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Fracture Healing Monitoring by Impact Tests: Single Case Study of a Fractured Tibia With External Fixator

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ABSTRACT The correct evaluation of the healing process is important to define proper times of fixator dynamization and removal, avoiding refractures. Unfortunately, a quantitative healing assessment is not yet available in clinical practice. The aim of the paper is to prove the feasibility of the mechanical vibration method to assess bone healing in fractures treated with external fixation, in *in vivo* conditions. The case study was a patient with a tibial fracture treated with a monoaxial fixator. The healing process was monitored for three months through a series of five impact tests. The pins screwed into the bone were used both to excite and measure vibrations. Fracture healing was quantitatively assessed by estimating the resonant frequencies of the leg. The first frequency increased of about 4% per week during the observation period. After the hard callus formation (13 week), also other frequencies increased within the range 1%–6% per week. X-ray observations confirmed the healing progress and proved the method potentiality. In addition, the vibratory response of the leg after fixator removal was evaluated and resulted characterized by five modes in the bandwidth 0–1000 Hz. The results suggest that the vibratory response of a fractured bone treated with external fixation can be a promising indicator for quantitative healing monitoring. The mechanical vibration method could be helpful for reducing X-ray exposure of patients and could be performed more frequently, as desirable for obtaining more attentive monitoring.

INDEX TERMS Bone healing, experimental modal analysis, external fixator, fracture healing monitoring, mechanical vibrations.

I. INTRODUCTION

A reliable assessment of bone healing is fundamental for the successful treatment of fractures. Delayed or non-union fractures have a quite high incidence, up to 5-10%, and can be very painful and dangerous for the patient health and furthermore lead to unavoidable high costs (10-80 k€ per failed treatment) [1]. Non-invasive and quantitative techniques for bone healing assessment could be very helpful for improving fracture monitoring procedures. Many approaches have been pursued in the last decades, based on different principles from ultrasounds to static angle deflection [2]. Most of them are focused on the estimation of bone stiffness, as it is well known from the literature that the stiffness of a fractured bone increases as the callus develops and evolves towards a healed condition. Bone stiffness has therefore been considered as a quantitative indicator for monitoring the healing process, as reviewed in [2]–[4]. As a variation in the bone stiffness produces a change in its resonant frequencies, the healing process affects also the vibratory response of the bone. Firstly proposed in 90ies [5]–[7], the mechanical vibrations (MV) approach was applied to fractured tibias both in ex-vivo [6], [8], [9] and in-vivo [5]–[8] conditions. However, despite the first promising results, it was soon abandoned mainly because of limitations due to soft tissue damping and to experimental instruments and data processing. Recently, the MV method has been reconsidered, e.g. [10], [11], in the research of

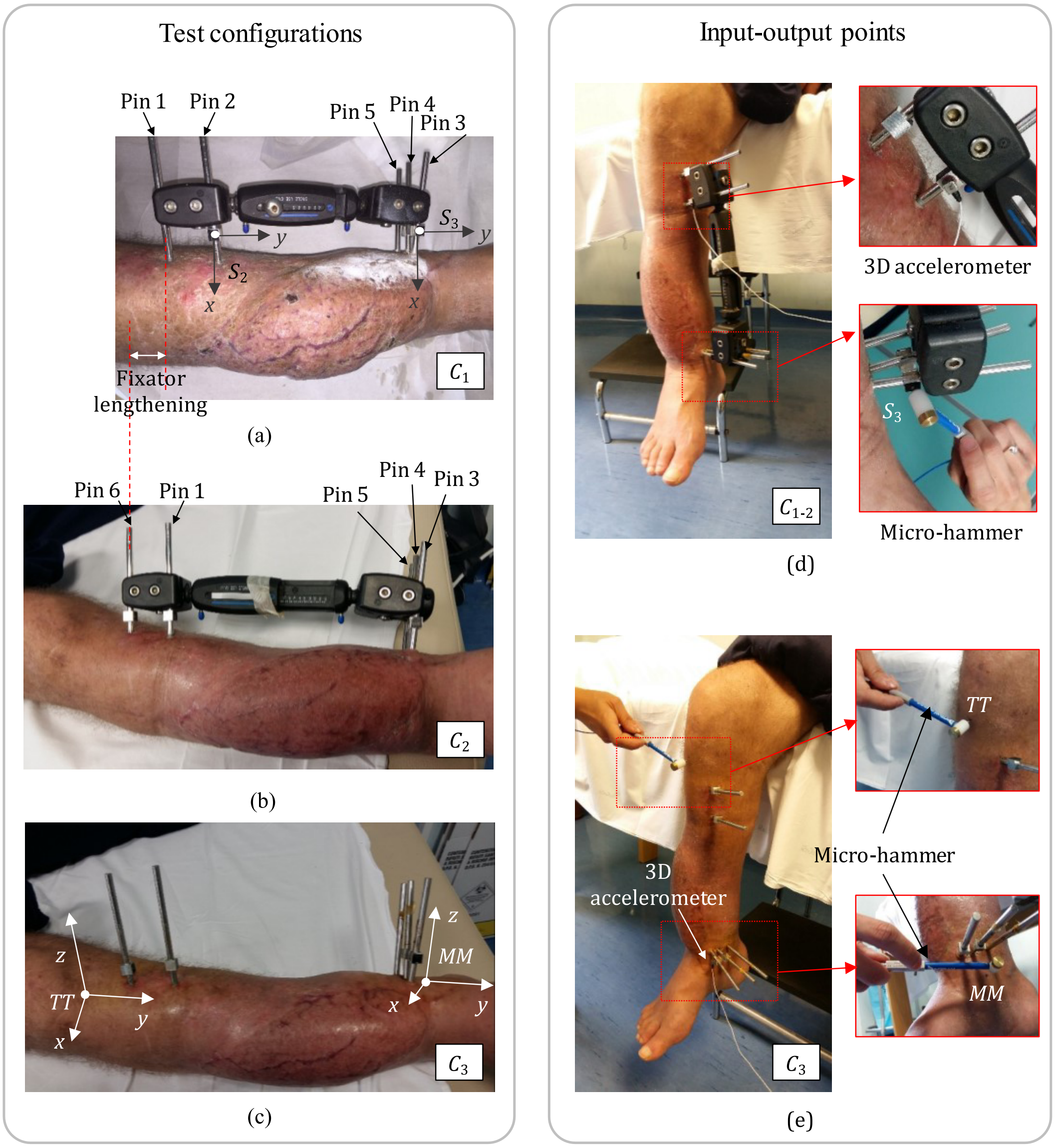


FIGURE 1. Test configurations C_{1-3} (a-c) and test set-up for $C_{1,2}$ (d) and C_3 (e).

non-invasive diagnostic tools for bone healing assessment. The present authors reported encouraging results obtained from impact tests on non-fractured and fractured tibia phantoms [12], [13]. The key point of these latter two studies was to focus on fractures treated with an external fixator, as it can be used to efficiently excite the bone and to measure its response, avoiding the transmission through the surrounding soft tissues. Additionally, the authors carried out a preliminary in-vivo study to evaluate whether MV could be a future option for non-invasive monitoring of fracture healing in a lengthening procedure and obtained promising results [14].

The aim of the present study is to test the MV approach to assess fracture healing in *in-vivo* conditions for a more complex case of leg fracture. The healing process of a fractured human tibia treated with an external fixator was monitored through resonant frequencies analysis and the evolution discussed in comparison to X-rays.

II. METHODS AND PROCEDURES

In the present study, impact tests [15]–[17] were performed to estimate the resonant frequencies (RFies) according to the procedure presented in [12]. It involves the determination of the Frequency Response Function (FRF) of the system and the extraction of the RFies through fitting algorithms (Polymax Plus). Additionally, the reciprocity and coherence of the system were estimated, since they are an indication of the linearity of the system and the quality of the measurements.

A. CASE STUDY

The case study was a patient, a 57 years-old male, with a four-part right leg fracture caused by a motorcycle crash. The anterior distal site of the tibia was exposed. The first surgical procedure consisted in the reduction and internal fixation performed by nailing the tibia. After four months, an osteomyelitis came out. The treatment was antibiotics and resection of the distal tibia, positioning of gentamicin added polymethyl methacrylate and, finally, the removal of the tibial nail. The fractures were stabilized using an Hoffmann II Hybrid Double Tenxor External Fixator (Stryker®). Later an eschar appeared anteriorly exposing the dorsal flexor tendons of the foot. Three months later, once the sign of infection disappeared, an exchange between the cement and an iliac crest bone autogenous grafting was performed and the external fixator was upgraded into an axial one, Xcaliber Meta-Diaphyseal External Fixator (Orhofix®), assembled through 5 pins. A Latissimus Dorsi pedicle free flap was used to cover the eschar. Four months later, the external fixator was taken out and the fracture, as well the osteomyelitis, were healed.

The research was carried out following the principles of the Declaration of Helsinki. The patient gave informed consent to this research.

B. EXPERIMENTAL SET-UP

The experimental set-up was defined according to [12] and [13] and consisted in an instrumented micro-hammer (5800SL, Dytran®) for the excitation and a 3D micro-accelerometer (3133A1, Dyrtran®) for response measurements. The LMS Scadas and LMS TestLab software by Siemens® were used for data acquisition and processing, respectively. Input/output (IO) signals were acquired in the frequency range 0-4096 Hz, with a resolution of 2 Hz. Resonant frequency analysis was restricted to 0-1500 Hz, according to [6], [9], and [10].

C. TEST CAMPAIGN

Vibrational tests were performed after autogenous grafting, assumed as time zero of the healing process (0 wk). A series of 5 sessions was carried out between weeks 6 and 17, every 2-4 weeks.

It must be observed that, during this period, several modifications occurred, so that three different configurations of the system were identified. A first configuration C_1 was used for the first three sessions (Fig.1(a)). In sessions 4 and 5, the system had a different configuration, C_2, due to changes performed at week 12 (Fig.1(b)): pin 2 was removed because of an infection and a new pin (#6) was added in a proximal position, so that the fixator was lengthened of about 5 cm. Furthermore, the locking nut of the central body was loosened and the fixator was dynamized. Finally, in the last session, another configuration C_3 was examined, with the fixator body removed leaving only the pins screwed into the bone (Fig.1(c)).

These three configurations were distinguished because a variation of the resonant frequencies can be attributed to a variation of the bone stiffness only if other changes of the system are negligible. Thus, the resonant frequencies obtained in different configurations cannot be compared.

In all sessions, the pins were used to both transmit the mechanical excitation and receive the vibration response. Input-Output (IO) points on supports glued to the pins were labelled according to the pin name j, i.e. S_j with $j = 1\text{-}6$. Furthermore, the tibial tuberosity (*TT*) and the medial malleolus (*MM*) were considered in the last session. IO directions were defined according to the local reference frames depicted in Fig.1 (a,c). The local z direction was normal to the surface for all IO points. Specifically, for S_j points, the local z direction resulted almost in the anterior-posterior direction, while the local x direction parallel to pin axis and the y direction almost along tibial axis.

Within each session, several combinations of Input and Output points and directions were examined. Furthermore, for each combination, ten impact tests were performed and the acquired signals averaged for achieving a single FRF. However, the repeatability of single measurements was preliminarily checked and the difference between the estimated RFs was less than 4 Hz.

TABLE 1. Experimental tests sessions: time from autogenous grafting (t) and time interval between two consecutive sessions (Δt), system configuration C_i ($i = 1\text{-}3$), IO points and directions (input in local z direction is assumed where not indicated) and boundary conditions (BCs), i.e. patient position (l = lying-down; s = sitting).

Ses.	t (wks)	Δt (wks)	Config.	Input	Output	BCs
1	6	--	C_1	S_2	S_3	l, s
				S_3	S_2	l, s
				$S_3(y)$	S_2	l
				$S_4(y)$	S_2	l
				$S_5(y)$	S_2	l
2	9	3	C_1	S_2	S_3	l, s
				S_3	S_2	l, s
3	11	2	C_1	S_2	S_3	l, s
				S_3	S_2	l, s
				S_1	S_3	l, s
				S_3	S_1	l, s
4	13	2	C_2	S_6	S_3	s
				S_1	S_3	s
				S_3	S_1	s
5	17	4	C_2	S_6	S_3	s
				S_1	S_3	s
				S_3	S_1	s
			C_3	S_6	S_3	s
				S_1	S_3	s
				S_3	S_1	s
				MM	S_1	s
				TT	S_3	s

As reported in Table 1, a total of 33 measurements were performed considering also two postures for the patient: lying-down (l), with the leg leaning on the examination table, and sitting (s), with the leg freely hanging off the end of the examination table (as in [7]). Figures 1(d) and (e) show the typical set up for $C_{1,2}$ and C_3, respectively, both with the patient in sitting conditions.

It is worth noting that the procedure was absolutely safe and not harmful: the impact force was less than 0.1 N and could not be even perceived by the patient. The healing process was monitored also using traditional X-rays.

III. RESULTS

For brevity, the following results will not be reported for the complete set of 33 tests, but will be focused on measurements having the highest coherence within each session, i.e. with IO points on the pins closer to the fracture site and excitation/response in local z direction.

As first step, the quality of the measurements was checked by analyzing the system reciprocity (same FRF inverting Input and Output points) and the coherence function, which was close to unit.

The different postures, sitting and lying down, affected results only slightly (differences of RFies lower than 2%), but the sitting condition was preferred because it was easier to achieve a correct impact.

A. HEALING ASSESSMENT

Figures 2(a), (b) and (c) show the FRFs for the configurations C_1 (weeks 6-9-11), C_2 (weeks 13 and 17) and C_3 (week 17) respectively. The estimated RFies are reported in Table 2. For the configuration C_1, 8 RFies were identified in the first two sessions, while 10 in the third one. Through the three sessions, only the first RF (f_1) increased markedly from 144 Hz, up to 162 Hz (+12.5%) and 176 Hz (+22.2%).

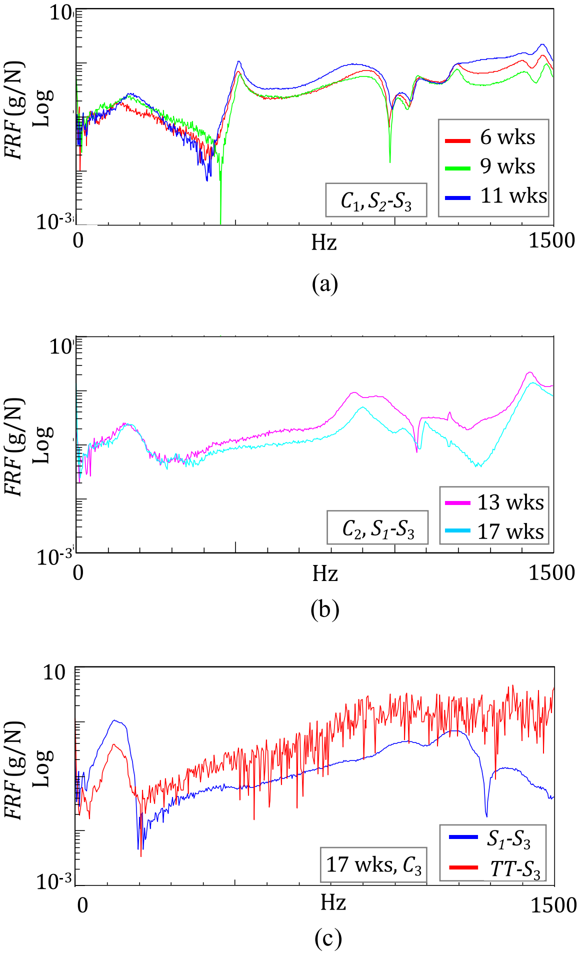
The FRFs obtained for the second configuration, plotted in Fig.2(b), had a similar trend but the curve from Ses.5 at 17 wks was translated towards higher frequencies. For example, f_1 and f_2 were found at 145, 390 Hz in Ses. 4 whilst in Ses.5 they were at 166 (+14.5%) and 486 (+24.6%) Hz, respectively.

Fracture healing was also monitored by means of X-rays, from the very beginning (wk 0) (Fig.3(a)) up to an advanced phase (wk. 29) (Fig.3 (e)).

B. LEG VIBRATORY RESPONSE

In the last session, the body of the fixator was removed but pins were left into the bone. This additional configuration, C_3, was studied to have a more direct estimate of the leg response, which in other configurations was partially hidden by the presence of the fixator. As an example, the FRF obtained for S_1-S_3 is given in Fig.2(c), with RFies in Table 2. As input points, also *TT* and *MM* were used but soft tissues damped the excitation signal above 150 Hz, thus limiting the range of frequency of reliable results. That is well demonstrated by the noisy FRF obtained for excitation through skin (Fig.2 (c)).

Using S_1-S_3 measurements, it was possible to estimate the percentage damping of the leg which resulted higher at low frequencies (<1000 Hz) and maximum for the first RF (f_1). The following damping percentage values were estimated for f_{1-9}: 19%, 8%, 7%, 17%, 5%, 2%, 4%, 2%, 2%.



(a)

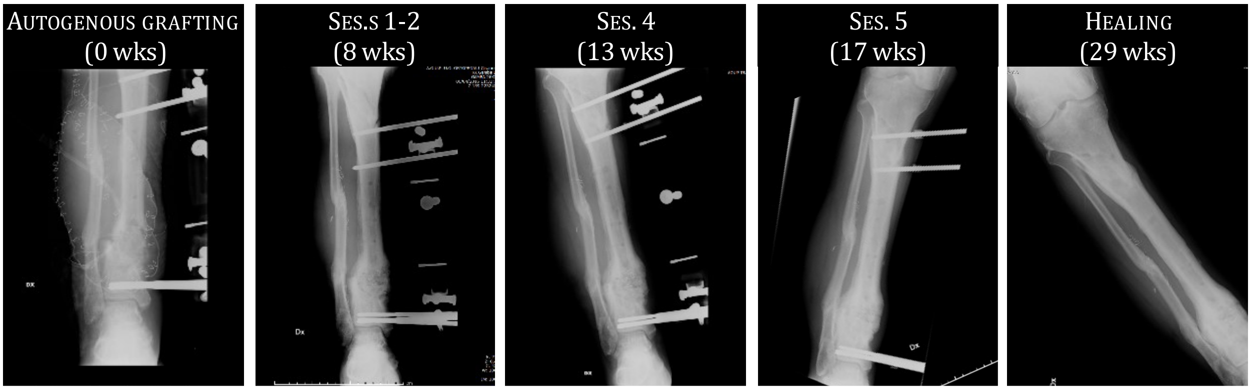
(b)

(c)

FIGURE 2. Evolution of the FRFs during fracture healing (a. b). FRF of the healed bone with only pins (c). FRFs were obtained in sitting condition, with both the input and output in local z direction (see Fig.1 a-c).

TABLE 2. Resonant frequencies of the fractured tibia during healing, with fixator ($C_{1,2}$) and with only pins (C_3). Local z direction (see Fig.1 (a-c)) was considered both for the input and output. For a given configuration, each column identifies the same vibrational mode.

Ses.	Config.	IO	f_1 (Hz)	f_2 (Hz)	f_3 (Hz)	f_4 (Hz)	f_5 (Hz)	f_6(Hz)	f_7 (Hz)	f_8 (Hz)	f_9 (Hz)	f_{10} (Hz)
1	C_1	S_2-S_3	144	505		920	980	1066	1191		1429	1439
2		S_2-S_3	162	512		902	988	1063	1194		1427	1459
3		S_2-S_3	176	508	639	865	978	1065	1181	1290	1413	1463
4	C_2	S_1-S_3	145	390	675	867	954	1073	1171	1264	1421	
5		S_1-S_3	166	486	687	901	1021	1094			1424	
5	C_3	S_1-S_3	107	150	400	821	995	1080	1188	1284	1385	



(a) (b) (c) (d) (e)

FIGURE 3. X-rays of the fractured leg from the autogenous grafting (0 wks) to the healing (29 wks). The formation of woven bone at wk 8 can be observed in (b). An initial hard callus constituted by trabecular bone is present, at least laterally, at wk 13 (c). At wk 17, a much more organized and tough structure was developing with the trabecular bone partially remodelled in compact bone (d). At 29 wk, the fracture appeared to be healed (e), though the bone remodelling will take many further months to restore the original structure and biomechanical properties of the bone.

IV. DISCUSSION AND CONCLUSIONS

In the present study, the bone healing of a human fractured tibia treated with external fixation was evaluated using mechanical vibrations. Different postures were compared, as well as IO points and directions. It was observed that the seated position with leg hanging freely should be preferred for practical reasons. Additionally, the IO points on pins closer to the fracture site and excited in the antero-posterior direction provided measurements with the highest coherence.

In the first three sessions (6-9-11 weeks), the vibrational responses were very similar, differing only for an increase of the first natural frequency of about 4% per wk, for a total of 22% from week 6 to 11. This is in agreement with the fact that, around 8 wk, X-rays showed the development of the woven bone and its successive stiffening. However, it is worth noting that such an increase could also be exalted by a reduction of the leg mass caused by the absorption of a considerable quantity of liquid.

In the last two sessions (13-17 wks) the leg exhibited a quite different response altering many frequencies ($f_{1,2,4,5}$). The most significant variation was observed for the second frequency that increased of 6% per wk. X-rays confirmed the reported increase of the resonant frequencies, highlighting that the woven bone was partially remodeled in hard callus at 13 wk, and in compact bone at 17 wk.

In the literature, the vibratory response of fractured legs during the healing process was investigated in *in-vivo* conditions only in a few studies [5], [7], [8] and, among these, only [5], [8] detailed the values of resonant frequencies at several healing stages. In such studies (apart from [7]) impact tests were performed on fractured tibias without external fixation, consequently the results are not directly comparable with the present ones. However, it is worth noting that they evaluated a percentage increase of the resonant frequencies of 1-4% per week between the weeks 5 and 20, post injury. In [7], Tower and coworkers described a wide test campaign including tibias with external fixators, using *TT-MM* as IO points. In their study, they did not report RFies, but plotted an indicator (TSI = Tibia Stiffness index), estimated as the ratio of highest RFies in the 250-400 Hz range for the fractured leg and for the contralateral leg. Thus, they focused only on one frequency, obtained through FFT, and it is not clear whether they kept the fixator or not for measurements.

Measurements made after the removal of the fixator body allowed to evaluate the resonant frequencies of the healed bone, which are rarely reported in the literature. Cunningham *et al.* [5], performed impact tests on 20 patients estimating 4 resonant frequencies at the average values of 110, 260, 370 and 850 Hz in the bandwidth 0-1000 Hz, using *MM* and *TT* as input/output points. The same procedure applied to a single patient by Benirschke and coworkers in [8], though with different output points, provided 3 RFies: 121, 312 and 1041 Hz. Nikiforidis, *et al.* [6] performed spectral testing using a shaker instead of a hammer, obtaining, for a single patient, RFies equal to 39, 103 and 139 Hz in the bandwidth 0-500 Hz. Unfortunately, no further details about measurements were provided or discussed (e.g. input-output location).

It is worth stressing that, with respect to similar studies based on the MV approach, performed decades ago, we could take advantage of recent advances in technologies and software, performing more accurate analyses, including coherence and reciprocity, and the Polymax algorithm to estimate RFies and damping ratios.

Limitations and Future Developments: As main limitation of the study, there is its single case focus. This was also a patient with a rather complex clinical history. We considered that this could be a strong point, because more 'standard' fractures are expected to behave more simply. The same approach has been recently applied to a case of femur lengthening with satisfactory results [14].

We need more patients to prove that the MV approach can be reliable for healing monitoring. What is required for a clinical application is a clear indication of the status of the fracture (healed/not healed), similarly to what proposed by Tower *et al.* [7]. This is the final aim of the research and in order to widen the dataset for improving the statistical significance of results, a collaboration with other groups would be desirable.

Future efforts will be focused on the identification of the most significant frequencies to be monitored (e.g. bending mode). This will require a complete experimental modal analysis to associate to each RF a vibratory shape. This could be useful also for optimizing the computational time required to process data, and for defining a synthetic indicator for healing assessment.

V. CONFLICT OF INTEREST STATEMENT

No conflicts of interest to declare. All the authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work.

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