



ENHANCE THE PREDICTION OF YOUR PATIENTS' FRACTURE RISK

Boost The Performance Of DXA & Add Value To Your Clinical Practice with TBS

TBS iNsight™ - an advanced imaging software for bone densitometers (DXA) - enhances the ability to predict osteoporotic fracture.

The result - expressed as a Trabecular Bone Score (TBS) - derives from a patented algorithm that evaluates spatial variations of the gray-levels in the AP spine DXA scan. TBS provides an indirect, yet highly correlated, index of bone microarchitecture. TBS predicts fractures independently of bone mineral density (BMD), clinical risk factors and FRAX®.

TBS' maximum impact is observed in patients with osteopenic/normal BMD values who display low TBS scores and consequently have a higher combined risk profile or in patients whose fracture risk is close to the intervention threshold. Moreover TBS shows potential in patients with secondary osteoporosis: While BMD is often limited to identify patients with secondary OP who are at risk for fractures, TBS can be used as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture.

TBS iNsight software

- ◆ calculates an index of microarchitecture in routine clinical practice
- ◆ incorporates FRAX adjusted for TBS
- ◆ shows monitoring trend curve for patients' follow up data including LSC
- ◆ allows retrospective analysis of patients' DXA scans
- ◆ enables automatic data export
- ◆ communicates with PACS systems thanks to DICOM module (optional)
- ◆ displays patient reports in various languages
- ◆ offers online training & certification
- ◆ includes TBS iNstats module to identify your patient management
- ◆ is calibrated by using a unique TBS phantom.

TBS iNsight software license is assigned to a specific DXA system.

Compatibility
GE Lunar Systems
Current compatible bone densitometers with TBS iNsight
iDXA™ Prodigy™ Series (all models)
Current BMD software versions compatible with TBS iNsight
enCORE™ versions from 8.10 to 17.10



Clinical Validation

- ◆ Several hundreds of peer-reviewed publications
- ◆ Included in international and national guidelines (e.g. ISCD, ESCEO, DVO, NOGG)
- ◆ TBS adjusted FRAX
- ◆ Thousands of TBS users worldwide
- ◆ Ethnicity reference curves for men and women derived from huge study cohorts (e.g. NHANES) integrated in the software.

- TBS** differentiates expert DXA clinics and can increase patient referrals. TBS is...
- FAST** no additional scan time, immediate results
- SAFE** no additional radiation to patients, derived from routine DXA exams
- EASY** automatic TBS report with BMD, TBS, FRAX adjusted for TBS

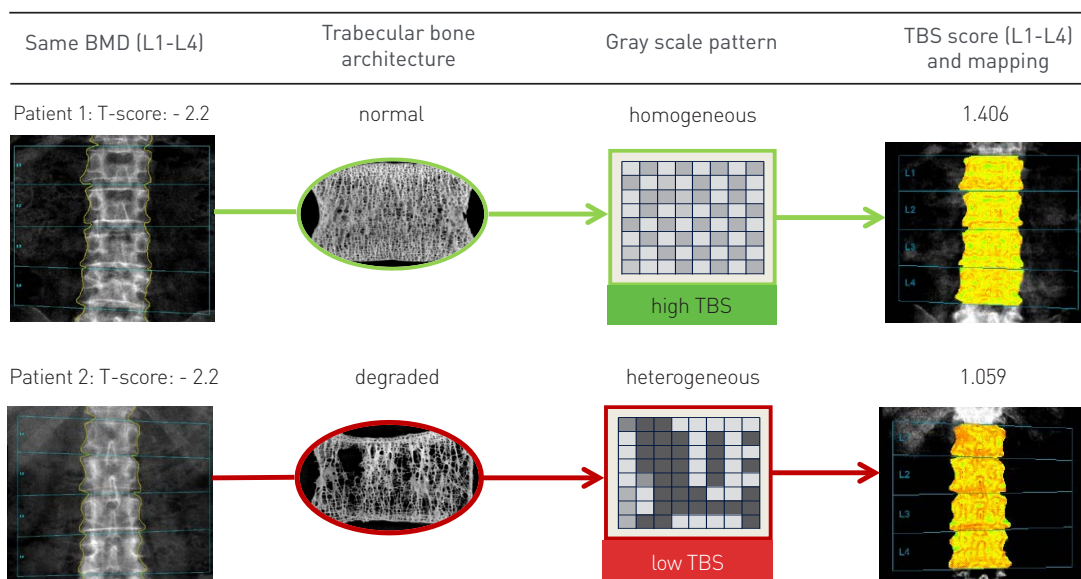
INTERPRETATION OF TBS & BMD VALUES



Interpretation grid

Same BMD but Different TBS

Two patients can have similar BMD but could display different structure (see graphic below)^[1] and subsequently have different fracture risk. According to scientific societies «decision-making about the patients to be treated and the treatments to be prescribed must be based on clinical judgement using the recommendations and all available clinical information.»^[2]. TBS has proved to be an additional aid to better characterize your patient's risk profile and thus can improve your patient management.



Risk stratification of TBS and BMD could improve the assessment of fracture risk, particularly in osteopenic patients and patients with secondary osteoporosis. The following interpretation table^[3] presents the level of risk expressed as the number of major osteoporotic fractures per 1000 women/year (based on a study conducted on 30,000 women). It shows that for a given BMD category the risk may almost double depending on TBS.

Level of risk based on classification of the WHO (BMD minimum T-score of proximal femur or lumbar spine)				Risk levels for major osteoporotic fractures per 1000 women/year	Colour code	
		Normal	Osteopenia			Osteoporosis
Risk level based on TBS of the spine	>1.310	Green	Yellow	Orange		
	≤1.310 and >1.230	Light Green	Yellow-Orange	Red		
	≤1.230	Yellow	Orange	Dark Red		
				>20		Red
				>14 and ≤20		Dark Red
				>10 and ≤14		Orange
				>7 and ≤10	Yellow-Orange	
				>5 and ≤7	Yellow	
				>4 and ≤5	Light Green	
				≤4	Green	

TBS is a risk factor for future low trauma fracture independent of BMD and clinical risk factors.

TBS should be interpreted in accordance with the recommendations of national & international societies, e.g. NOF^[1], ESCEO^[4], ISCD^[5] and GRIO^[6].

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1- Adapted from Silva et al. JBMR 2014. 29(3): 518-530
 2- NOF Clinician's Guidelines to prevention and Treatment of Osteoporosis 2010 - Last update in april 2014
 3- Adapted from Hans et al. JBMR 2011; 26(11): 2762-9 and meta-analysis from McCloskey et al. JBMR. 2016, 31(5): 940-948.
 4- Harvey et al. Bone, 2015. [78]: 216-224.
 5- ISCD <http://www.iscd.org/official-positions/> - Last update in june 2015 with TBS integration
 6- GRIO <http://www.grio.org/> Research and Information Group on Osteoporosis