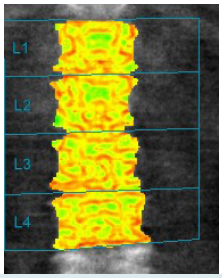
TBS osteo
bone structure matters

BONE HEALTH REPORT INTERPRETATION STEPS

powered by TBS iNsight™ medical AI technology

1. TBS Spine Mapping



The image is not intended for diagnosis.

Check your patient positioning and the bone mask

The TBS mapping is the local visual display of the TBS values for each pixel of the DXA image. A low TBS value is represented in red; a high TBS value is represented in green and a medium TBS value in yellow. (1)

It is intended to check patient positioning and the bone mask

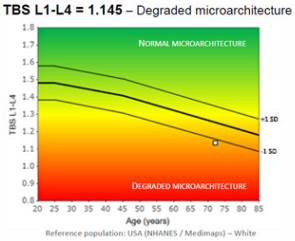
Why is this important?

Patient positioning and bone mask outlining are key for an accurate TBS computation, especially for patient monitoring.

What to do?

- L1-L4 vertebrae are clearly separated at intervertebral spaces.
- Bone edges include all relevant anatomy and exclude the osteophytes.
- Vertebral fractures or artifacts are excluded.

2. TBS Spine Results



Check the bone microarchitecture of the patient

The TBS result computed for the selected vertebrae is plotted onto a reference graph. The graph comprises 2 main parts: The TBS normal values according to age are represented by the thick black line. The thinner lines above and below represent this normative curve +/- 1 SD (standard deviation).

A gradient of different-colored zones representing different status of bone microarchitecture: high TBS values (TBS L1-L4 > 1.31) representing Normal microarchitecture, and low TBS values (TBS L1-L4 ≤ 1.23) representing Degraded microarchitecture.

Why is this important?

With this graph, you can see how the TBS score of the patient compares to the normal population (same age, same gender, same ethnicity) and see if the patient is at high risk of fracture based on the microarchitecture assessment only.

What to do?

Use the colors to assess your patient risk based on the microarchitecture assessment. If TBS is in the:

- Green zone: low risk of fracture, suggesting normal bone microarchitecture.
- Yellow zone: medium risk of fracture, suggesting partially degraded bone microarchitecture.
- Red zone: high risk of fracture, suggesting degraded bone microarchitecture.

3. Fracture Risk Assessment

Osteoporosis is a systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture.[1]

The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture and fracture risk. It provides information independent of BMD.

TBS ** \ BMD T-score *	Normal	Osteopenia	Osteoporosis
Normal		□	
Partially degraded			
Degraded			

* BMD T-score is the min value of spine, total hip and femoral neck
** Spine TBS L1-L4 Normal microarchitecture > 1.31; Degraded ≤ 1.23

Low risk	Medium risk	High risk	Very High risk

Color coded Bone Health categories based on Fracture Risk[2]

Assess the fracture risk of the patient

A color-coded grid shows the major osteoporotic fracture risk classification based on combined BMD (minimum T-score of spine, total hip and femoral neck) and TBS categories corresponding to 3 tertiles of TBS values (2). The colors of the different Bone health categories indicate the risk of fracture (1).

Why is this important?

Osteoporosis is "characterized by low bone mass and a microarchitectural deterioration of bone tissue". The BMD is an assessment of the bone mass. When only the BMD is considered, studies have shown that more than 50% of fractures occur in patients with BMD T-score outside the Osteoporosis category(3). TBS is intended to provide the microarchitecture information that has been missing in the bone densitometry examination. Both TBS and BMD and other clinical risk factors should be considered for an accurate fracture risk assessment.

What to do?

- Check the white dot representing the patient's risk of fracture based on minimum BMD T-score and TBS to identify his/her risk, consequently:
  - Osteopenic or osteoporotic patients with degraded TBS are at high risk (orange) or very high risk (red) of fracture.
  - Normal or osteopenic patients with partially degraded or normal microarchitecture are at medium (yellow) or low (green) risk of fracture.
- Note that Osteopenia and Degraded Microarchitecture may result from a secondary cause of osteoporosis (4).

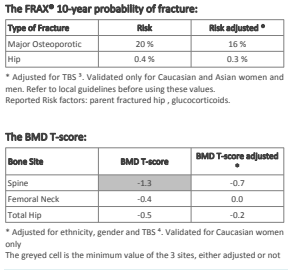
(1) Hans, D., Goertzen, A.L., Krieg, M.-A., Leslie, W.D., 2011. Bone microarchitecture assessed by TBS predicts osteoporotic fractures independent of bone density: the Manitoba study. J. Bone Miner. Res. 26, 2762–2769. https://doi.org/10.1002/jbmr.499.

(2) The TBS thresholds were defined from analysis of data from 14 prospective clinical studies (including data from: France, Germany, UK, Switzerland, Sweden, Netherlands, Canada, Australia, Hong-Kong and Japan) involving 17,809 men and women aged 40 and older. Osteoporos Int. 29, 751–758 (2018).

(3) Shevroja et al. J Clin Densitom 20, 334–345 (2017).

(4) Ulivieri, F. M. et al. Endocrine 47, 435–448 (2014).

4. Therapeutic Decision Tools



The FRAX® 10-year probability of fracture:

Type of Fracture	Risk	Risk adjusted *
Major Osteoporotic	20 %	16 %
Hip	0.4 %	0.3 %

* Adjusted for TBS [3]. Validated only for Caucasian and Asian women and men. Refer to local guidelines before using these values.
Reported Risk factors: parent fractured hip , glucocorticoids.

The BMD T-score:

Bone Site	BMD T-score	BMD T-score adjusted *
Spine	-1.3	-0.7
Femoral Neck	-0.4	0.0
Total Hip	-0.5	-0.2

* Adjusted for ethnicity, gender and TBS [4]. Validated for Caucasian women only
The greyed cell is the minimum value of the 3 sites, either adjusted or not

This section on the report is optional

Individualize treatments decisions

This section provides information tools that can be used to help you make the most appropriate therapeutic decisions:

- Using FRAX when appropriate:
  - Risk category: displays FRAX probabilities provided by the DXA software
  - Risk adjusted category: displays FRAX probabilities adjusted for TBS, taking into account the status of the trabecular bone microarchitecture in the fracture risk assessment [1]
- Using BMD T-score when appropriate.
  - BMD T-score: displays T-scores computed by the DXA software
  - BMD T-score adjusted: displays T-scores adjusted for TBS for women only. [2]

The adjustment of the T-score is just the application of the equation that is available in the scientific literature [2]. No indication is provided on how to use this adjusted value versus the regular BMD T-score. The formulas to adjust the BMD T-score are explained in the TBS iNsight – Technical Guide. In the BMD T-score column are the BMD T-scores provided by DXA software while BMD T-scores adjusted are BMD T-score adjusted for ethnicity, gender and TBS. The greyed cell is the minimum value of the 3 sites, either adjusted or not.

Why is this important?

Different drugs (anabolic or anti-resorptive) impact the bone density and the microarchitecture differently. Knowing both the BMD and TBS of your patient, as well as his/her clinical context, is crucial to better understand your patient's bone health and to choose the best beneficial approach.

What to do?

Based on the local guidelines in your country, these new decision tools (based on the FRAX Risk adjusted or the BMD T-score adjusted) may help you estimate the actual risk of fracture of the patient and take the most appropriate decisions regarding therapy.

5. Detailed Spine Results

Region	TBS	TBS Z-score	BMD (g/cm²)	BMD T-score
L1	1.186	-	0.826	-1.8
L2	1.262	-	0.843	-1.8
L3	1.123	-	0.861	-1.7
L4	1.135	-	0.855	-1.7
L1-L4	1.126	-1.06	0.849	-1.7
L1-L3	1.163	-1.11	0.841	-1.8
L1-L2	1.228	-0.97	0.837	-1.8
L1-L4 (L2)	1.123	-1.15	0.861	-1.7
L1-L4 (L3)	1.135	-1.08	0.855	-1.7
L1-L3 (L2)	1.126	-1.07	0.849	-1.8
L2-L4	1.193	-1.03	0.852	-1.7
L2-L3	1.113	-1.16	0.856	-1.7
L2-L4 (L3)	1.228	-1.06	0.863	-1.7
L3-L4	1.129	-1.05	0.858	-1.7
L1-L4 (L2L3)	1.228	-1.08	0.841	-1.7

This section on the report is optional

Do I need more detail?

This table displays the detail of results that have been calculated by TBS iNsight® according to the regions of interest on the DXA examination, and data pulled from the DXA software.

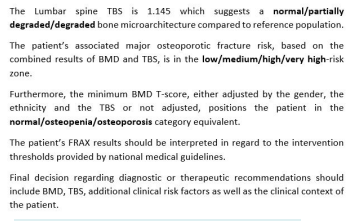
Why is this important?

Detailed TBS spine results in all vertebrae combinations can be useful to evaluate the impact each vertebra has on the TBS and/or BMD value. It can also help to determine if some vertebrae need to be excluded due to abnormalities.

What to do?

Check these additional results for better interpretation in case some values are questionable and/or you are performing a research study.

6. Conclusion



The Lumbar spine TBS is 1.145 which suggests a **normal/partially degraded/degraded** bone microarchitecture compared to reference population.

The patient's associated major osteoporotic fracture risk, based on the combined results of BMD and TBS, is in the **low/medium/high/very high**-risk zone.

Furthermore, the minimum BMD T-score, either adjusted by the gender, the ethnicity and the TBS or not adjusted, positions the patient in the **normal/osteopenia/osteoporosis** category equivalent.

The patient's FRAX results should be interpreted in regard to the intervention thresholds provided by national medical guidelines.

Final decision regarding diagnostic or therapeutic recommendations should include BMD, TBS, additional clinical risk factors as well as the clinical context of the patient.

This section on the report is optional

Make a conclusion and share it with referring doctors

This section displays either conclusions automatically generated by the software based on the TBS and the BMD T-score or a conclusion manually entered by the user. In the automatic conclusion you can find the summary of the various analyses that have been included in the Bone Health Report. These automatic conclusions have been proposed based on a consensus of experts using TBS iNsight in daily practice.

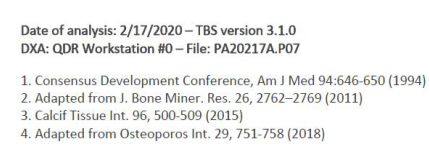
Why is this important?

Different clinical scenarios will require different solutions. We provide here a summary of the different analyses included in the Bone Health Report to help you get a better understanding of your patient's bone health.

What to do?

Conclusion is key to help the referring physicians better understand the TBS bone health report; that is why we recommend to use the automatic conclusion. if you prefer to customize the wording or the interpretation, you can write your own conclusion from the software interface

7. Notes & References



Date of analysis: 2/17/2020 – TBS version 3.1.0
DXA: QDR Workstation #0 – File: PA20217A.P07

1. Consensus Development Conference, Am J Med 94:646-650 (1994)
2. Adapted from J. Bone Miner. Res. 26, 2762–2769 (2011)
3. Calcif Tissue Int. 96, 500-509 (2015)
4. Adapted from Osteoporos Int. 29, 751-758 (2018)

This section displays the following information: Analysis date, TBS iNsight software version, DXA device model and Serial Number, Name of the DXA file from which the data has been pulled. The references to the scientific literature used in various sections of the report are listed here.

Why is this important?

All Medimaps' statements are based on scientific evidences. You can find the original studies here.

This document is extracted from TBS User Guide TM-011

(1) McCloskey, E.V., Oden, A., Harvey, N.C., Leslie, W.D., Hans, D., Johansson, H., Kanis, J.A., 2015. Adjusting fracture probability by trabecular bone score. Calcif Tissue Int 96, 500–509. https://doi.org/10.1007/s00223-015-9980-x

(2) Leslie, W.D., Shevroja, E., Johansson, H., McCloskey, E.V., Harvey, N.C., Kanis, J.A., Hans, D., 2018. Risk-equivalent T-score adjustment for using lumbar spine trabecular bone score (TBS): the Manitoba BMD registry. Osteoporos Int 29, 751–758. https://doi.org/10.1007/s00198-018-4405-0

medimapsgroup.com
contact@medimapsgroup.com

Geneva (CH) +41 22 884 8644
Bordeaux (FR) +33 55 611 2442
Wilmington (USA) +1 302 416 3063

AM-TM-170-001