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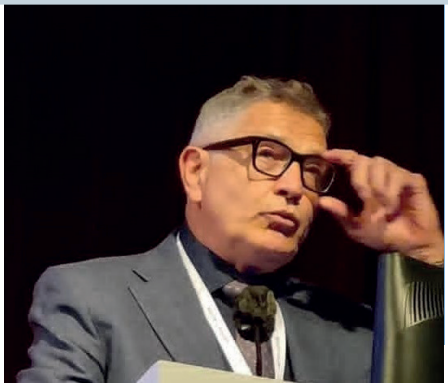

The Forearm Italian Performance Score (FIPS): development and statistical validation

Il Forearm Italian Performance Score (FIPS): ideazione e validazione statistica

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Summary

The forearm is an autonomous functional musculoskeletal unit based on three osseoligamentous stabilisers. However, until recently, no validated forearm specific assessment score was available. Two elbow surgeons and one hand surgeon developed the Forearm Italian Performance Score (FIPS) that proved to possess an adequate face validity. The aim of the study is to report on the convergent validity and reliability of the FIPS. One hundred patients operated for longitudinal malalignment of the forearm were recruited in a prospective cohort study. Four elbow-wrist scales were administered twice, one week and three months after surgery. Construct Validity, inter-intraobserver Reability and Internal Consistency were tested and found to be adequate. The FIPS was found to be simple and suitable for use in a clinical setting. The FIPS is the first validated tool available the osseoligamentous forearm lesions scoring.

Key words: forearm score, statistical validation, forearm fracture-dislocation

Riassunto

L'avambraccio è un'unità funzionale muscolo-scheletrica autonoma basata su tre stabilizzatori osteo-legamentosi. Tuttavia, fino a poco tempo fa, non era disponibile un punteggio di valutazione specifico per l'avambraccio convalidato. Due chirurghi del gomito e un chirurgo della mano hanno sviluppato il Forearm Italian Performance Score (FIPS), che ha dimostrato di possedere un'adeguata validità di facciata. Lo scopo dello studio è quello di validare la convergenza delle singole scale del punteggio e la sua affidabilità. Cento pazienti, operati per malallineamento longitudinale dell'avambraccio, sono stati reclutati in uno studio prospettico di coorte. Quattro scale gomito-polso sono state sottoposte ai pazienti una settimana e tre mesi dopo l'intervento. La Validità di Costrutto, l'Affidabilità inter-intraosservatore e la Coerenza Interna sono state testate e sono risultate adeguate. Il FIPS è risultato semplice e adatto all'uso in ambito clinico. Si tratta del primo strumento validato disponibile per la valutazione delle lesioni osteolegamentose dell'avambraccio.

Parole chiave: *forearm score, validazione statistica, frattura-lussazione dell'avambraccio*

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Conflitto di interessi
Gli Autori dichiarano di non avere alcun conflitto di interesse con l'argomento trattato nell'articolo.

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Introduction

Over the past century, the International Shoulder-Elbow and Wrist-Hand Surgical Societies have come to understand that the forearm is not simply a conduit between the elbow and wrist joint, thanks to improved knowledge based on clinical series and scientific research efforts[1,2]. In 2007, Soubeyrand, et al. (2007) proposed the concept of the "three forearm constraints"[3].

The forearm constraints are formed by the Proximal RadioUlnar Joint (PRUJ), represented by the Radial Head (RH), the Radial Notch of the ulna, and the Square and Annular Ligaments. The ulno-radial diaphysis and the InterOsseous Membrane (IOM), which together form the Middle RadioUlnar Joint (MRUJ). The IOM consists of the oblique Weitbrecht ligament proximally, the stronger Central Band Ligament (CB)[4,5] and the Distal Oblique Ligament (DOB)[6] when present. The Distal RadioUlnar Joint (DRUJ), represented by the distal Ulnar Head, the Ulnar Notch of the Radius, the Triangular FibroCartilage Complex (TFCC) and the dorsal-volar ligaments of the wrist[7]. All of these anatomical and functional structures can be referred to as the Forearm Unit[8].

We defined "Unstable Lesions of the Forearm" (ULF) [12] those lesions that cause horizontal and/or longitudinal instability of the functional unit of the forearm. They are most commonly osteoligamentous, but may be purely ligamentous in rarer cases. With increasing awareness, it has been suggested that these injuries may not be as rare as previously thought and it has become clear that appropriate management should be based on a early understanding of the various components that make up this complex injury. A quick treatment is recommended[9]. In addition, any fracture that causes malalignment between the two bones of the forearm may have clinical implications for elbow and wrist function. Fractures of the radius and ulna are common injuries, with over 644,000 such fractures in the United States alone in 1998. Falls are the most common mechanism and 26% occur in children under 15 years of age[10]. In Italy, about 110,000 forearm fractures are reported annually in the 18-64 age group, with a higher prevalence in men following high-energy trauma[11].

ULF can result in forearm dysfunction with high clinical impact. Despite the disabling nature of these injuries, a standardised and validated clinical tool to assess and monitor forearm function is still lacking.

The Forearm Italian Performance Score (FIPS) has been developed by two elbow surgeons and one hand surgeon who identified 75 ULF (Monteggia, Galeazzi, Essex-Lopresti, Criss-Cross & Variants lesions) from their series of 586 forearm injuries[12]. The tool was designed to be easy for clinicians to use in clinical practice, understandable for patients and valid for the assessment and monitoring of forearm function, disability including pain, radiological status, and its impact on return to work. As to the scoring system, it was agreed that clinical parameters had to be expressed as percentages or as standardised levels of function and that a simple, inexpensive manometer could be used for optimal assessment of grip strength compared with the contralateral side.

The FIPS scale was presented to international experts during a Consensus Conference on Forearm Trauma held on May the 24th 2018. During this meeting, the complexities of the classification of forearm trauma were discussed, and reproducible surgical techniques were proposed for each of the three areas involved[12].

The aim of this paper is to assess the concurrent validity, the internal consistency and the iintra and inter-rated reliability of the FIPS using data from a prospective multicentre study.

Materials and methods

This multicentre observational and prospective cohort study was approved by the Ethics Committee of Local Health Authority, protocol n. 2215, Sept. 20th 2018 and was conducted in two Orthopaedics and one Hand Surgery Unit between July 2018 and December 2020. The study was conducted on 100 consecutive patients with a fracture-dislocation of the radius and/or ulna resulting in misalignment of the forearm.

Inclusion criteria were: age 18 years or older, patients who had suffered an acute traumatic forearm injury causing malalignment or instability of the forearm and who were treated surgically, willingness to sign the informed consent to participation.

Exclusion criteria were: patients with pathological fractures, pre-existing conditions affecting forearm function (such as neurological conditions or congenital malformations), patients who were unable/unwilling to sign informed consent independently due to psychiatric disorders or who were under legal supervision for other reasons.

Written consent to participate in the study was requested from patients after providing information by the research physician. To ensure the protection of anonymity, each patient was assigned a unique identification code, known only to the local principal investigator.

All patients consenting to participate were evaluated twice: 7 days after surgery and three months later. During the first visit, the following questionnaires were filled out by the physician: Mayo Elbow Performance Score (MEPI), Mayo Wrist Performance Score (MWPS), Quick Disability Arm, Shoulder and Hand (QuickDASH) and Forearm Italian Performance Score (FIPS). Intra-observer and inter-observer reliability, i.e. the consistency of ratings of FIPS items within the same rater over time and between 2 raters was investigated in a subgroup of patients at two participant centers.

The following socio-demographic and clinical data were collected: sex, age at surgery, weight and height, type of fracture.

At the Consensus Conference (2018) the FIPS was judged valid by 9/10 experts with an Average Congruence Percentage (APC) > 90%, thus establishing the Face Validity of the questionnaire.
The FIPS is an interview-based tool with a 0-100 score that includes overall 6 items: 4 clinical items, i.e. pain, movement, stability and muscle strength, one item assessing two radio-pathological findings and one item assessing the work-related impact of the injury. The scoring details are provided in Table I. The total score is obtained as the sum

Table I. Description of FIPS scoring by the 6 items.

Forearm Italian Performance Score (FIPS)			
Pain	**Domain**	**Criteria**	***max score = 15***
Perceived pain	1	None Mild Moderate Severe	15 pts 10 pts 5 pts 0 pts
Movement	**Domain**	**Criteria**	***max score = 35***
Elbow/wrist flexion-extension range of motion supination-pronation arc	1	Elbow Flexion-Extension > 100°	10 pts
	2	Wrist Flexion-Extension > 60°	10 pts
	3	Pronation > 20°	10 pts
	4	Supination > 20°	5 pts
Stability	**Domain**	**Criteria**	***max score = 10***
Drawer test ulnar ballotment test	1	Elbow stability (Drawer)	5 pts
	2	Wrist stability (Ballotment)	5 pts
Grip strength	**Domain**	**Criteria**	***max score = 10***
Percentage of the controlateral limb	1	75-100% 50-75% 0-50 %	10 pts 5 pts 0 pts
5. Radiological findings	**Domain**	**Criteria**	***max score = 10***
Forearm in antero-posterior projection forearm in lateral-lateral projection ulnar plus configurations dorsal prominence of the distal ulna	1	DRUJ Ulnar Plus < 5 mm	5 pts
	2	Dorsal Ulnar prominence absent at the wrist	5 pts
Functional status	**Domain**	**Criteria**	***max score = 20***
Work resumption	1	Returned to regular employment Restricted employment Able to work but unemployed Unable to work	20 pts 15 pts 5 pts 0 pts
Interpretation of the Forearm Italian Performance Score: **90-100 = Excellent** **75-89 = Good** **60-74 = Fair** **< 60 = Poor**			

of the 6 items and is interpreted as follows: 90-100 Excellent status, 75-89 Good status, 60-74 Fair and < 60 Poor forearm functional status.
The Mayo Elbow Performance Index (MEPI) [13], measures elbow assessing four items: pain (max 45 points), range of motion (max 20 points), joint stability (max 15 points) and ability to perform 5 movements (max 20 points). Elbow function is categorised as follows: Excellent (score ⩾ 90), Good (score 75-89), Fair (score 60-74), and Poor (score < 60). This instrument proved to have good validity and reliability.
The Modified Mayo Wrist Performance Score (MWPS) [14], is a modification of the Green and O'Brien score. It assesses pain (max 25 points), arc of flexion-extension as a percentage of the contralateral wrist (max 25 points), percentage of grip strength relative to the contralateral side (max 25 points) and return to work activities (max 25 points). The higher total score indicating a better outcome[15,16]. An Excellent result is defined as 90–100 points, Good is 80–89 points, Fair is 65–79 points, and Poor is less than 65 points.
The Quick Disability of Arm, Shoulder and Hand Questionnaire (QuickDASH) was developed by reducing the full 30-item original scale DASH[17,18,19] The QuickDASH is a PROM divided into two sections. The first 11-item section assesses symptoms and disability of the upper extremity. The second section includes two optional 4-items, one related to the impact of arm, shoulder, or hand problem on the ability to work, one related the impact on playing a musical instrument or sport.

Sample size calculation

In line with the general rule of thumb that requires 10 patients per items to determine the Internal Consistency of a scale, we calculated a sample size of 60 patients. For the inter-rater and intra-rater Reability, to detect a correlation between assessments > = 0.70 with a 90% power and alpha = 0.05, with a null hypothesis that the correlation is 0.30, we calculated that 30 cases are needed.
We decided to increase the overall sample size to 100, in accordance with the guidelines of the COSMIN checklist[20,21], which suggest that this is minimum number is needed to investigate the Validity and the Internal Consistency of a scale.

Statistical analysis

Continuous variables were summarized using mean and standard deviation, median and interquartile range; categorical and dichotomous variables were summarized using frequencies and proportions. Normality assumption was tested using Shapiro-Wilks test on continuous outcome and covariate of interest. Wilcoxon's rank test was used to compare FIPS total score and single domains between the two assessment times.
The Concurrent Validity, inter and intra-rater Reability, and the Internal Consistency of the FIPS were investigated.
Concurrent validity is defined as the extent of the agreement between two measures or assessments taken at the same time. Specifically, we analysed the correlation of the FIPS with DASH, MWPS and MEPI that had already been tested and proven to be valid. Since normality assumption was not met for all the scale scores of interests, the non-parametric Spearman's rank correlation coefficient (ρ) was computed between FIPS items and total score and the total score from the MEPI, MMWS and DASH questionnaires.
Intra-observer reliability was tested on the subset of patients that were recalled to make a follow-up visit with the same physician, 7-10 days after the first outpatient visit; this interval of time was chosen as a suitable time because no major clinical or therapeutic changes were expected to occur, Inter-observer reproducibility was assessed by a first physician in a subgroup of patients, who were subsequently re-evaluated by a second physician blind to the first assessment. For both analyses the Intraclass Correlation Coefficient (ICC) was computed. A value of at least 0.70 was considered adequate[22].
Internal Consistency measures the average intercorrelation between items and was computed using Cronbach's alpha (α). As a rule of thumb, a value of $\alpha > 0.90$ indicates excellent internal consistency, $0.80 < \alpha < 0.89$ is good, $0.70 < \alpha < 0.79$ is acceptable, $0.60 < \alpha < 0.69$ is questionable, $0.50 < \alpha < 0.59$ is poor, and $\alpha < 0.50$ is unacceptable[23]. We also examined the item-total correlation and α value if an item is deleted to assess the contribution of each item to the total score and the effect on internal consistency of excluding each item in turn from the scale.
Responsiveness was evaluated by testing the difference between the item and total FIPS scores between the two assessments using the paired-sample Wilcoxon test. In addition, to reflect the ability of the FIPS to capture clinically significant differences over time we computed the effect size, that is the difference between the mean follow-up scores and the mean baseline scores, divided by the SD of the baseline score. In line with Cohen (1988), effect sizes of 0.20 were considered small, 0.5 moderate and 0.80 large[24].

Results

Table II reports the demographic characteristics of the study sample, that included 54 female and 46 male patients, with a mean age of 48.7 years (SD = 18.4) and a mean BMI of 27.5 (SD = 23.1).
Mean and standard deviation of the questionnaire scores at the two time points are summarized in Table III. A significant improvement was found for 5 items of FIPS and for the total score from 7 days to 3 months after surgery. On average the total FIPS score increased by 30 points, denoting a good responsiveness of the scale. In addition, the effect of the scales at 3 months was large for FIPS total score (Tab. III).

Table II. FIPS total and item mean score and standard deviation (SD) at the two time points.

		N	Mean	SD	Median	IQR
Center	Bologna	40				
	Faenza	20				
	Torino	40				
Sex	F	54				
	M	46				
Age	100	48.67	18.42	50	33 – 89	
BMI	100	27.52	23.07	25	23 – 27	
MEPI	100	75.44	23.44	80	55 – 100	
MWPS	100	68.11	24.35	70	55 – 90	
DASH	100	39.86	25.75	44	15 – 60	

**Wilcoxon test (W) and associated p-value (p), testing the difference in the frequency distributions between the two time points.*

Table III. Characteristics of the sample at baseline (N = 100).

	7 days		3 months					
	Mean	SD	Mean	SD	Effect size (ES)	Test*	p	
FIPS	Total	61.8	20.08	91.05	11.96	1.46	V =	< 0.001
	Pain	8.80	3.90	13.25	2.69	1.14	V = 8077.5	< 0.001
	Movement	20.30	8.70	28.45	5.98	0.94	V = 7727	< 0.001
	Stability	9.45	1.73	9.85	0.86	0.23	V = 5351.5	0.04
	Strength	6.90	5.21	12.50	4.05	1.07	V = 8048	< 0.001
	Radiological assessment	9.65	1.78	9.75	1.31	0.06	V = 5053	0.74
	Resumption of work	6.55	7.81	17.20	4.62	1.36	V = 8491	< 0.001

The "stability" item showed an effect size of 0.23 that can be considered small and the "radiological findings" item was unchanged over time (ES = 0.06).

Concurrent Validity of FIPS (total score) with MEPI (rho = 0.58, p < 0.01), MWPS (rho = 0.40, p < 0.01) and DASH (rho = –0.47, p < 0.01) was moderate (Tab. IV). The negative sign for the correlation with DASH is related to the opposite directionality of the 2 scales. All the FIPS items correlated significantly with the 3 scales, except for the radiological finding item, that had correlations ranging from -0-05 to 0.10 with the other scales.

Intra-observer Reability for the total score was almost perfect, ICC = 0.99 (95% CI 0.97 - 0.99). Only the "radiological findings" item did not achieve an ICC value > 0.70 (ICC = 0.66 IC95%: 0.44-0.80), while for the other items the ICC was close to 1. In addition, inter-observer reliability ICC was equal to 1 for all FIPS items

The internal consistency of the FIPS scale, as measured by Cronbach's alpha, was equal to 0.66, a value that can be considered questionable. However, excluding the item on radiological findings, the internal consistency increased to 0.689, indicating that the radiological assessment has a low correlation with the other items. On the other hand, when excluding the other domains from the computation of alpha, the consistency tended to decrease (Tab. V).

Concerning return to work, we found that out of the 77 par-

Table IV. Spearman's rho Correlation Coefficent (ρ) p-value (p).

		FIPS						
		Total	Resumption of work	Pain	Movement	Stability	Strength	Radiological assessment
MEPI	Spearman's ρ	0.58	**0.51**	0.52	0.45	0.29	0.29	-0.02
	ρ	< 0.001	< 0.001	< 0.001	< 0.001	0.003	0.004	0.81
MWPS	Spearman's ρ	0.40	0.21	0.34	0.38	0.13	0.62	-0.05
	ρ	< 0.001	0.04	< 0.001	< 0.001	0.200	< 0.001	0.60
DASH	Spearman's ρ	-0.47	-0.32	-0.45	-0.41	-0.18	-0.33	0.10
	ρ	< 0.001	0.001	< 0.001	< 0.001	0.08	< 0.001	0.33

Table V. Internal Consistency of FIPS score (Cronbach's Alpha) after excluding each item.

		Cronbach's alpha
FIPS	Total	0.66
	When excluding item "Pain"	0.57
	When excluding item "Movement"	0.60
	When excluding item "Stability"	0.66
	When excluding item "Strength"	0.56
	When excluding item "Radiological assessment"	0.69
	When excluding item "Resumption of work"	0.57

ticipant who were unable to work at 7 weeks from surgery, 41 (53%) were able to work without restrictions at 3 months.

Discussion

We developed a novel tool to assess the performance of the forearm and tested its psychometric properties in a multicentre study including 100 patients.

The FIPS proved to have an excellent inter- and intra-rater Reliability. As to the Internal Consistency, it proved to have limitations related to the low correlation of radiographic findings with the rest of the items. Concurrent Validity was moderate, as expected because the Mayo Elbow Performance Score (MEPI), Mayo Wrist Performance Score (MWPS), and the Disability Arm, Shoulder and Hand (DASH) do not have a specific focus on the forearm or do not assess exactly the same functioning domains. Responsiveness of the FIPS was excellent for three the clinical items pain, movement and strength and return to work, that showed effect sizes exceeding 0.80, while stability and radiological findings proved to only a modest or no change over time. Thus changes of the overall FIPS scores are mostly attributable to changes in 4 out of 6 items.

On the other hand, the MEPI and MWPS were found to be only partially useful to assess the performance of the forearm. In particular, the elbow score gave very high results for distal forearm injuries and the wrist score for proximal forearm injuries because they were "blind" in this area. These scores did not correlate well with the clinical status of these patients (case n. 1).

Recently, Hertzberg, et al. published New Computerized Elbow and Forearm Clinical Scores[25] based on four clinical criteria: pain, function, active range of motion and muscle strength. The radiological finding item is not included in this tool. This score is extremely accurate in detecting the movement arcs of the elbow and wrist, but requires the presence of two operators and the use of a computer. However, to our knowledge this score has not been statistically validated yet.

The FIPS study has the following strengths: firstly, the study population is homogeneous for diagnosis. Second, it is a multicentre study, with centres participating on a voluntary basis, which ensures good data quality. Third, the score was developed by expert clinicians with a focus on the forearm and the complex interplay with other anatomical structures involved in its performance. Fourth, the Sample Size is adequate to test the psychometric properties of the scale. Fifth, it was administered at a pre-determined point in time, rather than during a routine follow-up visit, so that responsiveness was assessed for the same period in all patients.

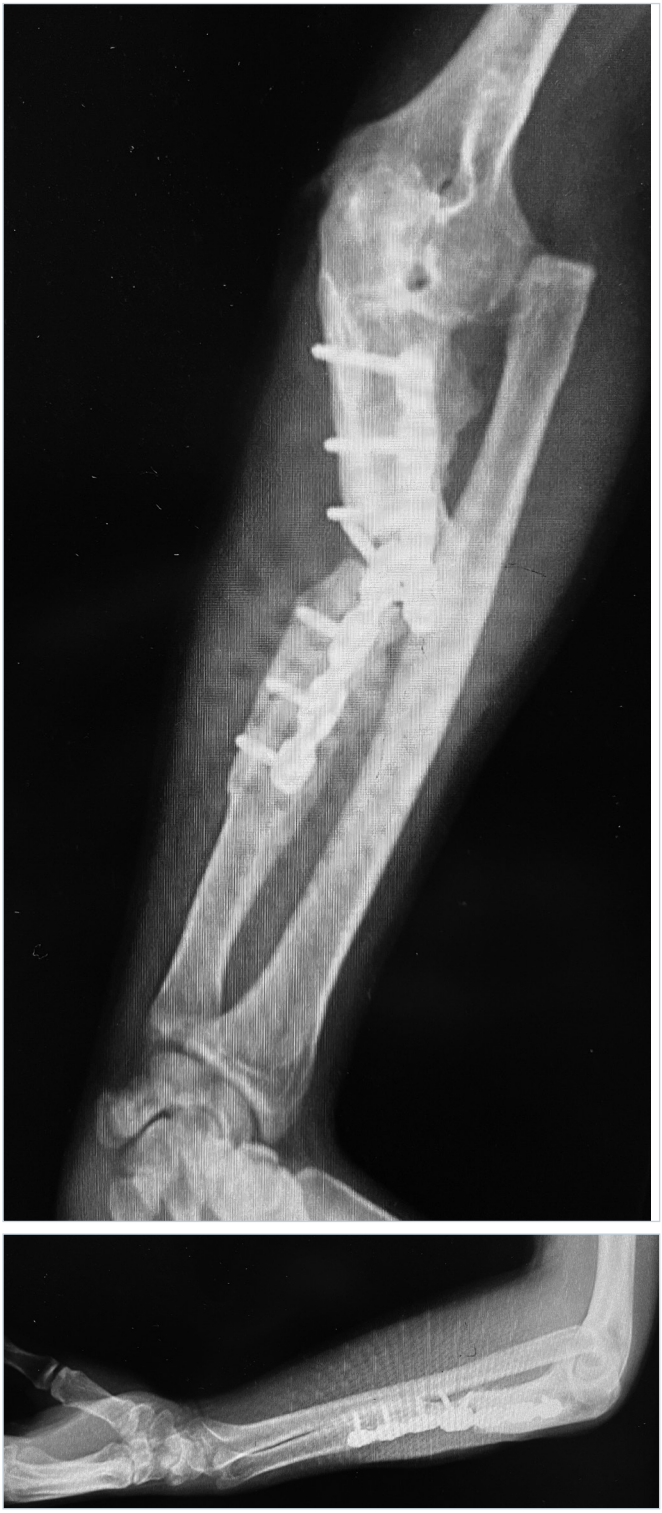


Figure 1-2. 37 yrs old aged male, farmer, failed surgery for Monteggia Lesion left forearm (Xray preop. a-p Fig n.1; preop. lateral Fig n.2).

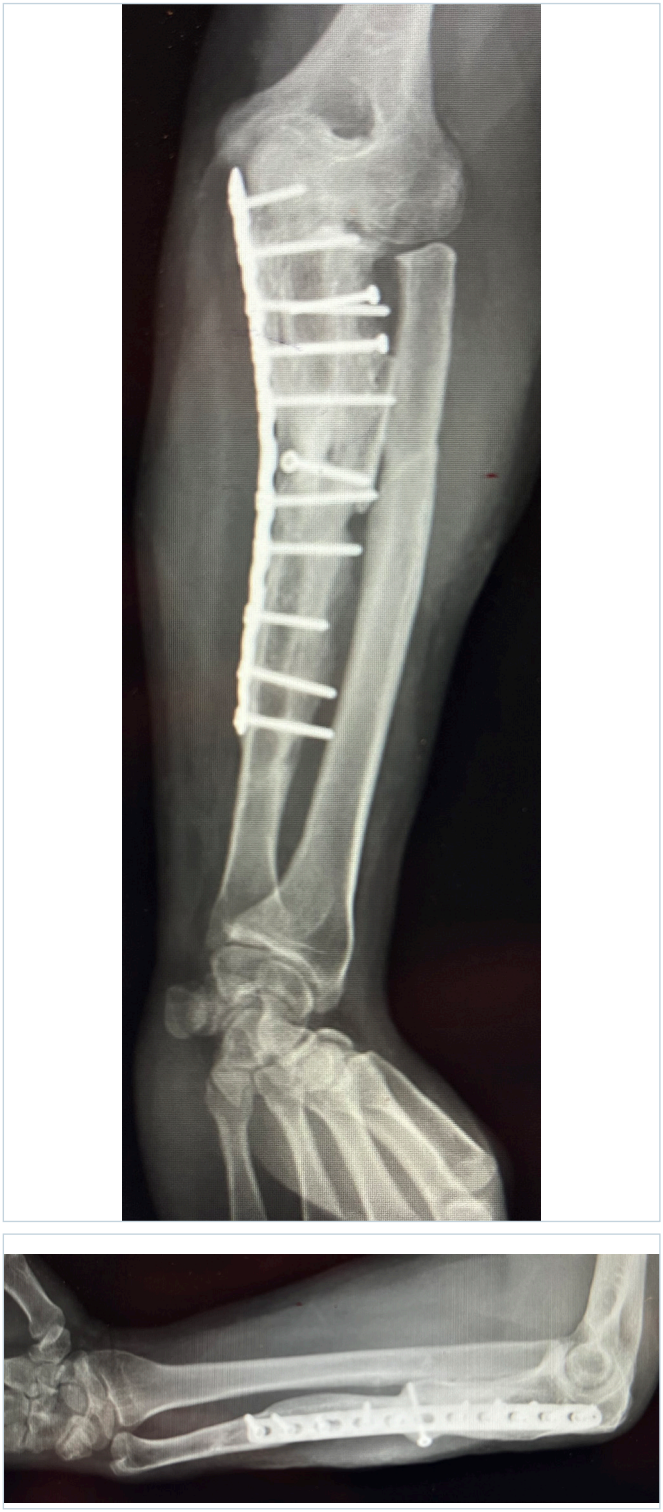
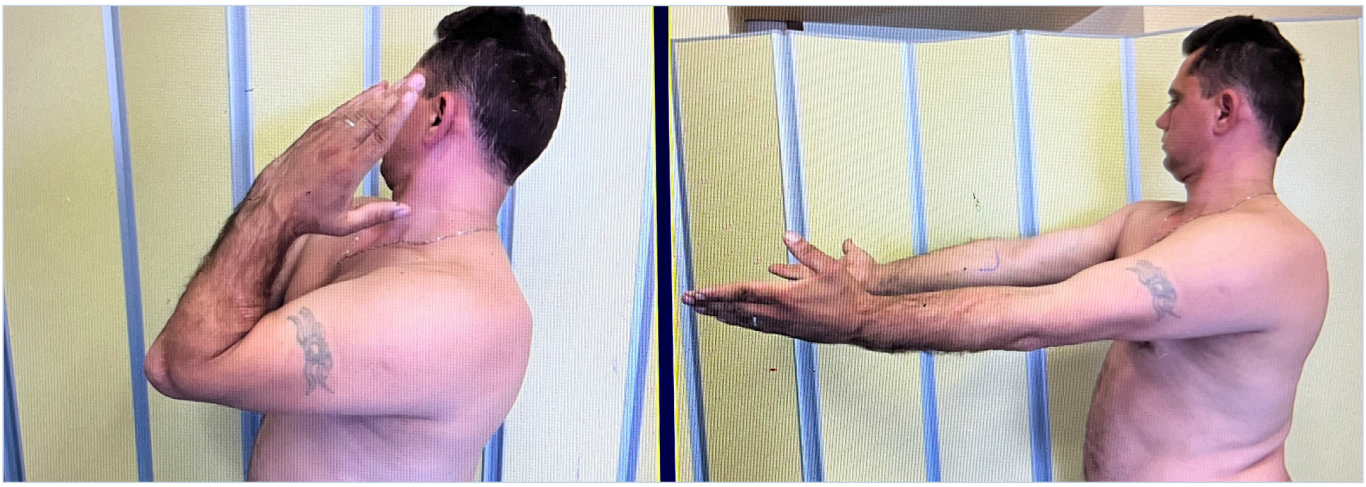
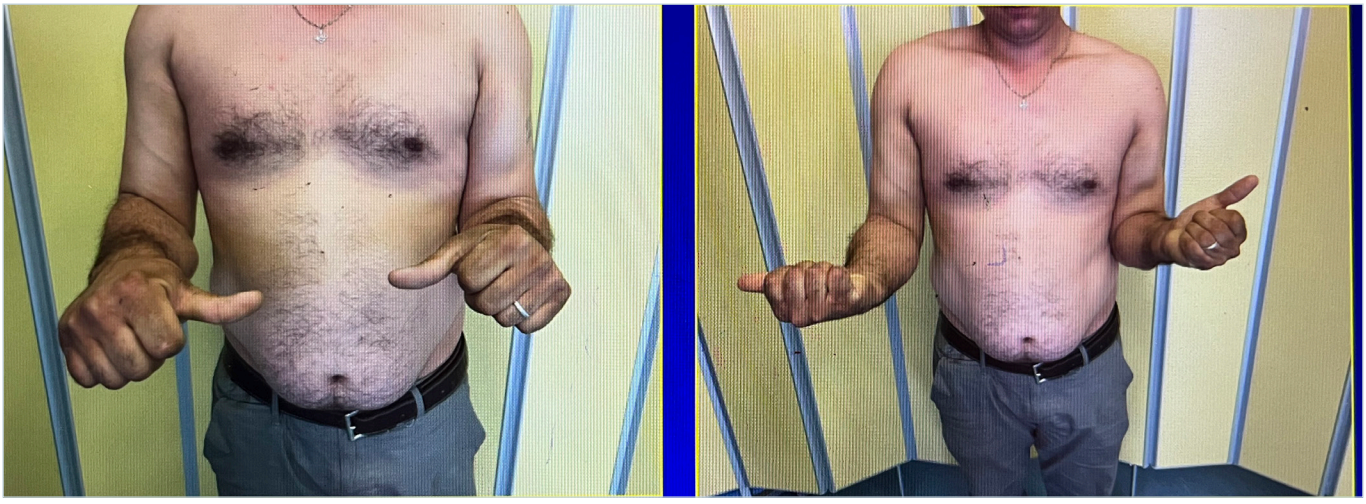


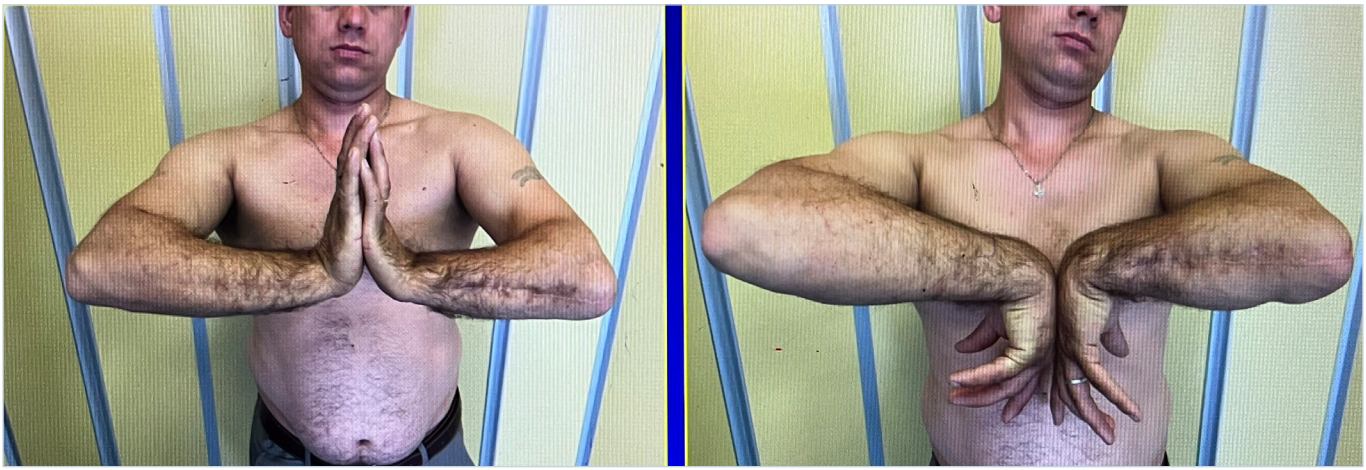
Figure 3-4. Follow up 3 years after reconstruction: boneplate, Interosseous Membrane plasty (Xray. postop a-p note the proximal-radial and distal ulnar Tunnels & lateral Fig 3-4).



20°-125°: 10 POINTS

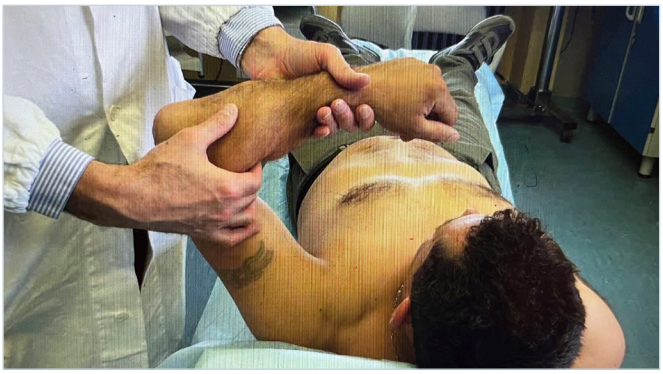


55-45°: 10 POINTS

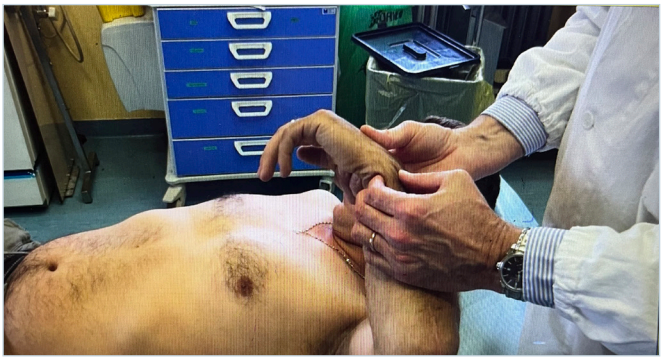


80°-80°: 10 POINTS

Figure 5-6-7. Clinical evaluation: R.O.M. (F-U 3 yrs elbow flex-ext Fig n. 5; prono-sup Fig n. 6; Wrist flex-ext Fig n.7)



ELBOW DRAWER TEST NEGATIVE: 05 POINTS



WRIST ULNAR TILT TEST NEGATIVE: 05 POINTS

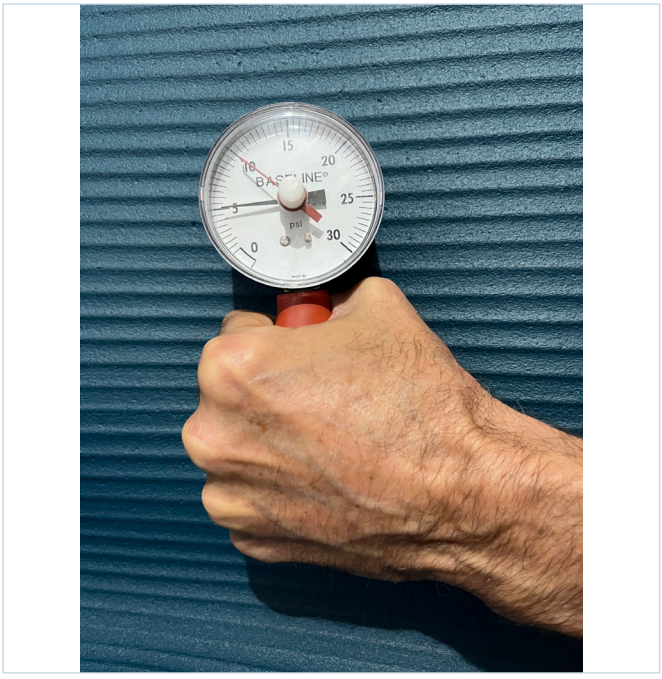


Figure 8-9-10. Stabilities: F-U Drawer Test proximal stab. Fig n.8; F-U Ballotm. Dist. stab. Fig n. 9). Grip strength (F-U Grip Fig n. 10).

Normally, forearm fracture consolidates within 90 days[26], which corresponds to the time when the second evaluation is made. Therefore, one possible limitation is the limited ability of the stability and radiological finding item to capture clinical changes after 3 months since it is possible that the forearm fracture is not completely consolidated.

Conclusion

As unstable forearm lesions can be encountered in all orthopaedic and trauma units, the FIPS score could be useful for all health care professionals involved in treatment and rehabilitation of this condition, including orthopaedic surgeons, physiatrists, forensic pathologists, physiotherapists. It can be completed by a single operator, either on paper or on a computer, and does not require any measurement equipment. The FIPS score proved to be valid, reliable and responsive to change.

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