

## A Clinical Application of the Bone Structure Index

Francesca Cosmi<sup>1,2</sup>, Alessandra Nicolosi<sup>2</sup>, Edoardo L. Rubattu<sup>3</sup>

<sup>1</sup>University of Trieste, Trieste, Italy, <sup>2</sup>M2TEST srl, Trieste, Italy, <sup>3</sup>Studio Medico Polispecialistico IGEA, Olbia, Italy  
cosmi@units.it

**INTRODUCTION:** It has been recently estimated that about 30% of women and 20% of men over 50 will develop osteoporosis, a disease characterized by decreasing bone strength. Although low bone mineral density is generally associated with higher fracture risk, the spatial arrangement of the trabecular structure is a second key factor of bone resistance [1] and about 40-60% of the fractures affect people that can be considered at moderate risk on the basis of densitometry (DXA) assessment alone [2, 3]. Hence the need to develop innovative and low-cost diagnostic methods that can be used together with the consolidated systems.

The recently introduced Bone Structure Index (BSI) gives an indication of the quality of the bone structure: it measures the weight-bearing capacity of the bone structure, evaluated from simulated application of loads on a virtual biopsy of the patient. The bone structure images are acquired by planar radiograms in the proximal epiphysis of the three central proximal phalanges of the non-dominant hand, a peripheral site of the human body [4-7]. In this work, we describe a recent application of the BSI in a clinical setting.

**METHODS:** The following data were collected from all female patients that accessed the IGEA clinic following a spontaneous or low impact fracture: age, Body Mass Index (BMI), femoral neck DXA results, BSI. The patients signed an informed consent according to the Italian laws.

**RESULTS:** The population consists of N=18 female patients, age 35-89 yrs, BMI range 18-3, all reporting a previous spontaneous or low impact fracture. The breakdown for collected data is shown in Fig.1.

Double Energy X-ray Absorption (DXA) is currently the gold standard for bone mineral density assessment and the diagnosis of osteoporosis. The results of densitometry examinations are expressed as a T-score, that is a number representing a person's bone density compared with the average bone density value of young Caucasian women, who are at peak bone density. A DXA\_T-score > -1 is considered normal, a  $-2.5 \leq \text{DXA\_T-score} \leq -1$  is classified as osteopenia (diminished bone density) and a DXA\_T-score < -2.5 corresponds to osteoporosis.

In 11 patients the DXA scan resulted in a diagnosis of osteoporosis, in 6 of osteopenia and in 1 case the DXA yielded a normality result.

The bone structure quality as measured by the BSI can also be interpreted using the T-score concept. In this study, the patient with a normal result had a BSI\_T-score = -3.0, an outcome representative of a significant deficiency in bone quality.

Of the 6 osteopenic patients, 4 exhibited a  $-2.5 \leq \text{BSI\_T-score} \leq -1$ , indicating that their bone quality is below normal as well.

**DISCUSSION:** The DXA and BSI results have already been shown to be independent [1, 7]. Of the fractured patients, only 61% had a diagnosis of osteoporosis according to the DXA scan alone. These results are in line with what reported in literature [2, 3].

A 89% rate of correct diagnosis was obtained with the additional consideration of the high risk associated with either a BSI\_T-score < 2.5 or the contemporary presence of DXA\_T-score < -1 and BSI\_T-score < -1.

**SIGNIFICANCE:** As mean average human lifespan is growing, the parallel rise in the rate of osteoporosis is projected to pose an even more significant burden on society in future years than it does already. As observed in several studies, about half of those at risk of fracture still go undetected, and, since it is widely accepted that the mechanical properties of bone depend on both its composition and its trabecular component micro-architectural arrangement, the fracture risk in these patients appears to be linked to alterations of the trabecular architecture.

The combination of both densitometry and trabecular structure assessment is likely to improve diagnostic accuracy in the evaluation of the risk of fracture. The very low X-ray doses used for BSI assessment and the quick response of the trabecular structure to changes entail that the treating physician can monitor the bone modifications in response to any therapeutic strategy and tailor the patient's treatment every few months if necessary, providing patients with a strong motivation to strictly adhere to their therapy and avoid discontinuation.

### REFERENCES:

1. Pasco J.A. et al. Osteoporos. Int. 17(9): 1404-1409 (2006)
2. Sornay-Rendu E. et al. J Bone Miner Res. 20(10): 1813-1819 (2005)
3. Consensus Development Conference. AM J Med. 94: 646-650 (1993)
4. Cosmi F., Dreossi D. Acta Bioeng. Biomech. 9(2), 35-39 (2007)
5. Cosmi F., USA Patent 7,386,154B2 (2008)
6. Cosmi F., Mazzoleni, G. J. Mech. Behav. Biomed. Mater. 29, 517-528 (2014)
7. Cosmi, F. MCB: Molecular & Cellular Biomechanics, 12(2): 87-105 (2015)

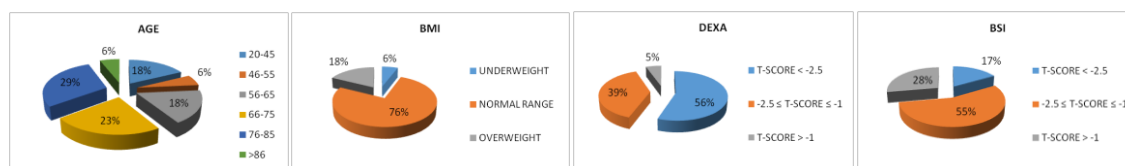


Fig.1 Population breakdown.