Proposed practice parameters for the performance of radiofrequency echographic multispectrometry (REMS) evaluations

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Cite this article: Bone Jt Open 2025;6(3): 291–297.

DOI: 10.1302/2633-1462. 63.BJO-2024-0107.R1

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Aims

Assessment of bone health is a multifaceted clinical process, incorporating biochemical and diagnostic tests that should be accurate and reproducible. Dual-energy X-ray absorptiometry (DXA) is the reference standard for evaluation of bone mineral density, but has known limitations. Alternatives include quantitative CT (q-CT), MRI, and peripheral quantitative ultrasound (QUS). Radiofrequency echographic multispectrometry (REMS) is a new generation of ultrasound technology used for the assessment of bone mineral density (BMD) at axial sites that is as accurate as quality-assured DXA scans. It also provides an assessment of the quality of bone architecture. This will be of direct value and significance to orthopaedic surgeons when planning surgical procedures, including fracture fixation and surgery of the hip and spine, since BMD alone is a poor predictor of fracture risk.

Methods

The various other fixed-site technologies such as high-resolution peripheral q-CT (HR-pQCT) and MRI offer no further significant prognostic advantages in terms of assessing bone structure and BMD to predict fracture risk. QUS was the only widely adopted non-fixed imaging option for bone health assessment, but it is not considered adequately accurate to provide a quantitative assessment of BMD or provide a prediction of fracture risk. In contrast, REMS has a robust evidence base that demonstrates its equivalence to DXA in determining BMD at axial sites. Fracture prediction using REMS, combining the output of fragility information and BMD, has been established as more accurate than when using BMD alone.

Conclusion

The practice parameters described in this protocol provide a framework for clinicians who provide REMS services that will, to the greatest possible extent, ensure the most accurate assessment possible from this diagnostic technology.

Take home message

- These practice parameters provide a robust framework for clinicians who offer radiofrequency echographic multispectrometry (REMS) services, particularly related to orthopaedic interventions, to work within, which should ensure accurate and reproducible diagnostic results.
- There will be a direct benefit from REMS scan results to orthopaedic surgeons involved in fracture fixation, elective

operations on the hip or elective spinal procedures, and for bone health status monitoring in special populations, such as fractured or bedridden subjects, pregnant females, and young people.

Introduction

Since the turn of the century, improved bone health diagnostic technologies have evolved to overcome the limitations of existing methods. It has long been recognized that



Table I. Screening techniques comparison.

Variable	DXA	HRpQCT	REMS
Radiation dose, mSv	~0.001 ^{5,18,19}	~3 to 5 ^{5,18,19}	None ^{5,8,11}
Examination time, mins	15 to 20 ²¹	3 to 5 ^{18,19}	10 to 15 ^{21,22}
Technology dependent	Yes ^{5,11,14}	No ^{5,17,18}	No ^{8,11}
Ease of positioning	No ^{*8,11}	Yes ¹⁹	Yes ^{5-9,11}
Availability	Yes ⁵	Limited ^{5,18}	Yes ¹¹
Low cost	Yes ²¹	No ¹⁸	Yes ^{21,23}
Dependence on bone size	Yes ¹⁸	No ^{17,19}	No ^{5,8}
Separates measurement between cortical and trabecular bone	No ^s	Yes ^{5,17}	Yes ⁵
Microarchitecture assessment	Spine: only if Trabecular Bone Score module fitted ^{5,11,24}	Yes ^{5,18,19}	Yes ^{5,24}
Sampling errors	Yes ^{5,8,13}	No ^{5,19}	No ^{5,8}

*In cases of bone deformities, immobilization/bedridden, paraparesis/ paralysis (e.g. stroke or spinal cord injury).

DXA, dual-energy X-ray absorptiometry; HR-qCT, high-resolution peripheral quantitative CT; REMS, radiofrequency echographic multispectrometry.

measurement of bone mineral density (BMD) alone is not a reliable predictor of fragility fracture occurrence, and improved bone quality metrics are needed to enhance the estimation of future fracture risk and to assess the extent of bone fragility,¹ especially in those individuals presenting to orthopaedic surgeons for treatment of musculoskeletal pathologies.²⁻⁴

Radiofrequency echographic multispectrometry (REMS) is a new generation of ultrasound technology used for the assessment of bone density and fragility that has overcome the limitations of quantitative ultrasound (QUS). Ultrasound advancements in the last two decades have resulted in the development of innovative hardware and software that now allows for the comprehensive assessment of bone health at axial sites with REMS.

Launched in Europe at the beginning of 2018, REMS received clearance from the USA Food and Drug Administration (FDA) for the measurement of the diagnostic parameters of bone mineral density (BMD), T-score, and Z-score, and for serial clinical monitoring of bone changes over time in the October of that year. REMS uses a non-ionizing approach to bone health assessment,⁵ and is based on the analysis of backscattered ultrasound signals.^{6,7} The BMD is calculated through comparisons of the patient's specific backscatter frequency spectrum of the target bone against a proprietary database of reference ultrasound spectral models. The corresponding T-score and Z-score values are derived using a normative reference database, i.e. the National Health and Nutrition Examination Survey (NHANES).⁵ This approach has been validated through several studies focused on specific age ranges.⁶⁻¹¹

Dual-energy X-ray absorptiometry (DXA) is considered the current reference standard for measurement of bone mass, expressed as BMD, in the lumbar spine (L1-L4), hips (total hip and femoral neck), and distal third of the radius, regions of interest (ROI). While DXA has served to screen and monitor changes in BMD over the last 40 years, it has a multitude of shortcomings including lack of portability, inability to evaluate the quality of bone if the trabecular bone score (TBS) is not applied, radiation exposure, reporting or measurement errors, and the necessity to follow BMD changes on the same scanner to minimize measurement error.¹²⁻¹⁵

DXA cannot be used in, or fails to provide accurate assessment in, many circumstances, including pregnancy, the presence of instrumentation in the hips or spine, scoliosis, degenerative changes in the spine or hip, very high or very low BMI, or when there are issues that can affect patient positioning. For instance, vertebral compression fractures and degenerative changes in the lumbar spine will result in artificially high BMD by DXA scan but will not affect REMS results.¹⁶ The presence of polymethylmethacrylate cement after vertebroplasty or kyphoplasty precludes using DXA on treated vertebral levels. Vertebral bodies containing cement should be excluded from the analysis. Exclusion occurs via post-processing manual input from the examiner and/or interpreter. In contrast, based on its advanced signal analysis, REMS can exclude polymethylmethacrylate cement artifacts from the analysis, as well as the biased estimation of BMD in cases of osteoarthritis and osteophytes.¹⁶ The REMS technique can be used in cases of vertebral fractures, as abnormal signal will be eliminated from the analysis, and in addition, REMS is not hindered by the presence of vertebral deformities. However, REMS cannot currently provide anatomical information regarding the presence of vertebral deformities, or incident/prevalent fractures that can affect the diagnosis and management of osteoporosis. Since the REMS technique evaluates each vertebral body separately, if a patient has scoliosis the transducer can easily be maneuvered over each vertebra to ensure an adequate visual acquisition of the bone, allowing the software to correctly analyze the backscatter pattern and derive the BMD, T-score, Z-score, and Fragility Score (FS).8 If a radiograph is already available, it can be used to study the patient's anatomy, thereby potentially decreasing the time needed to scan patients with severe curves. In general, dedicated advanced REMS training will be required to image severe cases of deformity accurately.

REMS is ionizing radiation-free, unlike platforms, such as DXA and high-resolution peripheral quantitative CT (HR-pQCT). Although REMS shares some features with these diagnostic methods, it also has some advantages not available on other platforms (Table I).¹⁷⁻²⁰

Responsible and reliable use of the technology requires initial training, which provides a good understanding of the relevant anatomy of the hips and lumbar spine reinforced by continuing professional development. The precision and diagnostic accuracy of REMS in comparison with DXA have been validated.^{5,8} A high linear correlation was found in the spine and hip BMD results, measured by standard DXA and REMS. The results demonstrated that the performance of REMS was excellent with a sensitivity and specificity for the identification of patients with osteoporosis of over 90%, a positive predictive value (PPV) in the range of 82% to 86% and a negative predictive value (NPV) of over 97% for the spine and hip.¹¹ Only one study, to our knowledge, by Lalli et al²⁵ has reported the results of REMS and DXA measurements in the hips of patients of both sexes with primary osteoporosis (n = 140) and disuse osteoporosis due to spinal cord injury (n = 35). There was good agreement between REMS and DXA in the primary osteoporosis group, as shown by other authors, but not in the disuse osteoporosis group. The authors did not consider in the limitations of their study the difficulties frequently encountered with all methods of bone density assessment in paralyzed patients, which means that with the small numbers in their cross-sectional study, definitive conclusions regarding the equivalence of REMS and DXA in these patients could not be drawn. Larger studies with adequate measurement controls are needed to clarify this issue.

Considering cost comparisons, REMS and DXA were evaluated through a process of qualitative expert analysis to determine what the relative costs were in the Italian National Health Service.²¹ REMS was found to be less expensive as a method to evaluate bone densitometry than DXA. A further study in the USA found REMS to be a cost-effective strategy for the diagnosis of osteoporosis treatment in the USA with substantial potential economic benefits.²³

This protocol presents a summary of the practice parameters of REMs scanning and the scientific validation of the technology that provides a robust framework for clinicians who offer REMS services, particularly related to orthopaedic interventions, to work within. This should ensure accurate and reproducible diagnostic results. It offers guidance for the effective performance of REMS scan that is comparable in scope to the performance parameters for DXA scanning published by the American College of Radiology.²⁶

REMS technique

Demographic data, including name, date of birth, height, weight, ethnicity, and age at menopause, are inputted by the examiner. The patient is positioned supine on an examination table. For the spine scan, the abdomen is exposed from the xiphoid process to the suprapubic area. For the hip/femoral neck scan, the upper thigh, distal to the inguinal crease, is exposed. Ultrasound gel is applied to the skin over the region of interest. The convex probe is placed on the midabdomen or on the upper thigh to visualize the target bone interface (vertebral body or hip/femoral neck). The operator selects the appropriate values of scan depth and transducer focus and starts the scan. As long as the B-Mode ultrasound image shows an appropriate anatomical acquisition, the REMS software automatically detects the bone interfaces at the target. From the sequences of frames generated during the scans (for the hip taking 40 seconds and for the spine taking 80 seconds), it identifies the regions of interest for the diagnostic evaluation. Artifact signals, such as those produced by vascular calcification, osteophytes, implanted metalwork, orthopaedic cement, are excluded by the software through a process of automatic identification of unexpected spectral features. Finally, the measured data are synthesized into a patient-specific spectrum of the cortical and trabecular bone of the selected region of interest forming a unique frequency curve of the backscattered radiofrequency signals. Patientspecific data acquired during the exam are compared with

sex-, age, site-, and BMI-matched reference spectral models extracted from a dedicated/proprietary database to generate BMD, T-score, Z-score, and FS results. A template for the comprehensive reporting of REMS scan outputs is shown in the Supplementary Material.

REMS criteria for osteoporosis/osteopenia

REMS outputs accord with the 2016 International Society for Clinical Densitometry (ISCD) Guidelines,²⁷ and the World Health Organization (WHO) international definition of the diagnosis of osteoporosis.²⁸ The reference standard from which the diagnosis of osteoporosis is derived is white, 20to 29-year old female data in the third National Health and Nutrition Examination Survey (NHANES III) database (Centers for Disease Control and Prevention, USA).⁵ This database is used for females and males of all ethnic groups for femoral neck and hip T-scores.

REMS technology uses the NHANES III database for T-scores, along with a proprietary database for determination of the FS. The proprietary database includes over 10,000 patients, whose data have been acquired and processed for both lumbar and femoral examinations.^{6,7} To ensure content integrity, the database has been validated through a dedicated procedure for the semi-automatic detection of possible input errors.

The procedure was defined and developed according to the requirements of the manufacturer's quality management system and was checked and verified through an audit by the relevant notified body. For diagnostic effectiveness, validation studies were performed using techniques analogous to those described by Casciaro et al⁶ and Conversano et al⁷ for specific age ranges. The overall diagnostic effectiveness has since been clinically validated in national and international multicentre studies in females and males.^{8,9,11,22,29}

Lumbar spine BMD measurements include L1-L4. At least two vertebrae must be assessed for reporting and monitoring purposes. Exclusion of a vertebra from analysis is considered when there is a clear abnormality of the vertebra or if there is more than 1.0 SD (i.e. a T-score difference of > 1.0) between adjacent vertebrae. If vertebrae are excluded, the remaining vertebral measurements are used to calculate the T-score.

For diagnosis in the hip region of interest, the T-score outputs of the femoral neck or total proximal femur are used, whichever is lowest. BMD can be measured at either or both hips and in the latter case the mean hip BMD is the preferred measurement for monitoring purposes.

The WHO international reference standard for osteoporosis diagnosis is a T-score of -2.5 or less at the femoral neck. According to ISCD 2023 guidelines, osteoporosis may be diagnosed in postmenopausal females, and males aged > 50 years if the T-score of the lumbar spine, total hip, or femoral neck is -2.5 or less. The term 'osteopenia' has been used for T-scores between -1.0 and -2.4. It does not represent a true diagnosis per se and the ISCD has recommended a change in terminology to reflect a status of 'low bone mass' or 'low bone density.'³⁰

According to ISCD guidelines, T-scores are preferred over Z-scores for reporting results in postmenopausal females and in males aged 50 years and above. In contrast, Z-scores are preferred in females prior to menopause and in males aged under 50 years. A BMD Z-score of -2.0 or lower is defined as 'below the expected range for age' and a BMD Z-score above -2.0 is 'within the expected range for age' (Table II).

The same guidelines are applied to results obtained from REMS evaluations for the diagnosis of osteoporosis and low bone mass/density.

Indications for BMD testing

Recommendations for the evaluation of BMD following ISCD guidelines are based on the Adult Official Positions statement by the ISCD in 2023.³⁰ These guidelines include the following:

- Females aged 65 years and older and males aged 70 years and older.
- Postmenopausal females aged < 65 years and males aged < 70 years if they have a risk factor for low bone mass such as low body weight, prior fracture, high-risk medication use, or a disease or condition associated with bone loss.
- Females during the menopausal transition with clinical risk factors for fracture as above.
- Adults sustaining a fragility fracture. Fragility is suggested by a fall from a standing height or less, which results in a fracture i.e. a low-energy fracture as opposed to a highenergy 'traumatic' injury.
- Adults with a disease or condition associated with low bone mass or bone loss (e.g. hyperparathyroidism, malabsorption syndromes).
- Adults taking medications associated with low bone mass or bone loss (e.g. females treated with an aromatase inhibitor drugs for breast cancer).
- Anyone being considered for pharmacological therapy for clinically presumed low bone mass.
- Anyone being treated, to monitor treatment effect.
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.
- Females discontinuing oestrogen should be considered for bone density testing according to the indications listed above.

Although DXA is considered the current reference standard for BMD measurements and monitoring, REMS extends the ability to evaluate BMD and bone quality, particularly in special populations when DXA cannot be used and for short-term monitoring of bone health.

Indications when both DXA and REMS can be used

- Primary and secondary osteoporosis.
- Patients with fragility fractures.
- Elderly patients with diabetes mellitus.^{31,32}
- · Long-term monitoring of osteoporosis therapy effect.
- In the perioperative period for evaluation/long-term monitoring of any BMD or bone quality changes.

Indications when REMS might be preferred

- Bedridden and/or immobilized patients due to transportation issues or neurological impairments.
- Patients affected by nephropathic diseases due to chronic kidney disease (CKD) or artifact presence in dialysis or transplanted patients.³³
- Patients affected by osteoarthritis.³⁴
- Females being treated for breast cancer with aromatase inhibitor drugs who may need annual bone health evaluations.³⁵

Table II. Criteria for diagnosing osteoporosis per International Society for Clinical Densitometry guidelines 2023.¹⁹

Group	Diagnosis of osteoporosis
Postmenopausal females	T-score -2.5 or less at any ROI
Males aged > 50 years or older	T-score -2.5 or less at any ROI
Females in menopause transition	WHO criteria hip -2.5 or less
Females prior to menopause	Z-score -2.0 'below expected range for age'
Males aged < 50 years	Z-score -2.0 'below expected range for age'

ROI, regions of interest; WHO, World Health Organization.

- Young and young adult patients for initial evaluation and follow-up after treatment when risk factors for low bone mass (e.g. eating disorders, scoliosis) are present and reduction of radiation exposure is desirable.³⁶⁻³⁹
- Pregnant patients: both the spine and hips can be measured during the first trimester; hips only can be measured in patients in the second or third trimester of pregnancy. The spine cannot be measured during the second and third trimesters.^{40,41}
- Lactating patients who do not meet the ISCD guideline criteria for monitoring of bone loss and fracture risk assessment.
- Patients with long bone or spinal deformity, severe scoliosis of any aetiology, or advanced spinal degenerative change.⁴²
- Patients with a significant discordance between the spine and hip T-scores based on DXA evaluation.⁴³
- Patients with the presence of instrumentation, such as those who have had a spinal fusion with implanted rods and screws, vertebroplasty or kyphoplasty, or those who have been treated for hip fractures with cannulated screws, intramedullary nails, or another similar implant.¹⁶ REMS cannot assess the bone density and bone fragility of the hip in cases of total hip arthroplasties (THAs) or hemiarthroplasty, but can still be used to evaluate the contralateral hip if it has not been replaced and the lumbar spine in those cases.
- In patients having an elective orthopaedic procedure to screen for low BMD and bone quality to determine the need for bone optimization therapy before surgery and for preoperative planning, allowing surgeons to prepare for the use of bone graft or augmentation, especially in spinal operations.
- Patients after surgery that can affect DXA interpretation such as laminectomies.
- Patients with diabetes in whom DXA results demonstrate discordance in spine and hip ROIs.³⁰
- Short-term monitoring of osteoporosis therapy effect.³⁴
- In the perioperative period for evaluation/short-term monitoring of any BMD or bone quality changes.

Recommended ROI measurement with REMS

Recommended ROI measurements with REMS are according to ISCD guidelines for the spine and hip. There are no reference ranges available for the distal third of the radius, currently.

Table III. Summary of precision and least significant change outcomes for REMS.⁸

Outcomes for REMS	Spine	Нір
Interoperator repeatability: precision, coefficient of variation (%)		
More than one operator	0.54	0.48
Least significant change, %		
One operator	1.05	0.88
More than one operator	1.59	1.36

REMS, radiofrequency echographic multispectrometry.

Spine

• L1-L4 should be used.

- A minimum of two vertebral bodies should be included in the analysis.
- The spine ROI can be used in the presence of instrumentation if enough bone tissue is available for analysis as defined in the descriptions above.
- Anatomically abnormal vertebrae should be excluded from the analysis if:²⁷
 - There is more than 1.0 SD (T-score) difference between the vertebra in question and the adjacent vertebrae.
 - When interpreting results, if more than one examination has been performed in an attempt to capture missing data, if each vertebral body (L1-L4) is evaluated separately, the data of missing vertebral bodies cannot be extracted from a repeat REMS scan to have a complete spine exam. For example, if during the first exam only L2-L4 were successfully measured and the repeated REMS scan on the same day successfully measured L1-L3, the L1 data cannot be added to the first exam to have L1-L4 measurements. Only one exam should be chosen.

Hip

- The ROIs are the same as the recommendations for DXA reporting (total hip and femoral neck).
- REMS can be used in patients in the presence of instrumentation used for fracture fixation. If enough bone tissue is available for analysis, such as in the presence of cannulated screws, intramedullary nails, or other instrumentation used for treating hip fractures, REMS is effective. However, REMS cannot be used to evaluate BMD in a hip after THA or hemiarthroplasty.

Distal third of radius

No reference ranges are available currently. The data collection is in progress at this time.

Vertebral fracture assessment

Although it may be possible to visualize some fractures of the femoral neck with REMS,⁴⁴ the DXA vertebral fracture assessment technique used to screen for spine fractures, is not currently supported. Although vertebral structural changes cannot be directly visualized with REMS via B-Mode, they can be sonologically detected and automatically excluded through broadband ultrasound backscatter analysis, therefore, additional imaging using plain radiographs, CT, or MRI without contrast is recommended if clinically indicated to obtain a detailed visualization of the whole vertebral morphology.

Fracture risk predictors based on REMS data

- REMS FS combined with the hip T-score estimates the fiveyear risk of hip fracture per 1,000 subjects related to the femoral neck (not total hip or trochanter) measurement.
- REMS FS combined with the spine T-score estimates the five-year risk of major osteoporotic fractures per 1,000 subjects related to the risk of any major osteoporotic fracture (clinical spine, upper limb, and hip).²²
- Risk stratification can be applied for patients aged between 21 and 90 years, regardless of menopausal status or sex.

Pisani et al²² showed that in females, above a FS lumbar spine cut-off of 37.2 the risk of fragility fractures increased by nine-fold, and above the femoral neck FS cut-off of 31.9 the risk for fragility fractures was six times higher than the risk of an incident hip fracture. The study demonstrated greater effectiveness of FS in estimating hip and lumbar spine fracture prediction compared to both DXA and REMS T-scores. For males, the same cut-off values showed ~9.5fold increased fragility fracture risk using the lumbar FS and 8.3-fold increased risk of a hip fracture using the femoral FS. There was a similar advantage of using the FS over the REMS and DXA T-scores in males as in females.

REMS studies: inter- and intraobserver comparisons

REMS precision, expressed as the root mean square coefficient of variation (RMS-CV) for interobserver observations, was shown in 2019 to be 0.38%, and the related least significant change (LSC) for comparison between studies is 1.05% for the lumbar spine (Table III).⁸

For the femoral neck, precision (RMS-CV) was 0.32% and the corresponding LSC was 0.88% if one technologist performed the studies.⁸ The interobserver comparisons for REMS measurements, showed RMS-CV of 0.54% and LSC equal to 1.50% for lumbar spine, while for the femoral neck RMS-CV was 0.48% and LSC was equal to 1.33%.⁸

A further evaluation of the precision and repeatability of REMS performed by Messina et al,²⁴ reported in 2023, showed very similar values for the RMS-CV (0.47% spine and 0.32% proximal femur) and the LSC (1.29% for the spine and 0.89% for the proximal femur).

If a previous REMS study was completed on a different scanner, because the hardware and software is identical, the data can be transferred for comparison. REMS studies that have been done on different scanners can therefore be directly compared.

Measurement suggestions with REMS

- Weight: 30 kg to 250 kg.
- Height: no limitation.
- BMI: < 50 kg/m² (although weight carried predominantly in the abdomen may hinder appropriate imaging of the lumbar spine).
- Aged ≥ 21 years: reference curves for younger patients are currently being finalized.
- Ascites: no available data
- Pregnancy:
 - First trimester: spine and hip ROIs can both be used.

- Second and third trimester: only hip ROIs can be used.
- Oral contrast/IV contrast or calcium tablets: no effect has been observed during REMS scans.

Summary

REMS has recently been extensively reviewed by the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO) Working Group,⁴⁵ which concluded that the published evidence shows it is a useful tool in the management of osteoporosis and is a suitable alternative to DXA. Its portability and lack of ionizing radiation means it can be used in previously underserved populations, including pregnant women and children. It will also have an increasing role in assessing bone health parameters in frail, hospitalized patients, in fracture clinics, primary care, the emergency department, and even at home. It is ideal for deployment in clinical situations remote from hospital, such as in geographically isolated and resource-poor areas. Added to these attributes, the ability of REMS to measure bone quality in both hips and the spine, which provides greater accuracy of fracture prediction, makes it unique among the available densitometry technologies. In the next decade, it is highly likely that REMS will become a commonplace technology in primary and secondary healthcare environments,⁴⁶ adding to clinicians' ability to accurately measure bone health parameters in a timely fashion. The practice parameters described in this protocol form a framework for REMS providers that will, to the greatest possible extent, ensure the most accurate assessment possible from the technology.

Supplementary material

Proposed radiofrequency echographic multispectrometry (REMS) interpretation template.

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K. Zambito and Y. Kushchayeva contributed equally to this work.

Funding statement

The author(s) disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: APC paid by Echolight SpA, Italy

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ICMJE COI statement

N. Birch reports being director of Osteoscan UK Ltd, a company delivering radiofrequency echographic multi-spectrometry (REMS) scanning services in the UK and Northern Europe. A. Bush declares quarterly royalty payments from Innomed for a clamp designed for hand surgery; and being an invited speaker at the annual meeting of the American College for Advancement in Medicine, which are unrelated to this manuscript. K. Zambito discloses a lecture payment for Osteometrix; and being on the board of directors of the Pennsylvania Orthopaedic Society, both of which are also unrelated. Y. Kushchayeva, P. Pisani, S. Kushchayeva, and M. Peters report no conflicts of interest.

Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Acknowledgements

The authors are grateful to Dr Iryna Pestun for her technical assistance in the final preparation of the manuscript submission.

Open access funding

The open access fee for this manuscript was funded by Echolight, Lecce, Italy.

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