From biology experimentation in space to orthopaedic surgery innovation. Encouraging results of a DTM project performed for the Italian Space Agency

F. Cassese
C. Calderoni
A. Malagoli
D. Santachiara
V. Cotronei[1]
W. Piperno[1]

DTM Technology was born in 1994 from the Space Division of Ferrari, following an explicit Ferrari desire (return to *core business*).

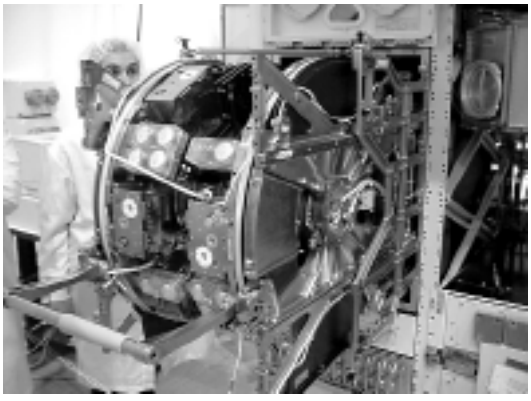
DTM srl, Modena, Italy (www.dtm.it);
[1] ASI, Rome, Italy

Indirizzo per la corrispondenza:
dtm@dtm.it
Tel. + 39 059 847337

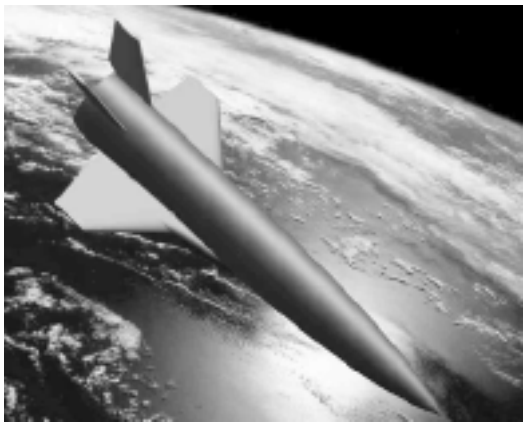
As Ferrari first, and as DTM after 1994, our activity has been mainly focused on

Automotive …

… Microgravity …



… and Space



A short look at the main medical and biological devices have been successfully completed for the International Space Station (ISS),

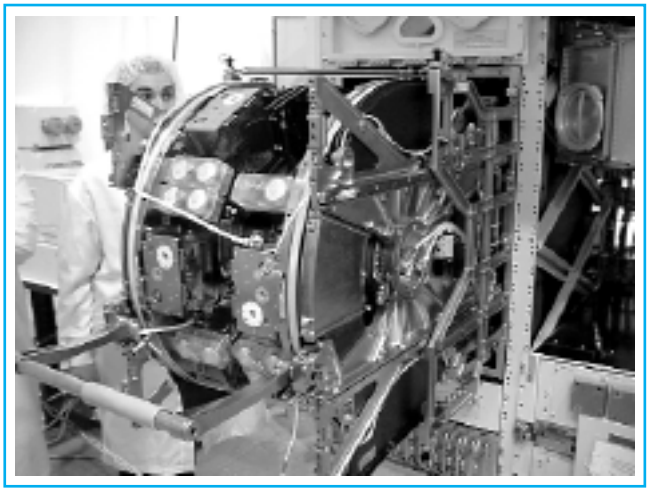
Matroskha,

Biolab (Biological laboratory) and EMCS (European Modular Cultivation System),

BIG (Biological Gravitrophism).

Matroskha, a radiological apparatus to monitor the cosmic ray impact on the astronauts living and working on the Space Station, especially during their EVA (Extra Vehicular) activities.

Biolab (Biological laboratory), a thermal incubator equipped with two centrifuges to perform biological experimentation in µg conditions.



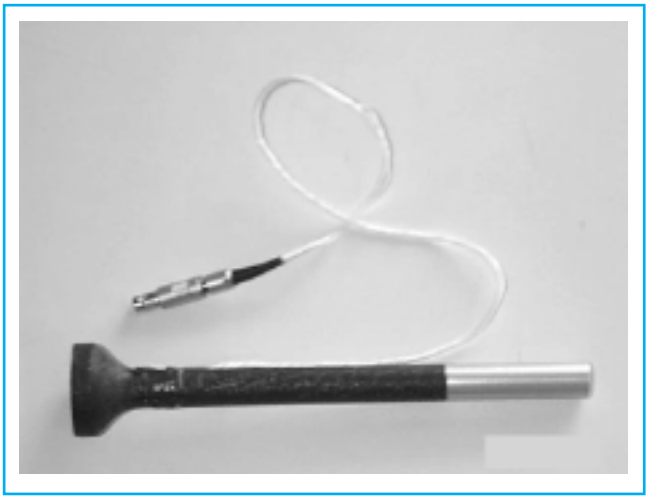
BIG (Biological Gravitrophism), a device used on sounding rockets to study the modification in Space of neurological cellular tissue.

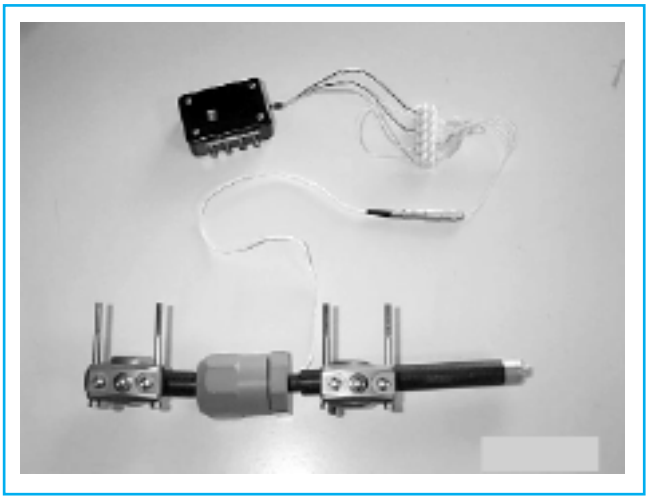
Recently DTM developed a surgical device, to improve the rehabilitation of patients suffering for art problems, as a consequence of osteoporosis or traumatic injuries. This product is an innovative lateral bone-setting device, based on carbon fibre reinforced plastic (CFRP) technology.

The main advantages over conventional products are the mass saving, the properly tuned rigidity, perfectly tailored over the patient's need, the X ray transparency, and the possibility to monitor the stress and strain level, in real time, thanks to a miniaturised and rugged electronic apparatus, fully embedded into the CFRP structure.

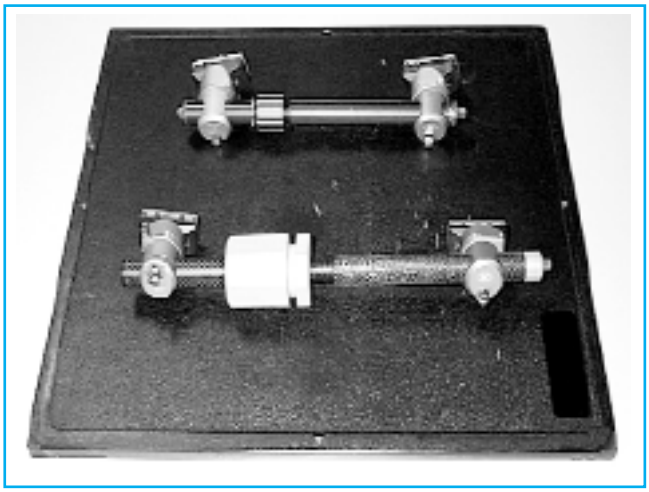
This device is worldwide patented by DTM and ASI together.

View of the lateral bone-setting device with quick connect system and radio transmitter:

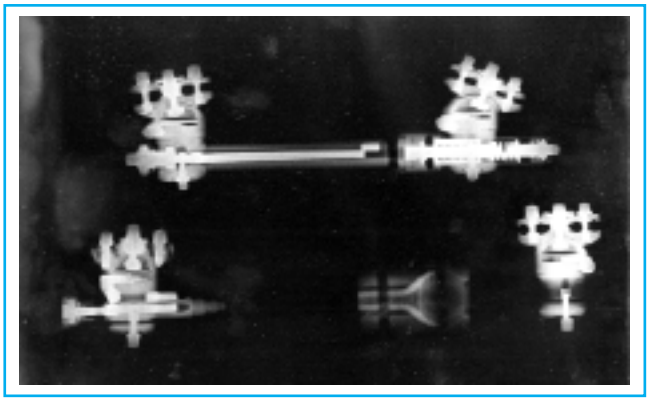




Telemetry data receiver (left) and transmitter (right) implemented on the DTM bone-setting device:



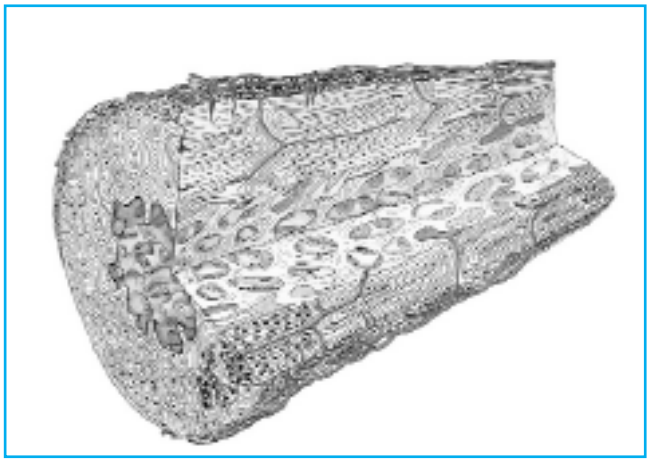
X-Ray comparison with a conventional lateral bone-setting device:

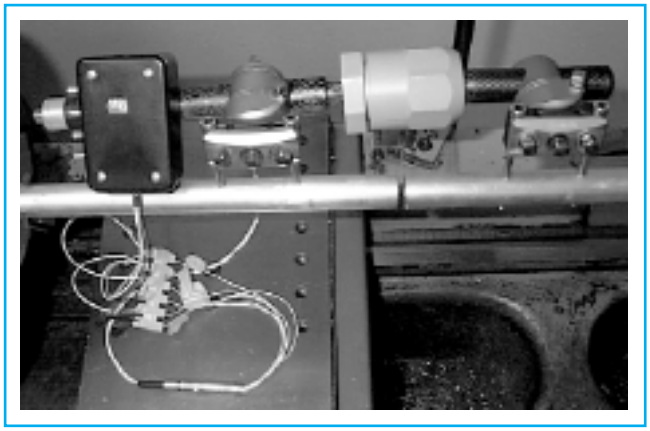


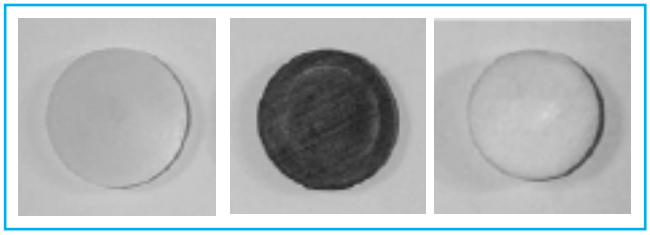
LABORATORY TESTING ON TELEMETRY SYSTEM

How to simulate the mechanical behaviour of a healing fracture?

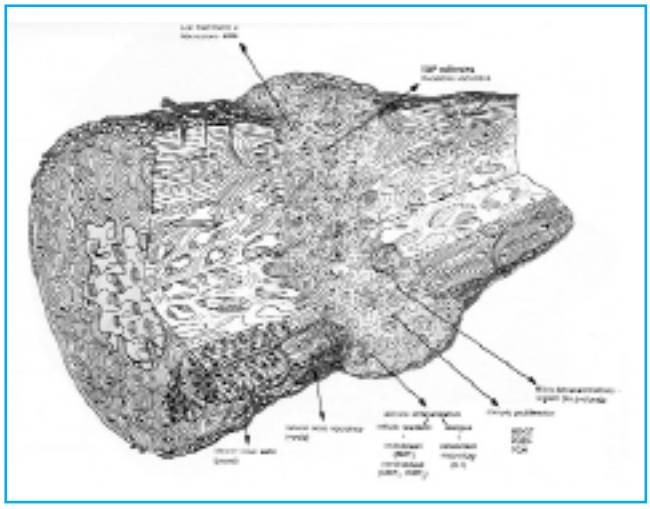
Normal bone structure:



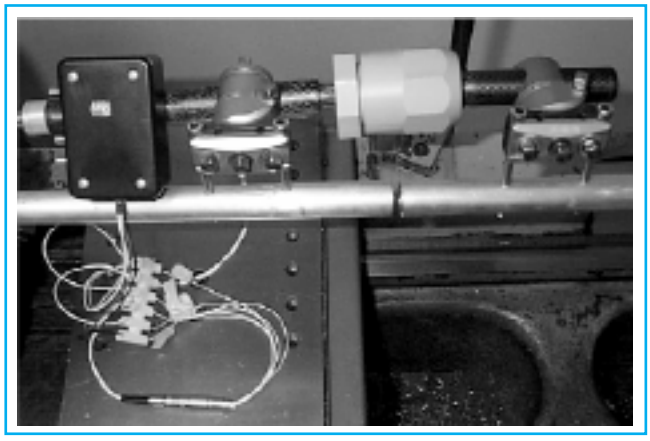


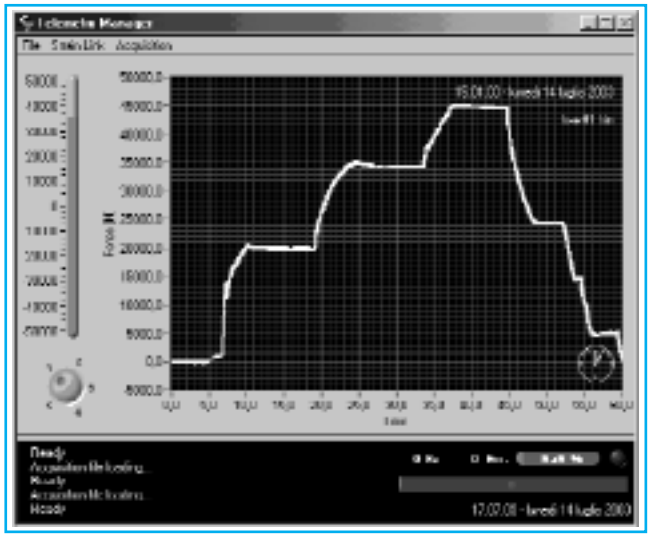


FRACTURED BONE: INITIAL STAGE

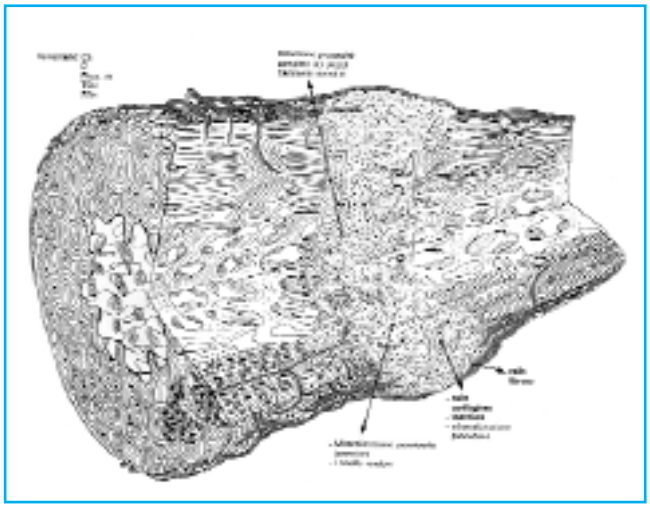


Test set-up (no rubber disk interposed) and diagram of telemetry data obtained during simulation

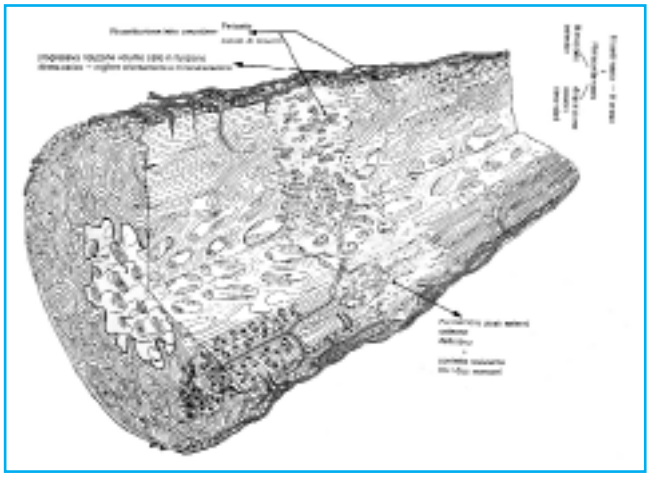




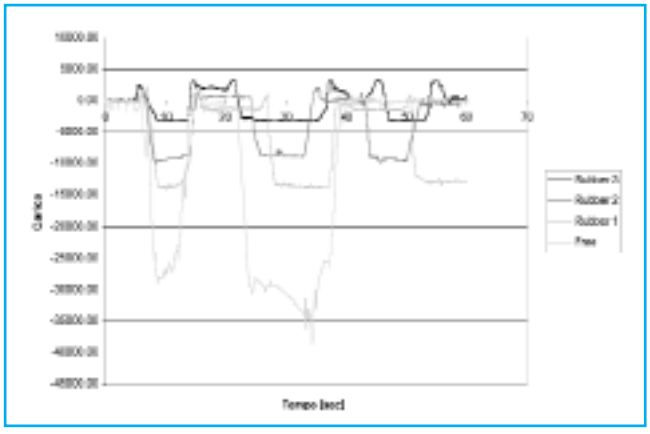
SECOND STAGE: GROWING OF THE CALLUS



FINAL STAGE: FRACTURE FULLY HEALED



OUTPUT FROM TELEMETRY: STRESS DIAGRAMS DEPENDING ON THE HEALING PROGRESS



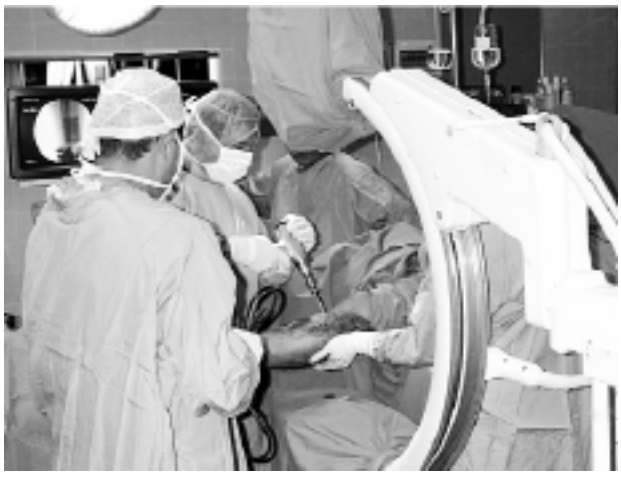
APPLICATION OF THE LATERAL BONE-SETTING DEVICE. TWO SIGNIFICANT CASE REPORTS.

1° patient	2° patient
Male	Male
25 years	85 years
Good general conditions	Poor general conditions

1ST PATIENT: X-RAY EXAMINATION BEFORE SURGERY:

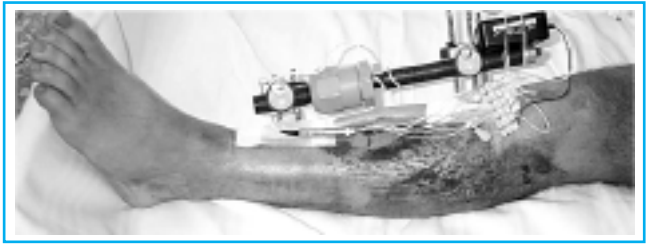
PREPARATION OF THE PATIENT FOR SURGERY:

SCREWING PROCESS TO INSTALL THE PINS ON THE TWO SIDES OF THE BROKEN TIBIA:



THE LATERAL BONE-SETTING DEVICE IS INSTALLED, AND CORRECT BONE ALIGNMENT EASILY CHECKED (THANKS TO THE RADIO-TRANSPARENT COMPOSITE MATERIAL):

THE TELEMETRY SYSTEM IS IMPLEMENTED FOR THE FIRST CHECK, JUST A FEW DAYS AFTER SURGERY:

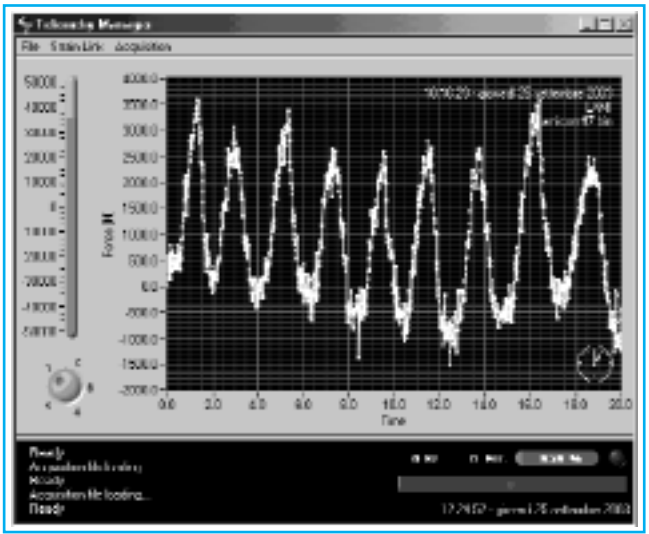


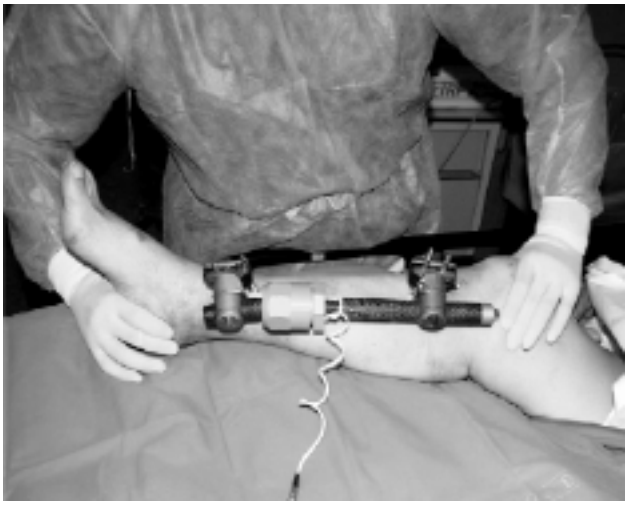
2ND PATIENT AFTER SURGERY

X-RAY EVALUATION AFTER SURGERY

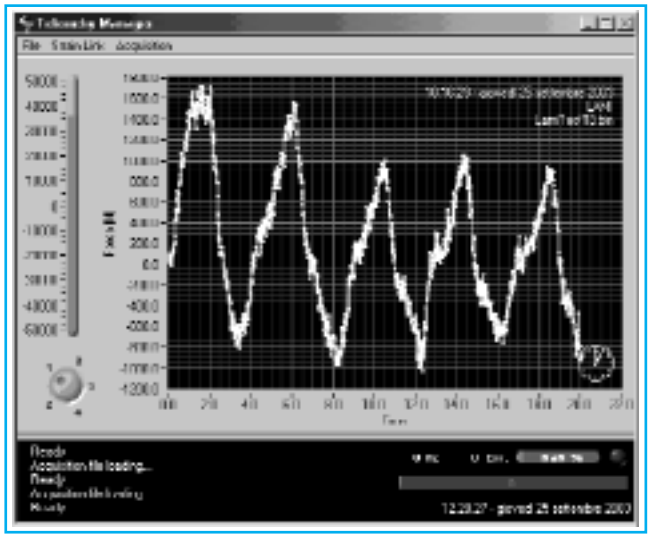
2ND PATIENT. SOME EXERCISES, MADE BY THE SURGEON.

COMPRESSION:

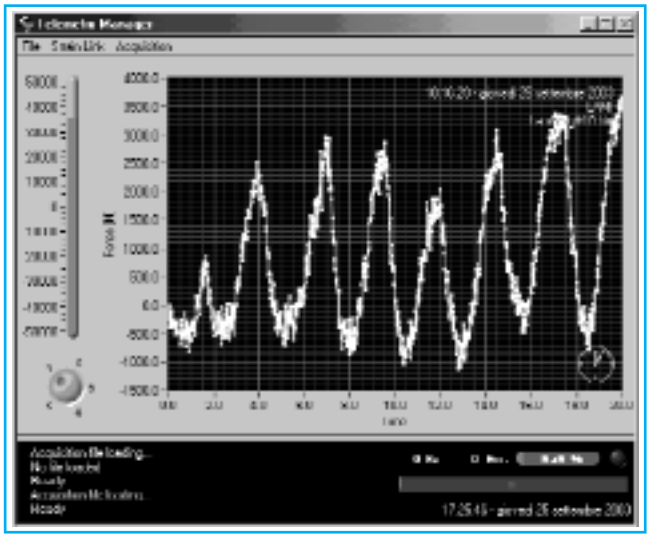




TORSION:

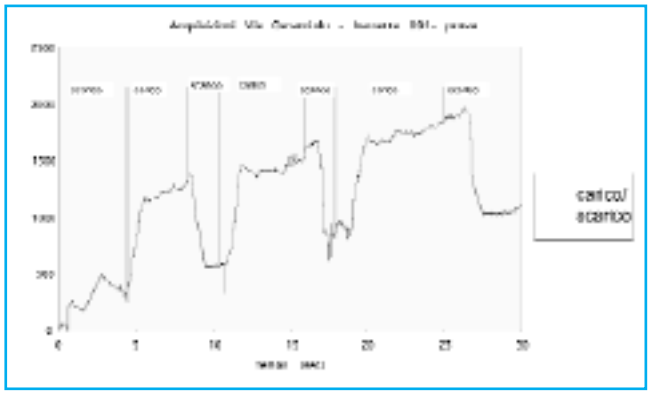


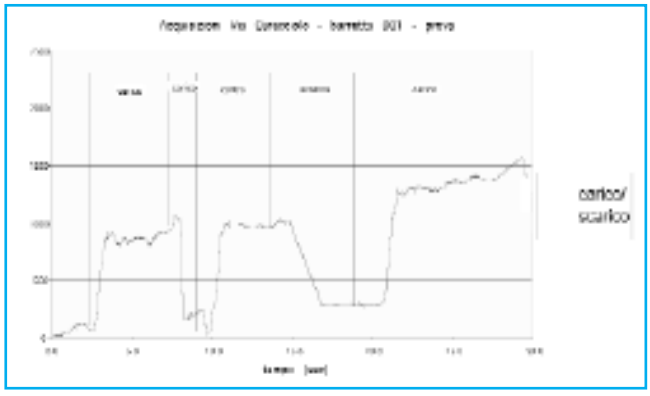
VALGUS:



Thanks to the telemetry, the patient can walk freely, in open spaces and outside. He can then act naturally so that the data collected are really representative of the level of recovery achieved so far.
In the following picture, a patient equipped with a bone-setting device with DTM stress monitoring system is just coming back from a walk in the country. The data collected are presented in the following charts.

TEST DATA EVALUATION: FIRST RESULTS ACHIEVED BY COMPARING DATA OF TWO SUBSEQUENT TEST CAMPAIGNS, OF JULY 12/03 AND AUGUST 10/03.





The comparison between the two graphs shows a strong reduction of the load supported by the lateral bone-setting device, during a period of 30 days. This load drop witnesses the good progress in the healing process of the tibia. While the bone is recovering, it can bear higher loads, reducing consequently the load bypassed by the bone-setting device.

The DTM bone-setting device can be operated in conjunction with several other medical apparatus, in order to check, monitor and register data related to cardio-vascular system, in parallel to the data pertaining the bone rehabilitation.
Among the others, the EXER apparatus, designed and manufactured for the University of Udine, Prof. PE di Prampero and Prof. G Antonutto, under ESA and ASI contracts.

The patient, shown here in the DTM premises, can pedal or jump, pushing on the instrumented load cells, and transmit via telemetry data on the data acquisition system. Cardiovascular parameters can also be recorded in parallel, due to the large number of channels available in the telemetry system, and also thanks to the high acquisition frequency rate.

CONCLUSIONS

The application of the DTM telemetry system on bone-setting devices, to monitor data on fractured bones, is a very promising technique able to:
– reduce the need for X-ray examinations;
– objectify the real recovery condition of the patient;
– keep closer the orthopaedic surgeons worldwide, in their data analysis and comparison process.

Moreover, the DTM telemetry used on the other biomedical apparatus can show the patient overall health condition. The progresses of the patient during rehabilitation, taking into account:
– osseous, muscular, respiratory, and cardiovascular systems,

can be observed, allowing the patient to get the best and quickest recovery.