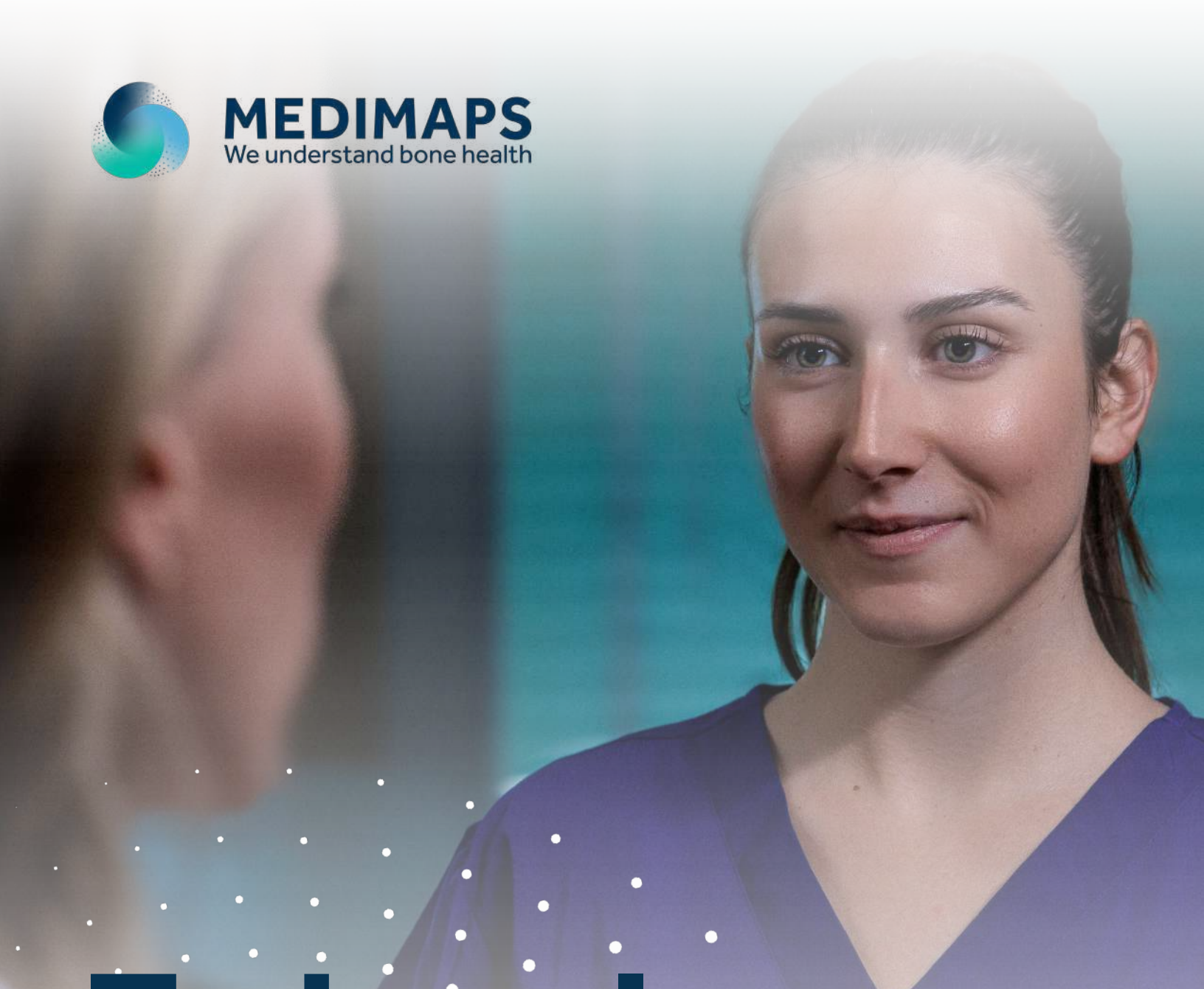
MEDIMAPS
We understand bone health



Trabecular Bone Score (TBS)

A paradigm shift in osteoporosis assessment and management

Executive summary

Osteoporosis is a systemic skeletal disease characterized by diminished bone mass and the degradation of bone microarchitecture. These dual components — bone mass and bone microarchitecture — underpin the structural integrity necessary for bone resilience against fractures [1]. Traditional densitometric evaluations, centered around a bone mineral density (BMD) T-score of -2.5 or lower, capture the bone mass dimension of this risk, effectively discerning a subset of individuals predisposed to fragility fracture [2,3]. Yet, this approach does not fully address the spectrum of fracture risk, because most of these fractures occur in patients with T-scores outside the osteoporotic range [2-5]. A more comprehensive assessment framework is requisite — one that integrates bone microarchitecture, the second critical determinant of bone strength, to refine the identification of those at increased fracture risk.

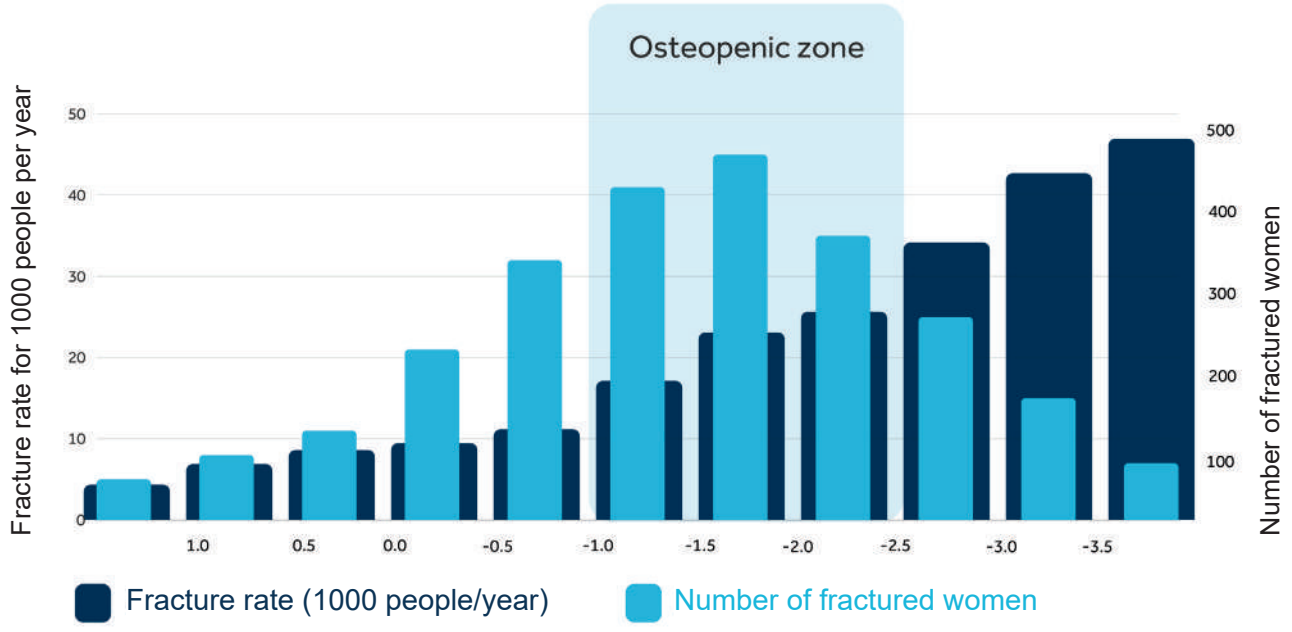
In addressing this clinical need, Trabecular Bone Score (TBS) is a pivotal advancement. TBS is an innovative analytic method that derives a grey-level textural index from dual-energy X-ray absorptiometry (DXA) scans, delivering a quantifiable assessment of bone microarchitecture. This index exhibits a strong correlation with the intrinsic microarchitecture and mechanical competencies of bone, thus complementing the BMD T-score and enriching fracture risk assessment [6-11]. Clinical application of TBS has demonstrated its efficacy, either as an adjunctive metric that refines FRAX probabilities and BMD T-scores, or as an independent measure with established clinical cut-off values [12,13].

This white paper elucidates the scientific underpinnings, clinical utility, and the value of TBS in improving osteoporosis management and patient outcomes. It affirms TBS's integral role in a paradigm shift toward more complete and effective fracture risk assessments, therapeutic decision-making and monitoring.

Problem statement: current challenges in osteoporosis

The global burden of fragility fractures is substantial, with around 9 million cases occurring annually, and at least one in three women and one in five men aged over the age of 50 years sustaining an osteoporotic fracture [14]. This equates to one major osteoporotic fracture every 3 seconds [14]. Such fractures, especially those of the hip and spine which are associated with significant pain and disability, bringing substantial burdens for patients, their families and healthcare systems. Of those patients who sustain a hip fracture, around one third will die within 12 months [15,16]. Current trends and demographic shifts predict a rise in the burden of osteoporosis, yet research demonstrates that a large proportion of fractures could be prevented with better risk identification [17,18].

In most cases, osteoporosis remains undiagnosed until a fracture occurs, highlighting the inadequacies of current risk assessment strategies. Although BMD is integral for determining bone mass, it does not address the micro-architectural quality of bone, which is a vital factor for bone strength. It is also noteworthy that over 70% of fragility fractures occur in women who are non-osteoporotic by BMD alone [3,4] (Figure 1) – which highlights a critical imitation of relying solely on BMD for risk stratification.



Source: Siris ES, Brenneman SK, Barrett-Connor E, Miller PD, Sajjan S, Berger ML, et al. The NORA cohort. Arch Intern Med. 2004;164(10):1108-12.

Figure 1. The majority of fractures occur in individuals who are not osteoporotic by BMD alone, from Siris et al., (2004) [2].

Solution: introduction to trabecular bone score

TBS iNsight™ is an advanced software which enhances DXA system capabilities, by providing a non-invasive validated index of bone microarchitecture, alongside the standard BMD evaluation. The software operates by assessing bone texture and providing a trabecular bone score (TBS) —a quantifiable index that correlates with the micro-architectural status and mechanical properties of trabecular bone.

Utilizing a modified experimental variogram-based approach, the patented TBS algorithm interprets the complexity of the bone's projected image, translating subtle grey-level pixel-by-pixel variations into an estimate of three-dimensional microarchitecture. This process is based on fractal analytics and the calculation of TBS involves determining the slope from a log-log transformation of the modified experimental variograms of the DXA image. Conceptually, a steeper slope indicates a dense and well-connected trabecular pattern, equating to a higher TBS, while a flatter slope signifies greater disconnection and porosity, reflected by a lower TBS (Figure 2). The process requires no additional scan time or radiation exposure for the patient. It is noteworthy that two patients may have comparable BMD but can differ in terms of bone microarchitecture reflected by TBS, predisposing to a different level of fracture risk (Figure 2).

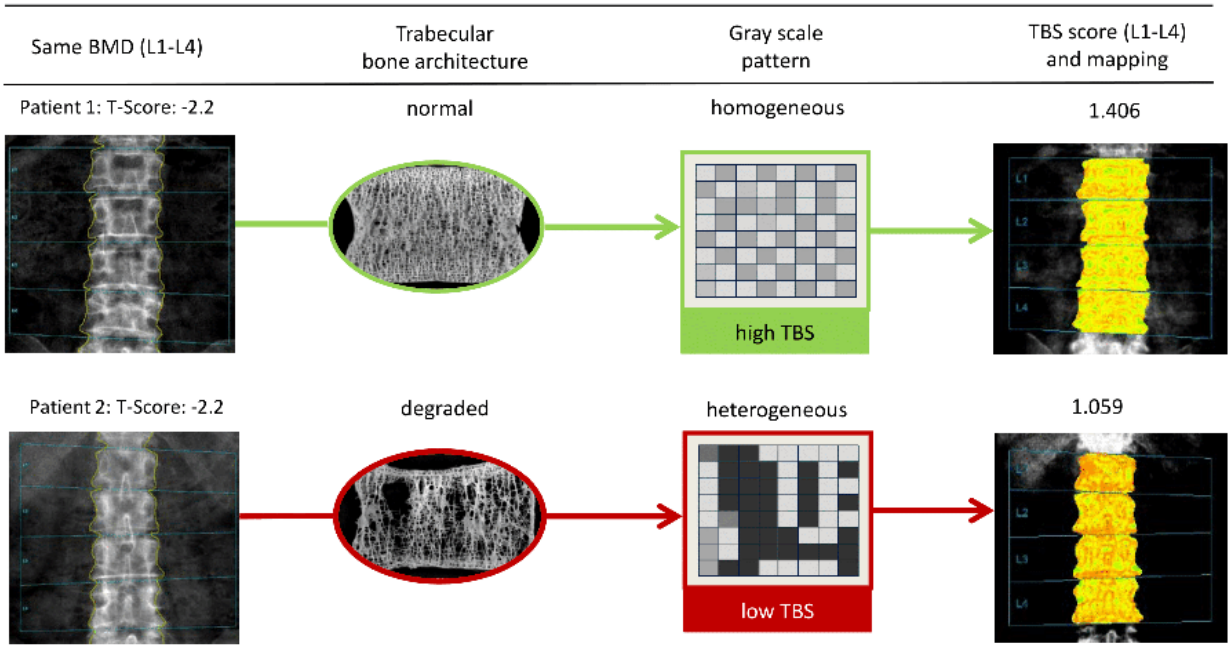


Figure 2. TBS is derived from an algorithm that provides a grey-scale pixel-by-pixel analysis which relates to trabecular microarchitecture and mechanical properties of bone

Clinical evidence

The efficacy of TBS in predicting fragility fracture is underpinned by over one decade of peer-reviewed research. The global research community has contributed to this evidence base with over 1,500 peer-reviewed publications, and the clinical utility of TBS is underscored by its widespread adoption—over 4.5 million TBS evaluations are performed annually across more than 90 countries*[1].

Fracture risk assessment

TBS is established as a significant predictor of fragility fracture among postmenopausal women and men over 50 years of age, independent of BMD and clinical risk factors, including those integrated into FRAX® [19]. This has been consistently demonstrated by over 20 prospective population cohort studies. In addition, an international meta-analysis of 14 population cohort studies showed that FRAX adjusted for TBS resulted in a significant increase in fracture risk prediction, independent of sex and ethnicity [12]. This predictive enhancement is similarly observed when BMD T-score is adjusted for TBS [13].

In the Manitoba cohort of 45,185 postmenopausal women each SD decrease in TBS was significantly associated with a 26%, 25% and 22% greater risk of fragility fracture in models incorporating BMD at the lumbar spine, femoral neck and total hip, respectively, and the results were not attenuated after adjustment for age and BMI [13].

The clinical relevance of TBS extends to secondary osteoporosis, having an important role in the assessment and management of patients with conditions that affect bone health. Degraded TBS is a common finding across most diseases associated with secondary osteoporosis and is associated with an increased risk of fracture, even when BMD is normal [19] (Figure 3). In particular, TBS independently predicts fracture risk in patients with diabetes [20,21], rheumatological diseases [22,23], chronic kidney disease [24,25] and those undergoing long-term glucocorticoid therapy [26,27] or treatment with aromatase inhibitors [28,29] - conditions known to compromise bone integrity [19]. An additional advantage of TBS is its relative insensitivity to certain spinal changes, including the presence of osteophytes and syndesmophytes, which can erroneously increase BMD assessments [30].

**Internal Medimaps Group estimates, as of 14 November 2023*

Figure 3. Published evidence on the value of TBS for the assessment and management of secondary osteoporosis

Treatment decision-making

Pharmacotherapy for osteoporosis can effectively reduce fracture risk by 30% to 70% [31], highlighting the importance of risk assessment and timely treatment intervention. TBS is a particularly valuable tool in this risk assessment process, especially for patients who are close to a treatment intervention threshold according to FRAX probability or BMD T-score assessments [32], for example, in patients with osteopenia, where the greatest fracture burden is observed [2-4]. In these instances, the addition of TBS can fine-tune risk assessment by determining the necessity and timing of therapeutic intervention, thereby avoiding overtreatment or delaying necessary treatment [19,32].

Treatment monitoring

TBS as an adjunct to BMD, offers insights into changes in bone microarchitecture over time and in response to treatment. Adjusting therapy based on TBS as well as BMD, may help clinicians optimize patient outcomes in the management of osteoporosis. Given that TBS and BMD reflect different entities of bone strength, a differential response to treatment is expected [19]. When interpreting patient results, it is important to align them with the anticipated effects of the treatment molecule. In cases where the results deviate from expectations, it is advisable to check both clinical and technical factors [19].

Evidence demonstrates that while BMD is responsive to anti-resorptive therapies such as bisphosphonates, the effect on TBS appears to be one mostly of preservation [33-35], which is in line with the known treatment mechanism of action [19]. On the other hand, TBS is more responsive to therapies including denosumab, parathyroid hormone agents, and Romosozumab [36-43] (Figure 4).

It is recommended that the monitoring of treatment effect on TBS at the individual level should be made by applying least significant change (LSC). Over 12 studies have published the precision of TBS, which averages at 1.37% and corresponds to a LSC 3.79% [19].

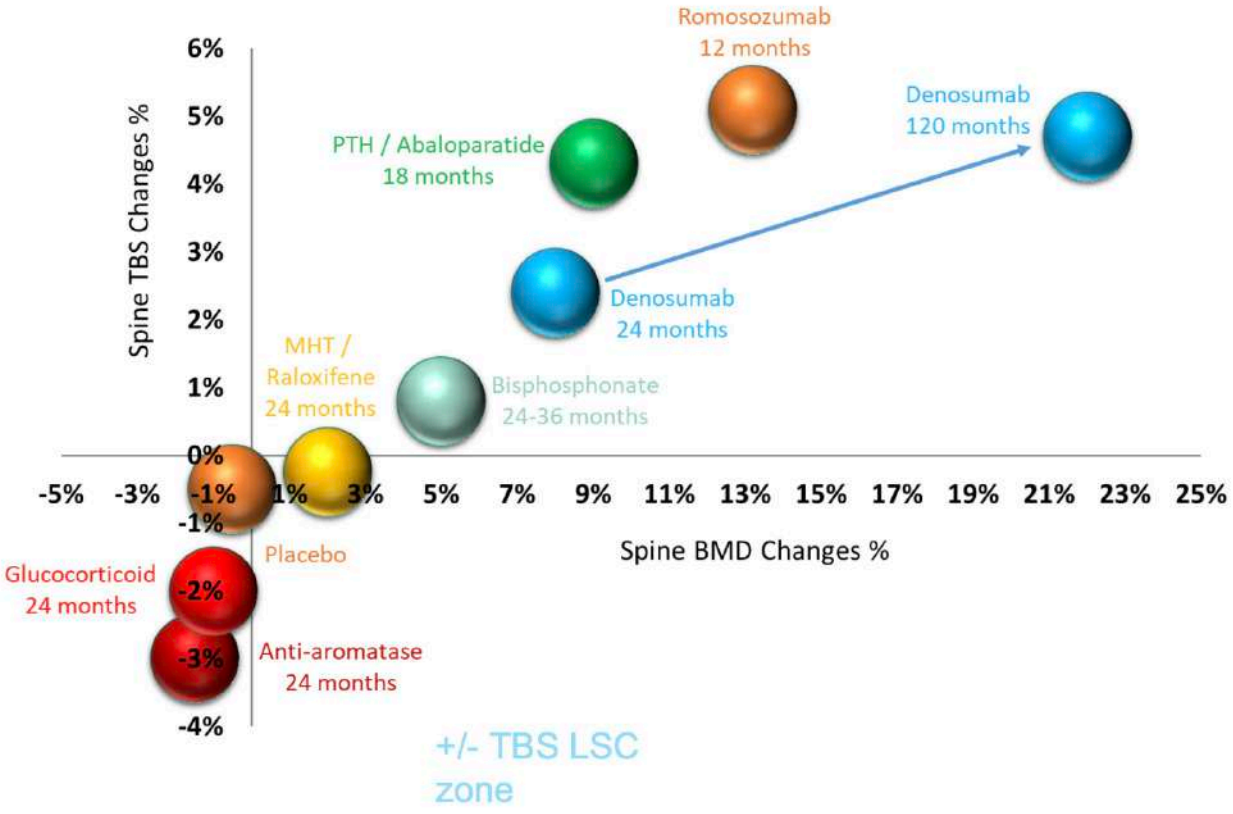


Figure 4. Graphical representation of published changes in TBS and BMD in response to treatment

International positions: enhancing osteoporosis assessment and management

Over 35 national and international clinical guidelines, including the International Society for Clinical Densitometry [44], recommend TBS as a significant predictor of hip and major osteoporotic fractures. The 2023 position paper, published by the European Society for Clinical and Economic Aspects of Osteoporosis (ESCEO) and the International Osteoporosis Foundation (IOF) under the WHO Collaborating Centre on Epidemiology of Musculoskeletal Health and Ageing, represents the most comprehensive and updated synthesis of knowledge in the field to date [19]. This document surpasses its predecessors, including the 2015 ESCEO position paper [45] and the ISCD positions [44, 46], in terms of its breadth and depth of analysis. It reflects the expanding evidence base and the increasing global adoption of TBS, marking a significant advancement in the understanding and management of bone health. This comprehensive paper resulted from a series of systematic reviews by an Expert Working Group, appraising evidence from 96 qualifying studies and providing 22 expert statements to guide the use of TBS in clinical practice [19]. The group confirmed the additional value of TBS in fracture risk prediction and the instrumental role of TBS for informing the initiation and monitoring of osteoporosis treatments. The 2023 update emphasized TBS's enhanced utility in clinical decision-making, particularly regarding the choice and usefulness for monitoring long-term pharmacotherapies such as denosumab, and anabolic agents.

Integration into the clinical work flow

With a commitment to both user experience and patient outcomes, TBS technology has undergone regular updates and enhancements. These enhancements have focused on refining features for greater ease of use and seamless integration within existing clinical workflows, for example, with the addition of FRAX-adjusted for TBS curves according to country-specific guidelines. This commitment reflects our recognition of the importance of practicality and efficiency in clinical settings, allowing healthcare professionals to leverage TBS effectively without disrupting their routine patient care processes for the benefit of the patient.

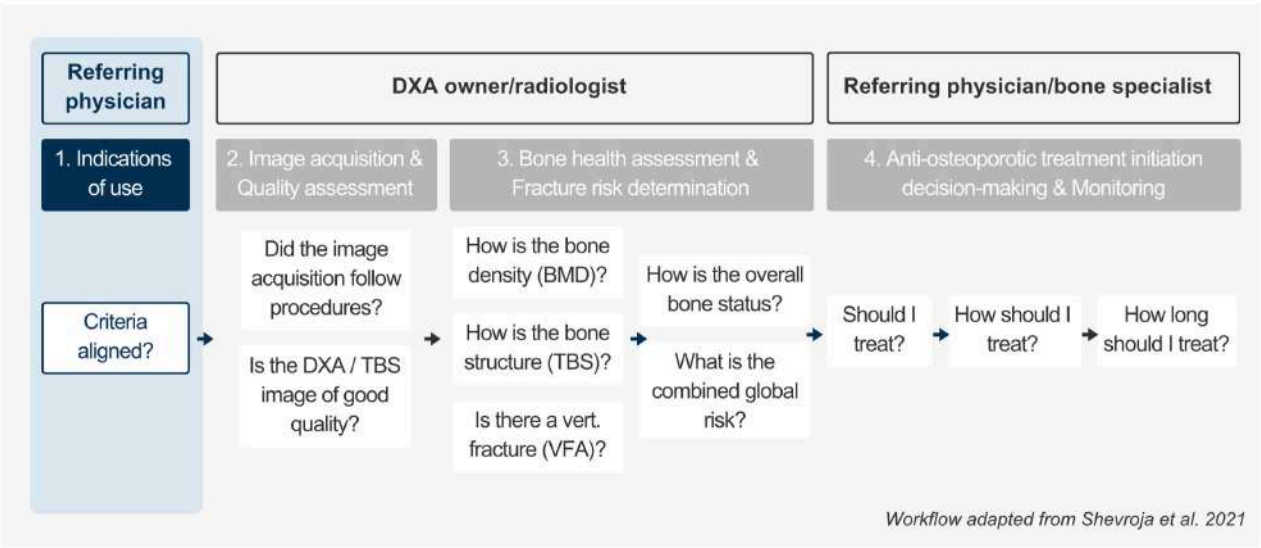


Figure 5. Schematic example of TBS integration into the workflow for osteoporosis assessment and management, from Shevroja et al., (2023) [19]

The fully automatic and DICOM-compatible TBS report is provided simultaneously with the BMD report and enables the assessment of overall bone status and combined risk of fracture, based on FRAX-adjusted for TBS or lowest BMD T-score adjusted for TBS (Figure 6).

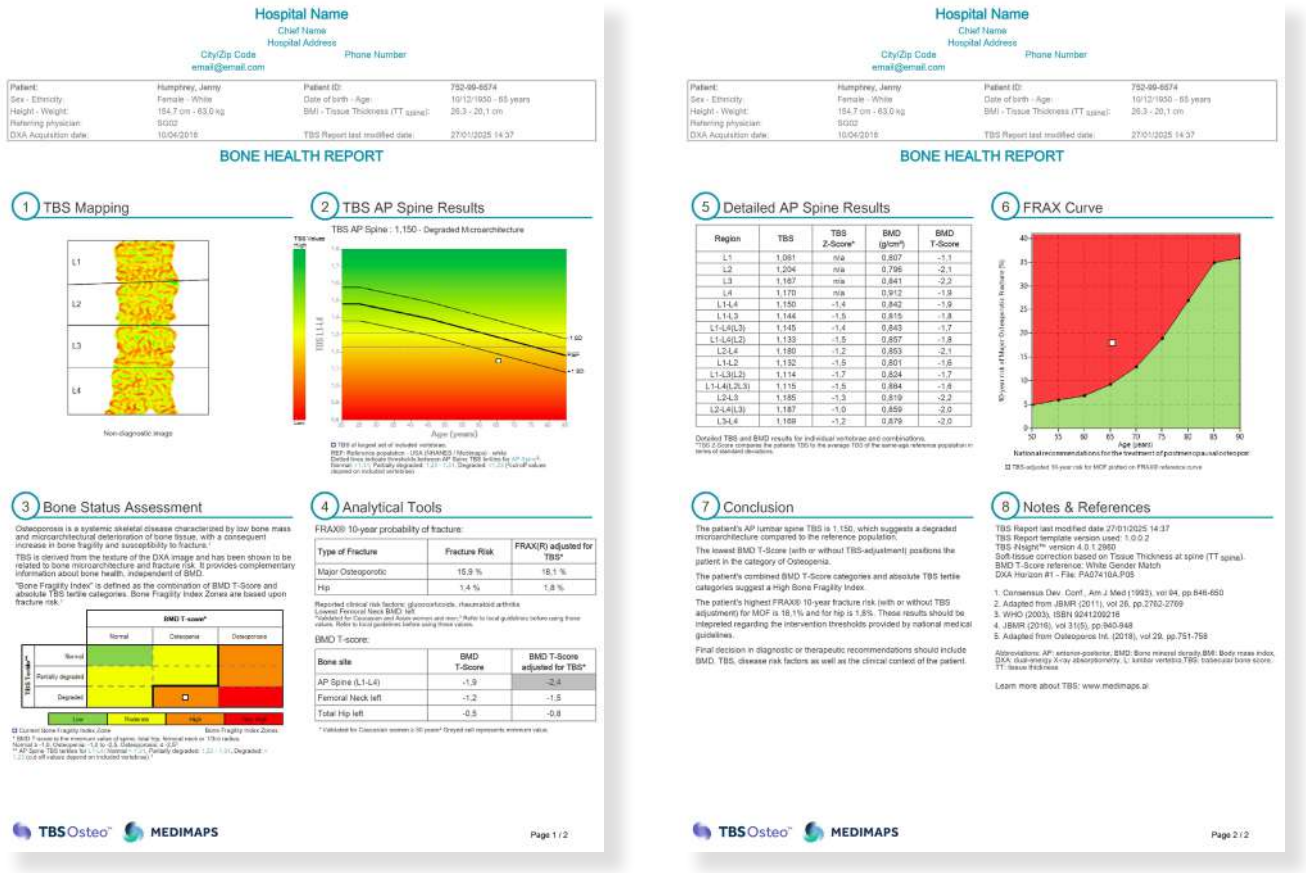


Figure 6. TBS report providing an overall assessment of bone status and fracture risk

TBS regulatory clearance and reimbursement

TBS is CE marked as a class 2a medical device, demonstrating compliance with the essential requirements of the relevant European health, safety, and environmental protection legislation. In the United States, TBS was cleared by the Food and Drug Administration (FDA) in 2013, with a subsequent clearance in 2016, affirming its efficacy and safety for clinical use. In 2023, TBS achieved MDR certification, meeting the requirements of the EU Medical Device Regulation, which provides a robust framework for medical device approval in the European Union.

For healthcare providers in the United States, the integration of TBS into patient assessments has been reimbursed since January 1st, 2022, with Medicare providing additional reimbursement for TBS on top of the existing provisions for DXA scans. This reimbursement policy not only facilitates greater access to TBS for patients but also underscores the importance of comprehensive bone health evaluation in clinical practice.

Advancements in TBS

At Medimaps Group, research and innovation drive our mission to elevate patient care. With this commitment at the core of our work, we are proud to introduce TBS Osteo next generation software (version 4), which brings advancements in TBS assessment and clinical usability [47].

A key enhancement in this version is the refined correction for soft tissue thickness anterior to the lumbar spine. Unlike previous iterations that relied on body mass index (BMI) as a surrogate for soft tissue interference, TBS next generation directly measures soft tissue thickness from DXA imaging. This advancement improves precision and expands the applicability of TBS across a broader spectrum of body phenotypes, ensuring assessments are no longer constrained by BMI-based limitations.

The software also introduces a centralized system for managing multiple DXA units with TBS across a hospital network. This capability is particularly valuable for large hospital groups, streamlining workflow efficiency and facilitating consistent, standardized management across different scanning locations.

Additionally, TBS Osteo next generation is available through a subscription model, enabling users to seamlessly benefit from a continuous, exciting evolution of features. With planned annual enhancements, clinical organizations can stay at the forefront of innovation without incurring additional costs, ensuring they always have access to the latest advancements in TBS technology.

Summary

For over ten years, TBS has provided clinicians with additional, valuable insights into bone quality and fracture risk, complementing information provided by BMD and clinical risk factors. With a robust foundation of research and clinical application, TBS has become standard care alongside BMD and FRAX, for many osteoporosis healthcare professionals around the globe.

As a leader in bone health innovation, Medimaps Group continues to advance TBS technology, integrating the latest scientific developments to enhance diagnostic precision and clinical utility. The introduction of TBS Osteo next generation (version 4) exemplifies this commitment, incorporating state-of-the-art soft tissue thickness adjustments and a scalable, centralized platform for hospital networks. These advancements not only strengthen the role of TBS in osteoporosis management today but also set the stage for ongoing innovation, ensuring that healthcare professionals have access to the most advanced tools for optimizing patient care and fracture risk assessment.

Acknowledgements

We extend our appreciation to collaborators worldwide, whose pursuit of knowledge and dedication to clinical excellence have been pivotal in the research and validation of TBS. Our gratitude is also expressed to healthcare professionals who have incorporated TBS into their practices and offered valuable feedback and insights that have helped to steer user enhancements. Recognition is also given to patients who have participated in TBS research over the years and who continue to be the reason for driving higher standards of care in the assessment and management of osteoporosis.

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MEDIMAPS

We understand bone health

Founded by medical practitioners and clinical researchers, Medimaps combines Swiss innovation with a global presence to lead in bone health management. We provide healthcare professionals worldwide with advanced AI-driven software that enables comprehensive bone microarchitecture assessment.

Our passion for musculoskeletal health is underpinned by scientific knowledge, collaborations with world-class academics, clinicians, industry partners, and direct patient engagement. The science behind our cutting-edge imaging applications and clinical evidence forms the core of our company's DNA.

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