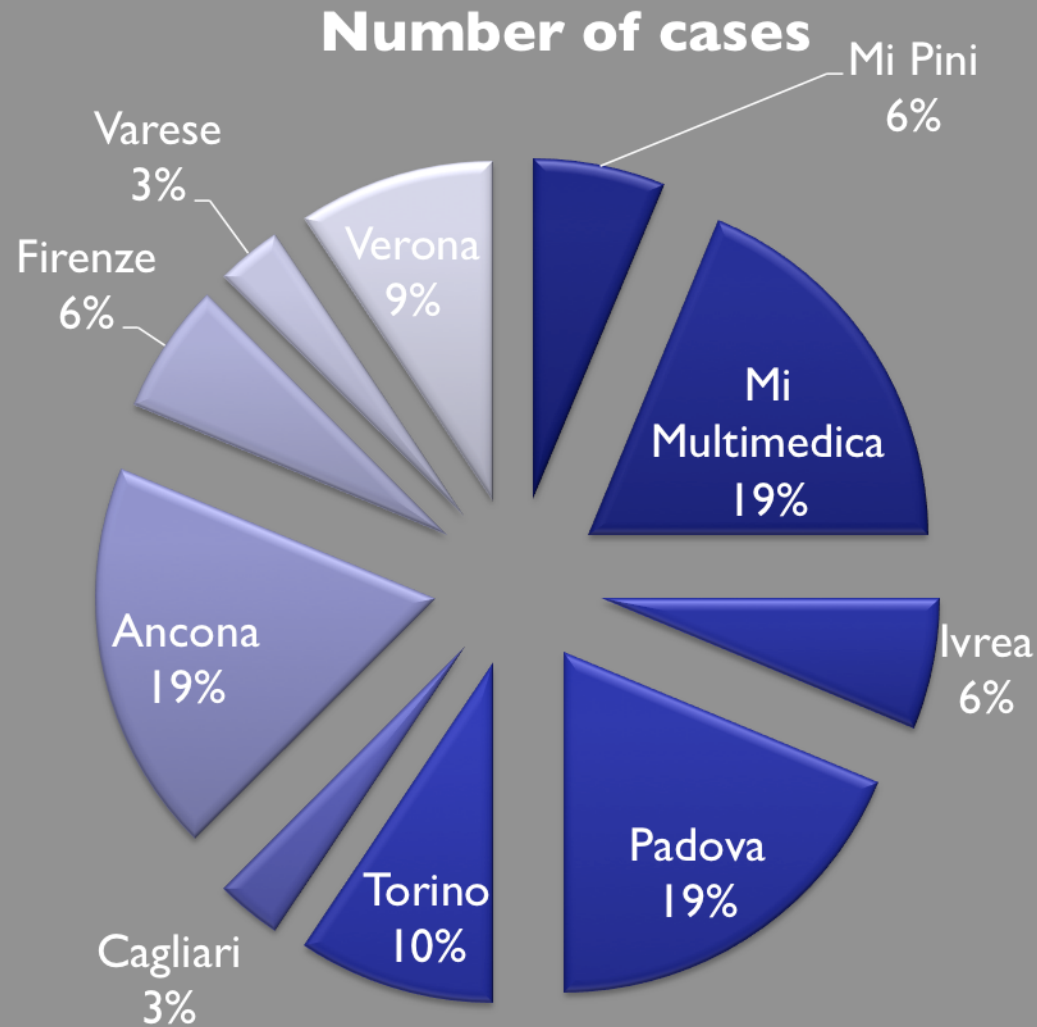


Cases In Clinical Trial

Centre	Referral	Cases		
Pordenone	De Mas	1		
Verona	Adani	3		
Roma	Felici	none		
Padova	Bassetto	6		
Napoli	Passaretti/Lanni	none		
Roma Sapienza	Spagnoli	none		
Savona	Rossello/Budroni	none		
Ivrea	Ghiggio	2		
Firenze CTO	Ceruso/Bigazzi	none		
Torino	Battiston	3		
Cagliari	Cara	1		
Ancona	Riccio	6		
Milano MultiMedica	Pajardi/Novelli	6		
Firenze IOT Palagi	Caruso	2		
Milano Pini	Messina	2		
Varese Insubria	Cherubino/Valdatta	1		
Messina Policlinico	Colonna	none		
	TOTAL	33		

Preliminary results

Data evaluation



Preliminary results

Data record (1)

patient	centre	Sex and age	Use of dynamic	lesion	date surgery	Follow up t.30	Follow up t.60	Follow up t.90	Vas Day 2/ day30	TAM PRE-OP	TAM POST-OP
SML	MI Pini	F-64	Y	3°digit T+N	31 may 2012	Ifp: 10°/50° Ifd: 0°/30	Ifp: 10°/68° Ifd: 0°/35°	Ifp: 10°/70° Ifd: 0°/40°	4/2	Mcf: 0°/100° Ifp: 10°/20° Ifd: 0°/10	Mcf: 0°/100° Ifp: 20°/80° Ifd: 0°/40°
NR	MI Pini	F-40	N	fdp	10 june 2013	Mcf : 0°-60° Ifp: 0°-30° Ifd: 0°-10°	Mcf : 0°-60° Ifp: 0°-30° Ifd: 0°-20°	Mcf : 0°/80° Ifp: 0°/40° Ifd: 0°/20°	6/1	Mcf : 0°-40° Ifp: 0°-10° Ifd: 0°-0°	Mcf : 0°/80° Ifp: 0°/40° Ifd: 0°/20°

Preliminary results Data record ⁽²⁾

patient	centre	Sex and age	Use of dyna visc	lesion	date surgery	Follow up t.30	Follow up t.60	Follow up t.90	VAS day2 / day 30	TAM PRE-OP	TAM POST-OP (t.180)
SA	MI MultiMedica	M-28	Y	Fdp+f sp 2	6 march 2014	Ifp: 0°/70° Ifd: 0°/56°	Ifp: 0°/85° Ifd: 0°/60°	Ifp: 0°/92° Ifd: 0°/64°	8/1	Mcf : 0°/90° Ifp:-10°/20° Ifd: 0°/0°	Mcf : 0°/90° Ifp: 0°/92° Ifd: 0°/64°
CD	MI MultiMedica	M-54	N	Fdp+f sp 3	30 April 2014	Mcf : 0°/50° Ifp: -10°/50° Ifd: -4°/30°	Mcf : 0-40 Ifp:-10°/50° Ifd: 0°/35°	Mcf :0-70 Ifp:-10°/68° Ifd: 0°/44°	5/1	Mcf;-16°/ 40° Ifp: -28°/ 20° Ifd: -4°/ 13°	Mcf : 0°/70° Ifp: -10°/68° Ifd: 0°/44°
AP	MI MultiMedica	m-54	Y	Fdp+f sp 5	23 July 2014	Ifp: -12°/60° Ifd: -4°/23°	Ifp:-12°/70° Ifd: -4°/30°	Ifp: -12°/78° Ifd: -4°/144	6/1	Mcf : 0°/ 40° Ifp: -20°/ 30° Ifd: -4°/ 13°	Mcf : 0°/ 90° Ifp: -12°/ 78° Ifd: -4°/ 44°
FA	MI MultiMedica	F-55	N	Fdp+f sp 2	17 July 2014	Ifp: -10°/60° Ifd: -10°/30°	Ifp: 0°/80° Ifd: -8°/40°	Ifp: 0°/80° Ifd: -8°/46°	7/1	Mcf : 0°/ 90° Ifp: -10°/ 30° Ifd: -10°/ 16°	Mcf : 0°/ 90° Ifp: 0°/ 80° Ifd: -8°/ 46°
FD	MI MultiMedica	F-35	Y	Fdp+f sp 2	27 may 2014	Ifp: -10°/55° Ifd: -12°/50°	Ifp: -10°/62° Ifd: 0°/67°	Ifp: -10°/68° Ifd: 0°/67°	7/1	Mcf : 0°/ 78° Ifp: -18°/ 30° Ifd: -12°/ 12°	Mcf : 0°/ 84° Ifp: -10°/ 68° Ifd: 0°/ 67°
RD	MI MultiMedica	M41	N	Fdp+f sp 4	29 september 2014	Ifp: -10°/40° Ifd: -10°/30°	Ifp: -10°/50° Ifd: -10°/30°	Ifp: -10°/50° Ifd: -10°/42°	4/1	Mcf : 0°/ 90° Ifp: -10°/ 20° Ifd: -10°/ 16°	Mcf : 0°/ 90° Ifp: -10°/ 50° Ifd: -12°/ 42°

Preliminary results

Data record ⁽³⁾

patient	cent re	Sex and age	Use of dyna visc	lesion	date surgery	Follow up t.30	Follow up t.60	Follow up t.90	VAS day2/ day30	TAM PRE-OP	TAM POST-OP
VK	Ivrea	38	Y	Fdp+f sp 3	13 february 2014	Ifp: 0°/ 20° Ifd: 0° /0°	Ifp: 0°/ 70° Ifd: 0° /15°	Ifp: 0°/ 90° Ifd: 0°/ 15°	6/1	Mcf : 0°/ 90° Ifp: 0°/ 20° Ifd: 0° /0°	Mcf : 0°/ 90° Ifp: 0°/ 90° Ifd: 0°/ 15°
RLM	Ivrea	39	N	Fdp+f sp 4	3 April 2014	Ifp: -10°/ 20° Ifd: -10°/ 20°	Ifp: -10°/ 40° Ifd: -10°/ 20°	Ifp: -10°/ 50° Ifd: -10°/ 20°	7/1	Mcf : -15°/ 30° Ifp: -40°/ 40° Ifd: -10°/ 13°	Mcf : 0°/ 40° Ifp: -10°/ 50° Ifd: -10°/ 20°

Preliminary results

Data record (4)

patient	centre	Sex and age	Use of dynavisc	lesion	date surgery	Follow up t.30	Follow up t.60	Follow up t.90	VAS Day 2 /Day 30	TAM PRE-OP	TAM POST-OP
ZD	FI-IOT	F-27	Y	Fdp+ fsp 5	16 Decembre 2013	Ifp: 0°/ 30° Ifd: 0°/ 35°	Ifp: 0°/ 30° Ifd: 0°/ 35°	Ifp: 0°/ 50° Ifd: 0°/ 45°	4/1	Mcf : 0°/ 90° Ifp: 0°/ 30° Ifd: 0°/ 15°	Mcf : 0°/ 90° Ifp: 0°/ 90° Ifd: 0°/ 45°
TA	FI-IOT	M-65	N	Fdp+ fsp 2	9 decembre 2013	Ifp:0°/57 Ifd: 0°/ 30°	Ifp:0°/57 Ifd: 0°/ 30°	Ifp: 0°/ 70° Ifd: 0°/ 45°	5/2	Mcf : 0°/ 90° Ifp: -10°/ 30° Ifd: 0°/ 15°	Mcf : 0°/ 90° Ifp: 0°/ 80° Ifd: 0°/ 45°

Preliminary results

Data record ⁽⁵⁾

[illegible]

T90						T180					QUICK DASH
PZ	PIP flex	PIP est. Def	DIP flex	DIP est. Def	TAM%	PIP flex	PIP est. Def	DIP flex	DIP est. Def	TAM%	
B.G. 52aa M IV DX grave deficit ROM	95	0	75	0	97,14285714	95	0	75	0	97,14285714	2
C.D.S. 37aa F II DX ifp 70/20 ifd 20/10	95	0	45	5	77,14285714	95	0	45	5	77,14285714	5
R.C. 32aa V M DX ifp 25/50 ifd 0/30	90	30	40	15	48,57142857	90	30	40	15	48,57142857	11
C.D. 48 IV M DX ifp 30/70 ifd 30/40	95	20	60	0	77,14285714	95	15	60	0	80	4
D.C. 48aa M V DX ifp 40/60 ifd 0/0	90	10	50	0	74,28571429	90	10	50	0	74,28571429	6
C.D. 39aa. F III SX deficit gradi medi	50	30	20	10	17,14285714	50	30	20	10	17,14285714	41
					0					0	
					0					0	
					0					0	
					0					0	
					0					0	

Preliminary results

EVALUATION DATA (1)

patient	centre	Sex and age	Use of dynavisc	lesion	date surgery	TAM PRE-OP	TAM POST-OP	TOTAL TAM post-op	TAM %
SML	MI Pini	F-64	y	3°digit T+N	31 may 2012	Mcf : 0°/100° Ifp: -10°/10° Ifd: 0°/0°	Mcf: 0°/100° Ifp: -20°/80° Ifd: 0°/40°	200 /260	0,76923077
NR	MI Pini	F-40	n	fdp	10 june 2013	Mcf : 0°-40° Ifp: 0°-10° Ifd: 0°-0°	Mcf : 0°/80° Ifp: 0°/40° Ifd: 0°/20°	160/260	0,61538462

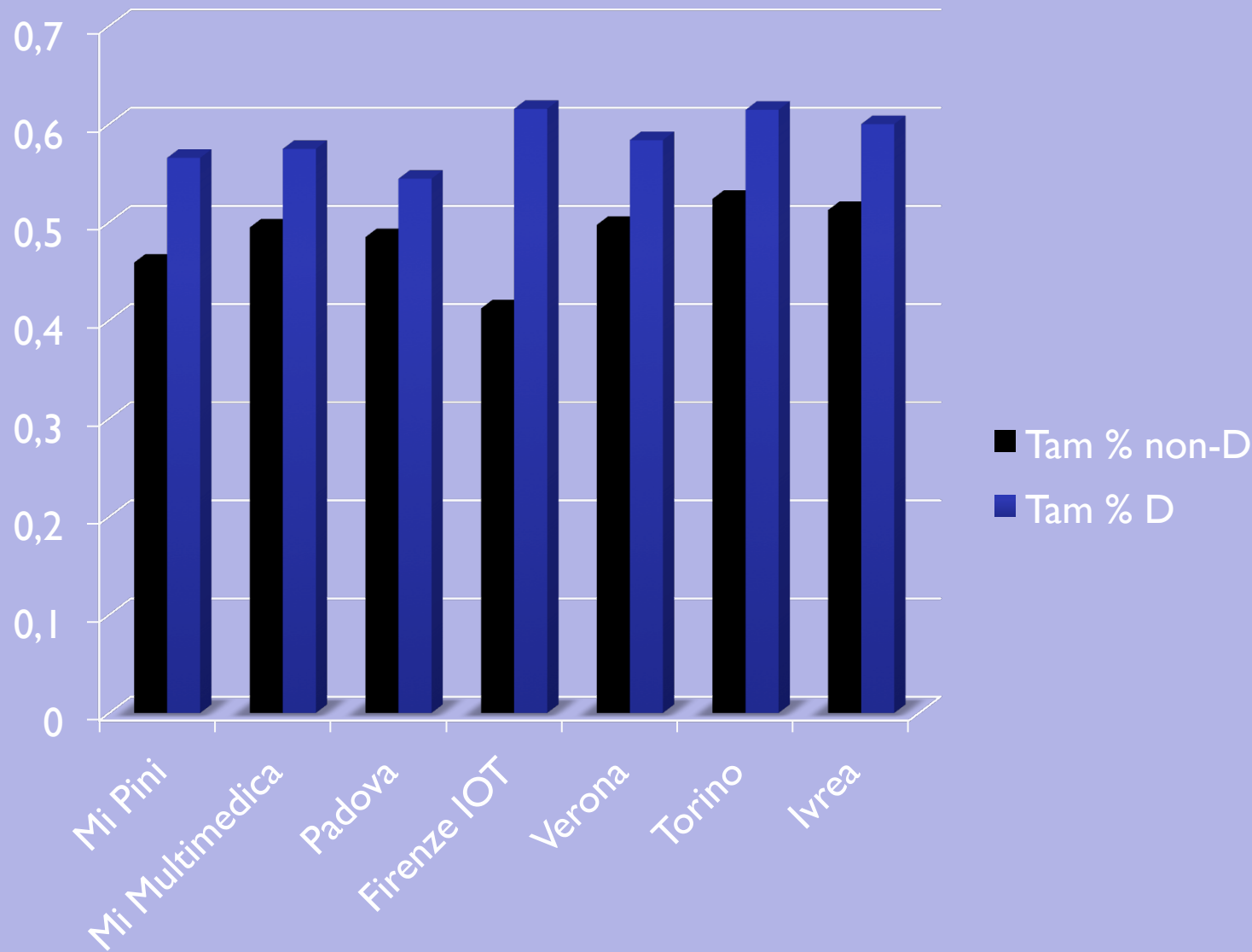
Preliminary results

EVALUATION DATA (2)

patient	centre	Sex and age	Use of dyna visc	lesion	date surgery	TAM PRE-OP	TAM POST-OP	Total TAM post-op	TAM %
VK	Ivrea	38	y	Fdp+f sp 3	13 february 2014	Mcf : 0° / 90° Ifp: 0° / 20° Ifd: 0° / 0°	Mcf : 0° / 90° Ifp: 0° / 90° Ifd: 0° / 15°	195/260	0.75
RLM	Ivrea	39	n	Fdp+f sp 4	3 April 2014	Mcf : -15° / 30° Ifp: -40° / 40° Ifd: -10° / 13°	Mcf : 0° / 40° Ifp: -10° / 50° Ifd: -10° / 20°	90/260	0,34615385

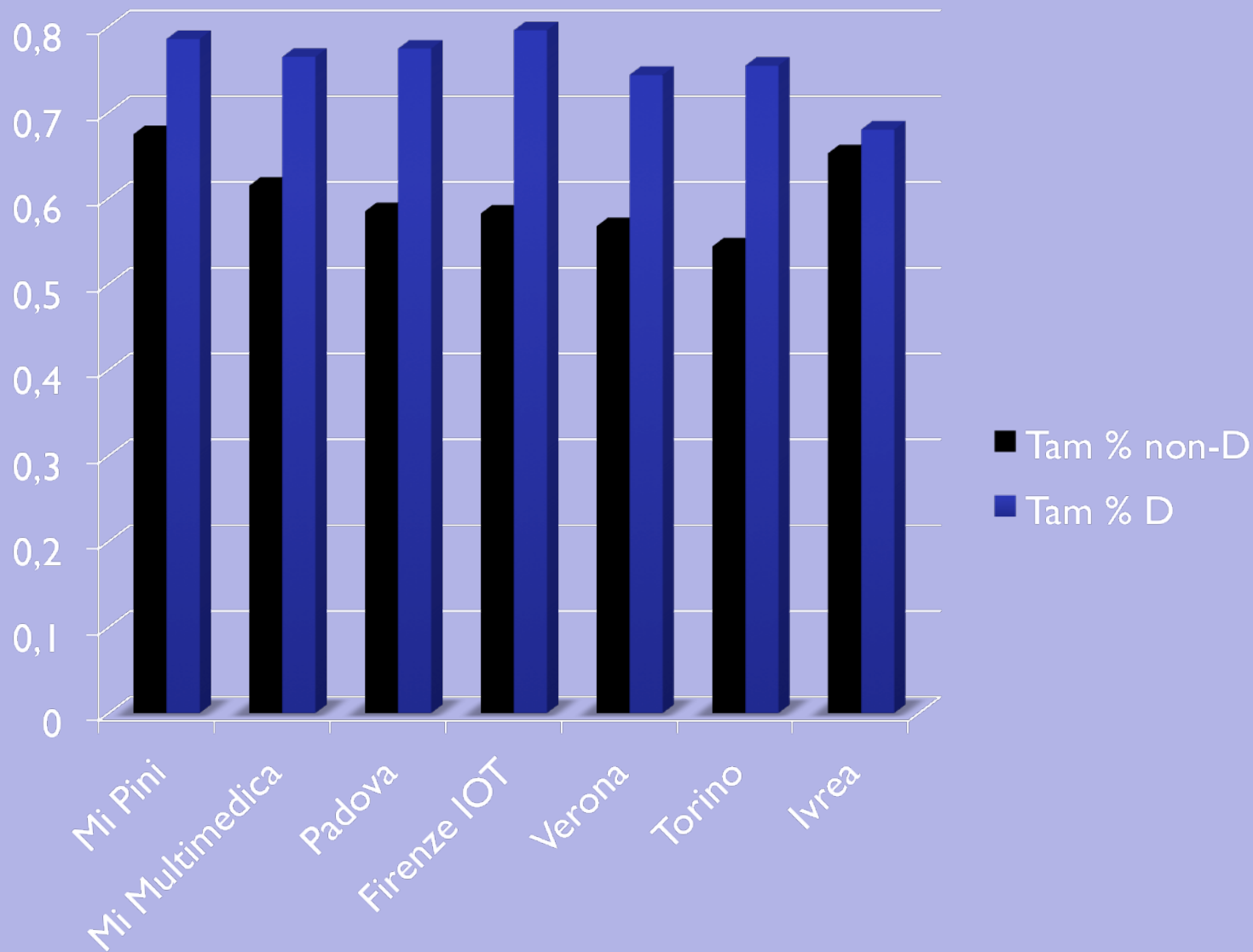
Preliminary results - Data evaluation

TAM % (30 day post-op)



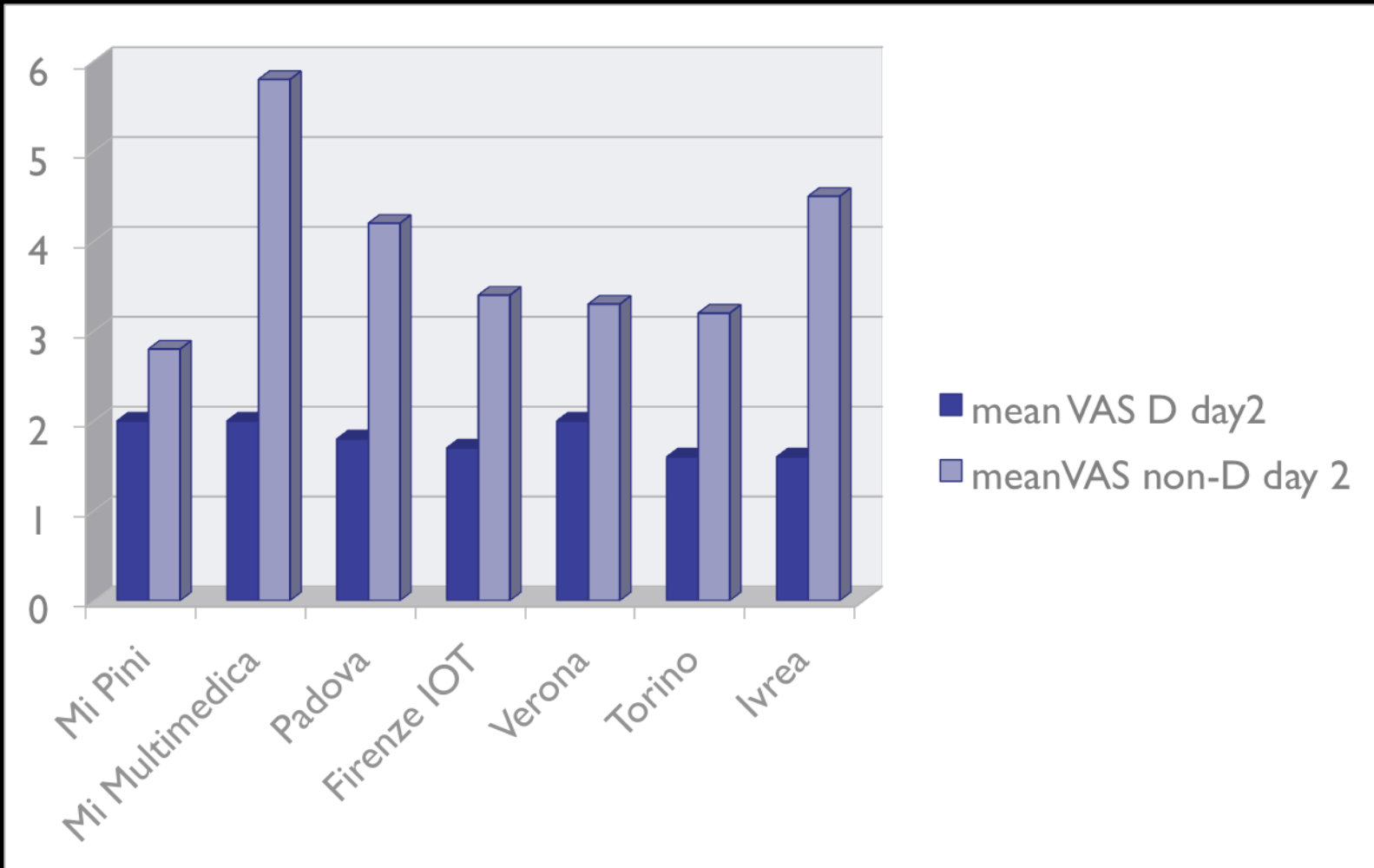
Preliminary results - Data evaluation

TAM % (180 day post-op)



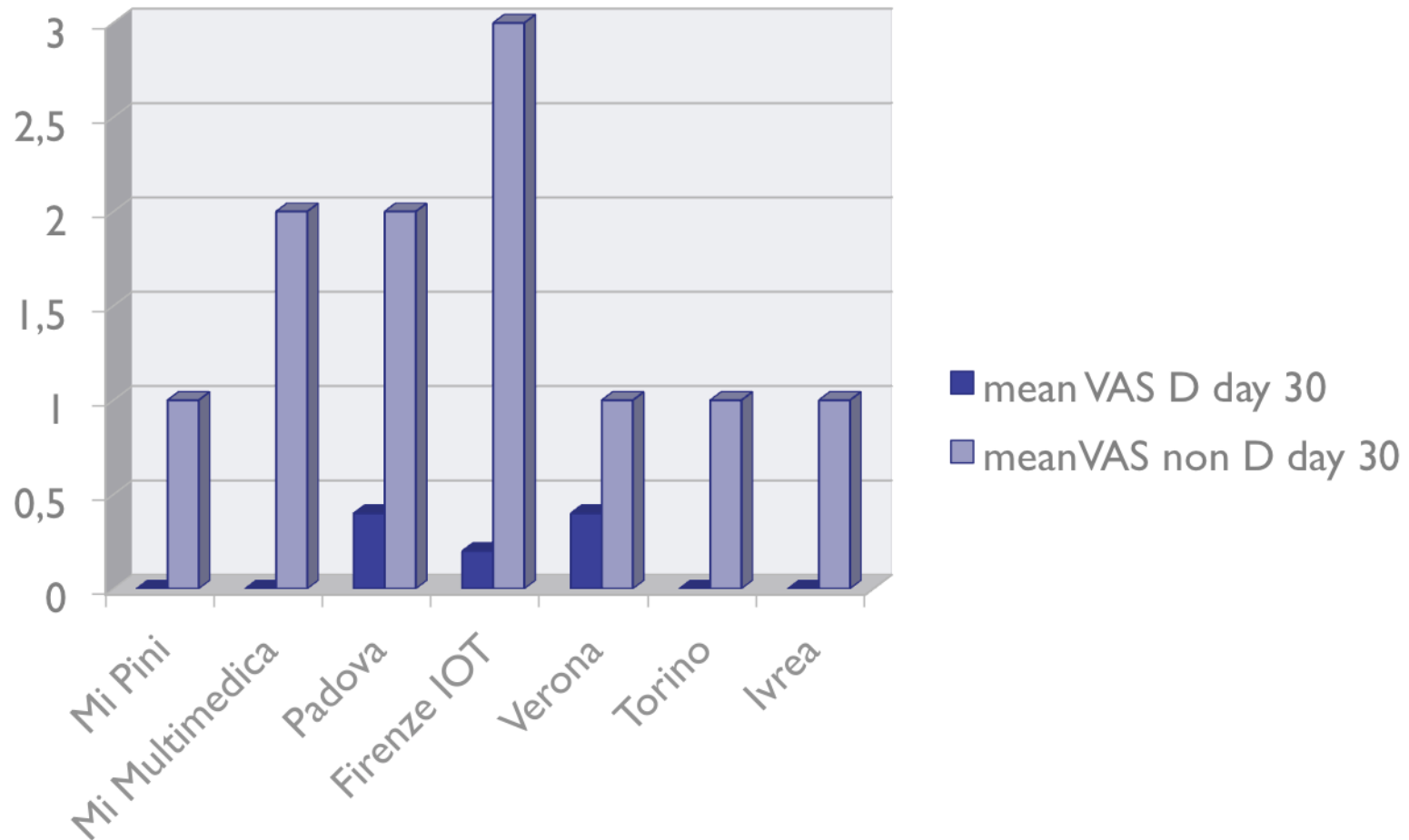
Preliminary results - Data evaluation

VAS day 2



Preliminary results - Data evaluation

VAS day 30



Preliminary report

- Tenolysis and in general tendon surgery is followed by an inflammatory response which leads to: scar tissue formation - preventing regeneration of synovial sheaths and interfere with final tendon gliding
- Dynavisc – as shown in other studies in literature (M. Riccio, *Hand Surg*, 2015) – is demonstrating to reduce inflammatory response reducing pain (VAS<<) and improving range of motion (TAM >>) after tenolysis