Introduction
Osteoporosis is characterized by low bone density combined with a bone microarchitecture alteration increasing overall bone fragility and consequently the fracture risk. Until recently, Bone Mineral Density (BMD), as assessed by Dual Energy X-Ray Absorptiometry (DXA), was the sole gold standard for osteoporosis management. However, only 50% of patients sustaining an osteoporotic fracture have a BMD in the osteoporotic zone. This implies that the other 50% of the total osteoporotic fracture occurred in subjects considered, based on the BMD, at low risk of fracture. By 2025, it is estimated that roughly 1.3 million hip fractures will occur in subjects that have previously been diagnosed with low or almost minimal risk of fracture (subjects with osteopenic or normal BMD).

TBS iNsight: A New Clinical Software Tool for Osteoporosis Management
To address the gap in identifying patients at risk of fracture in the normal and osteopenic groups, Medimaps has developed a new clinical software tool; TBS iNsight, which estimates fracture risk based on a determination of bone texture (an index related to bone microarchitecture). TBS iNsight can be used in addition to risks determined by DXA bone density and clinical risk factors. The result is expressed as a Trabecular Bone Score (TBS). TBS iNsight integrates seamlessly with most existing DXA scanners. The exam, performed at the same time as DXA, requires no additional scan time or additional radiation exposure. Once the standard DXA spine scan is completed, TBS results are displayed automatically within seconds.

A number of studies have now demonstrated the added clinical value of TBS for osteoporosis management. It has been shown that TBS is able to discriminate subjects with fractures from subjects without fractures (matched for age, BMD or both, even after adjusting for BMI), and that TBS can predict major osteoporotic, spine and hip fractures as well as BMD does, and independently of BMD and/or common clinical risk factors.

A significant improvement in the accuracy of patient fracture risk assessment has been demonstrated when BMD and TBS scores are combined for the determination of fracture risk.

To illustrate this – in Figure 1 – the incident fracture rate obtained from a large prospective cohort has been stratified using TBS (tertile approach) subsequent to BMD stratification (T-score approach).

Based on this data, a low TBS value (lowest tertile) provides the identification of additional patients at higher risk for fracture in the normal and the osteopenic zones (Figure 1, columns A3 and B3) despite being considered normal or osteopenic for BMD.

Osteoporotic patients – as classified by BMD – with a high TBS value (highest tertile) tend to have a slightly lower risk of fracture than osteopenic subjects with a low TBS value (Figure 1, columns C1 vs B3).

Figure 1: Major osteoporotic incident fractures rate (per 1,000 women per year) stratified by the densitometric status (A=normal, B=osteopenia and C=osteoporosis) and TBS (Tertiles, 1=High to 3=Low) obtained from a large prospective cohort.

- A3 & B3: Additional subjects with high risk of fracture detected if TBS is considered in addition to BMD.
- C1: Osteoporotic subjects with a risk of fracture lower than an osteopenic subject with a low TBS value (B3).
- C1 to C3: Subjects detected when BMD is considered alone.
- C3: Specific selection of very high risk of fracture subjects with defect in both bone density and microarchitecture.
Patients for whom the risk for fracture has been considered as low or almost minimal based on their BMD values (osteopenic or normal) alone could have an underestimated fracture risk level if they present with a low TBS value. Conversely, those for whom the risk for fracture has been considered as high (BMD osteoporotic zone) might have a slightly overestimated fracture risk level if they present with a high TBS value. The risk for fracture for all of these patients based on BMD and clinical risk factors could be reconsidered taking into account TBS scores.

After adjustment for classical clinical risk factors of a large prospective cohort of 29,407 women, 22% of the overall patients have a fracture risk level which could be reconsidered (Figure 2). Among them, 17% of the overall patients had a fracture risk level which had potentially been underestimated (low TBS and normal or osteopenic BMD) and 5% of overall patients had a fracture risk level potentially overestimated (high TBS and osteoporotic BMD).

The number of patients for whom the risk for fracture could be reconsidered depends of the densitometric status and can be more or less important. In a large prospective cohort, this number of patients for whom fracture risk level was underestimated corresponded to 21% and 29% in the normal and in the osteopenic zone respectively (Figure 3A & B).

**Figure 2:** Proportion of patients for whom the fracture risk could be reconsidered when using TBS in addition to BMD, since it might have been either underestimated or over estimated

**Figure 3A:** Additional patients with normal BMD for whom the fracture risk level could be reconsidered if their low TBS was considered in addition to BMD (computed from raw data of a large prospective cohort)

**Figure 3B:** Additional patients with osteopenic BMD for whom the fracture risk level could be reconsidered if their low TBS was considered in addition to BMD (computed from raw data of a large prospective cohort)
Summary
In concrete terms, TBS iNsight can be used by a clinician to fine tune the fracture risk of his patient population, prospectively or retrospectively. With this new fracture risk information clinicians will have new information to use in patient care management. For example, when using TBS in addition to BMD, a clinician with a patient population of 5,000 patients could retrospectively run TBS scores and re-evaluate the fracture risk level of patients. In such a scenario they would find the following:

1,100 patients (22%) for whom the risk for fracture could be reconsidered. Among them, 850 for whom their fracture risk level has potentially been underestimated and 250 for whom their fracture risk level has potentially been overestimated.

In addition to existing gold standard tools like BMD and clinical risk factors, TBS is clearly a complimentary tool for clinicians to reconsider fracture risk for a given subject and to refine patient management for overall fracture risk mitigation – the overarching objective of best practice osteoporosis treatment.

To Learn More About How TBS iNsight Works
Please review the white paper entitled Advanced DXA Using TBS iNsight™: A New Bone Structure Assessment Technique Enhances Identification of Fracture Risk.

References