Article published online: 2024-01-30

Effectiveness of Vertebroplasty and Kyphoplasty for Pain Reduction in Patients with Sarcopenia and Osteoporosis

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J Clin Interv Radiol ISVIR 2024;8:22–28.

Abstract

Purpose Vertebral compression fractures (VCFs) are common and associated with high morbidity including severe, debilitating pain. Percutaneous vertebroplasty/kyphoplasty is a demonstrated effective treatment for VCF. Sarcopenia has been implicated as a risk factor for VCF and refracture following cement augmentation, and as a risk factor for procedural complications in some populations; however, the effect of sarcopenia on VCF patients undergoing these procedures is unknown. This study aims to improve outcomes and patient selection by investigating the effects of highly common VCF comorbidities.

Methods A retrospective study was performed of all patients who underwent vertebroplasty/kyphoplasty for treatment of VCF at a single center from 2007 to 2020. Sarcopenia was quantified by normalized total psoas area (TPA) as measured on computed tomography. The effect of sarcopenia, bone density *t*-score, and clinical and demographic covariates on periprocedural pain scores was evaluated with linear mixed-effects models.

Results Out of 458 procedures performed, 146 and 130 were included in the sarcopenia and osteoporosis analyses, respectively. Sarcopenia and osteoporosis were highly comorbid in VCF patients undergoing vertebroplasty/kyphoplasty. Linear mixed-effects modeling showed no significant association between change in pain score and TPA score ($p = 0.827$) or bone density *t*-score ($p = 0.818$).

Conclusion Postprocedural pain reduction after vertebroplasty/kyphoplasty is not associated with the presence or severity of sarcopenia or osteoporosis/osteopenia. Appropriate patient selection remains critical to optimize the risk–benefit ratio of vertebroplasty/kyphoplasty, and sarcopenia and osteoporosis should not be considered contraindications to these procedures.

Keywords
- kyphoplasty
- sarcopenia
- osteoporosis

article published online
January 30, 2024

DOI https://doi.org/10.1055/s-0043-1777864.
ISSN 2457-0214.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Introduction

Vertebral compression fractures (VCFs) often occur among older adults, particularly in the elderly, and are the most common complication of osteoporosis with an estimated 700,000 cases annually in the United States.[1] Risk factors for VCF include osteopenia/osteoporosis, advanced age, decreased activity, female sex, Asian/Caucasian race, history of prior VCF, and corticosteroid use.[2] They also occur secondary to trauma and pathologic fracture in the setting of an underlying tumor.[3] In addition to severe pain, VCFs are associated with significant morbidity including decreased mobility/functional status, higher risk of decubitus ulcers and deep venous thrombosis, impaired pulmonary function and pneumonia, and worse nutrition.[1] VCFs are also associated with lower health-related quality of life indicators.[4] Given demographic shifts in the proportion of elderly Americans, the incidence of VCFs will likely continue to increase.

Percutaneous vertebroplasty/kyphoplasty procedures are a safe and effective treatment for VCF, and are associated with earlier hospital discharge, lower readmission rates, and reduced mortality in the setting of acute ($<$ 6 weeks) VCF.[5–7] Vertebroplasty/kyphoplasty is highly effective at relieving pain related to VCFs.[8–10] Although vertebroplasty/kyphoplasty has been associated with a higher upfront cost than nonoperative management, it has been suggested that this cost is offset by reduction in use of medical resources in the postoperative setting compared to conservative management.[11]

Sarcopenia is the progressive and accelerated loss of muscle mass and function, and has been shown to be an independent risk factor for VCFs, as well as a risk factor for additional VCF after cement augmentation.[12,13] There is high comorbidity between sarcopenia and degenerative spine disease, and sarcopenia is associated with detrimental changes in spinal biomechanics, augmenting the risk for VCF.[14,15] Additionally, sarcopenia is a risk factor for surgical complications, including higher mortality and adverse event risk in cancer patients undergoing emergent spinal surgery and patients with traumatic spinal cord injury.[16–18] Sarcopenia has been associated with increased adverse events, 1-year mortality, and increased length of hospital stay in patients undergoing spinal surgery; however, the literature in this population is mixed, which may be partially due to variations in the definition and measurement of sarcopenia.[19]

This study aims to investigate the incidence and effects of sarcopenia, defined by normalized total psoas area (TPA), and osteoporosis, defined by bone density *t*-score, as they relate to clinical outcomes of vertebroplasty/kyphoplasty in VCF patients. The goal of this analysis is to improve the evidence basis of patient selection in this population by evaluating the effect of highly common comorbidities.

Materials and Methods

The study was performed under approval of an institutional review board. The study was carried out in ethical accordance with the Declaration of Helsinki for experiments involving human subjects and a STROBE Statement checklist was completed. As a deidentified retrospective imaging/medical record review study, individual consent for the study was waived. All patients who underwent vertebroplasty/kyphoplasty at a tertiary academic hospital from 2007 to 2020 were retrospectively reviewed. The study population included patients treated for osteoporotic, pathologic, and traumatic VCFs. The standard visual analog pain scale (VAS) was scored preprocedure and 2 hours postprocedure with 0/10 reflecting no pain and 10/10 reflecting extreme pain.[20] Other clinical information was collected using the electronic medical chart: gender, age, body mass index, inpatient/outpatient status, bone density *t*-score, history of diabetes mellitus, and applicable cancer history.

Sarcopenia can be assessed morphometrically on computed tomography (CT) or magnetic resonance imaging (MRI) by calculating TPA and normalizing this value with patient height, and has been defined as a TPA of less than 385 mm^2/m^2 in females, and less than 545 mm^2/m^2 in males.[16,21] TPA was measured by a single radiology attending with musculoskeletal subspecialty training and 3 years of experience. Using any available CT imaging that included the lumbar spine and performed less than 6 months prior to the date of vertebroplasty/kyphoplasty, the psoas muscle was outlined at the level of L4 using a picture archiving and communication system (PACS) measuring palette tool. This method was chosen as almost all PACS software has this ability without the need of supplemental segmentation software. TPA was calculated within the outlined boundaries and normalized to each patient's height using Equation 1.[16] TPA was recorded as a continuous variable to better evaluate its relationship to pain score outcomes and other analyzed covariates. ►**Fig. 1** demonstrates

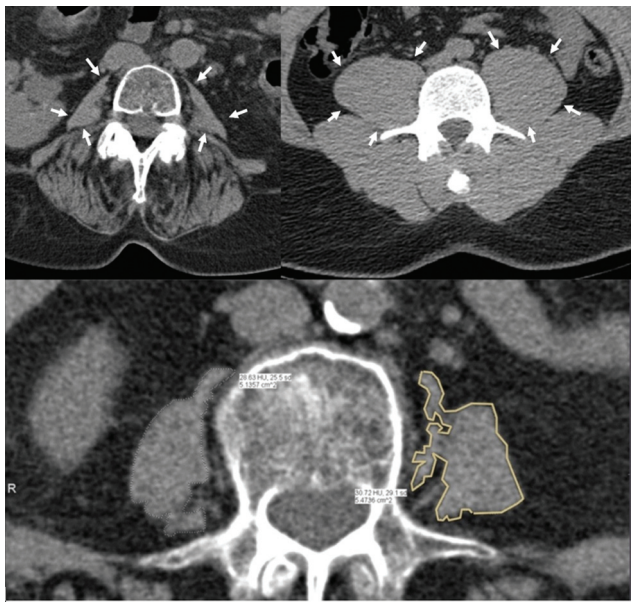

Fig. 1 Psoas muscles (outlined by white arrows) measured on axial computed tomography at the level of L4 in patients with sarcopenia (top–left) and healthy muscle mass (top–right), with total psoas area normalizing to 376 and 1,366 mm^2/m^2, respectively. The psoas muscles are outlined (bottom) demonstrating the technique of cross-sectional psoas area measurement, highlighted on the left psoas muscle.

example CT slices used to measure psoas muscle area and a highlighted outline of the measurement area. Patients were excluded from the analysis on the basis of unavailability of pre- and/or postprocedural pain scores or CT imaging to calculate TPA.

$$TPA = (RPA + LPA)/height^2$$

Equation 1: Normalized TPA calculation. RPA = right psoas area in mm^2. LPA = left psoas area in mm^2. Height = patient height in meters.

Linear mixed-effects models with a per-subject random intercept were utilized to analyze the effect of sarcopenia and bone density *t*-score on change in pain score. Five potential confounders were adjusted for, namely sex, body mass index, age, presence of type II diabetes mellitus, and inpatient/outpatient status. Multiple models with different forms of the exposures were estimated to thoroughly investigate any potential associations. Sarcopenia was modeled both as a continuous TPA value and as a dichotomous variable (absent/present). Bone density was modeled both as a continuous *t*-score and as a trichotomous variable (normal/osteopenia/osteoporosis).[16] *p*-Values were assessed at a false positive rate of 5%. All *p*-values from linear mixed models were estimated via Satterthwaite's approximation. Coefficient estimates and confidence intervals should be interpreted as the difference in change in pain score associated with a one-unit increase of the exposure.

Results

A total of 458 kyphoplasty/vertebroplasty procedures were performed over the study time period. After exclusion related to lack of data, 146 and 130 procedures were included for the sarcopenia and osteoporosis analyses, respectively (see ►**Fig. 2**). The procedures used in the analyses demonstrated comorbid sarcopenia in 82.9% of cases, osteopenia in 36.2% of cases, and osteoporosis in 55.4% of cases. ►**Tables 1** and **2** summarize the demographic and clinical characteristics included as covariates in the sarcopenia and osteoporosis analyses, respectively.

The linear mixed-effect models found no association between change in pain score and sarcopenia TPA value (95% confidence interval [CI]: −0.002, 2.8×10^{-3}; $p = 0.827$) or bone density t-score (95% CI: −0.56, 0.44; $p = 0.818$). A univariate plot of change in pain score against sarcopenia TPA value for each patient (►**Fig. 3**) demonstrated a relatively uniform distribution with no obvious trend. Box plots of change in pain score stratified bone density status (►**Fig. 4**) also demonstrated no obvious trend across worsening bone density.

Similarly, no association was found between change in pain score and sarcopenia dichotomized according to clinically established cutoffs (95% CI: −1.37, 1.21; $p = 0.906$), change in pain score and osteopenia (95% CI: −2.72, 1.21; $p = 0.449$), or change in pain score and osteoporosis (95% CI: −1.92, 1.89; $p = 0.987$; see ►**Figs. 3** and **4**). Lower sarcopenia values (95% CI: −0.88, 9.2×10^{-3}; $p = 0.056$) and lower bone density *t*-score (95% CI: 2.8×10^{-3} $^{-}2.2 \times 10^{-3}$, 1.2×10^{-3} $p = 0.055$) were associated with higher preprocedural pain scores at levels approaching significance.

Discussion

Sarcopenia has increasingly been described as a risk factor for adverse events in surgical patients including spinal surgery patients and cancer patients,[16–18] and is also a risk factor for VCF and same level refracture following vertebroplasty and kyphoplasty.[12,13] Vertebroplasty and kyphoplasty have been demonstrated as safe and effective methods for treating VCFs[5,6,10] however, severe sarcopenia or osteoporosis may be seen as relative contraindications, making interventionalists averse to treating patients with these highly common comorbidities in the setting of acute VCF. To our knowledge, this is the first study to evaluate the effect of sarcopenia and osteoporosis severity on the efficacy of vertebroplasty/kyphoplasty to treat VCF. Our analysis found no evidence of a relationship between sarcopenia or

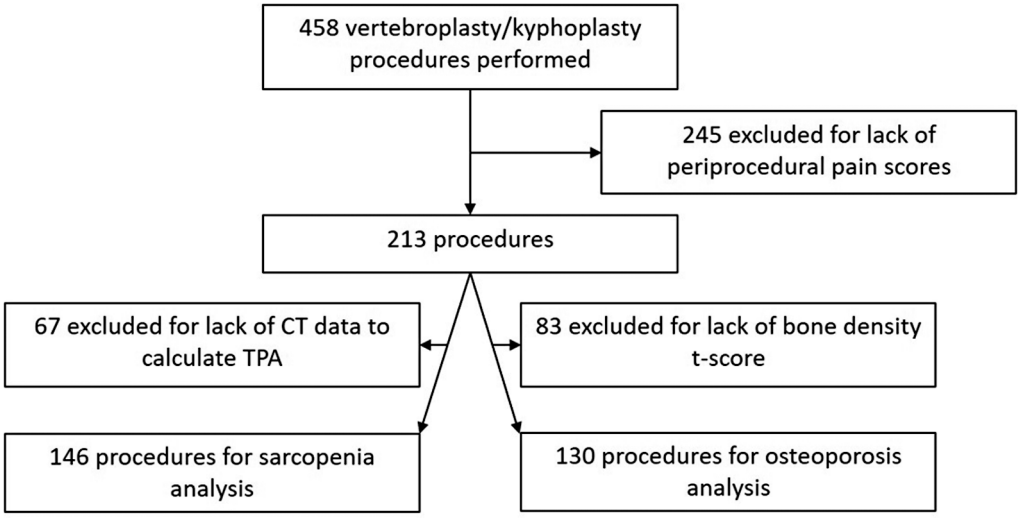

Fig. 2 Flow diagram of procedures included for analyses. CT, computed tomography; TPA, total psoas area.

Table 1 Demographic and clinical characteristics of all patients in the sarcopenia (TPA) analysis

Age	All ($n = 146$)		
Mean (SD)	67.0 (13.8)		
Median (min, max)	68.5 (25.0, 93.0)		
BMI			
Mean (SD)	26.3 (5.59)		
Median (min, max)	26.2 (14.5, 45.1)		
Type II diabetes mellitus			
No	108 (74.0%)		
Yes	38 (26.0%)		
Patient type			
Inpatient	29 (19.9%)		
Outpatient	117 (80.1%)		
TPA value[a]	Female ($n = 77$)	Male ($n = 69$)	All ($n = 146$)
Mean (SD)	585 (154)	718 (208)	648 (193)
Median (min, max)	591 (222, 991)	709 (391, 1,370)	626 (222, 1,370)
Dichotomized sarcopenia[b]			
Absent	6 (7.8%)	19 (27.5%)	25 (17.1%)
Present	71 (92.2%)	50 (72.5%)	121 (82.9%)

Abbreviations: BMI, body mass index; SD, standard deviation; TPA, total psoas area.
[a]Normalized total psoas area as calculated by Equation 1. Results are stratified by sex due to normal physiological differences in these populations.
[b]Presence of sarcopenia as defined by a cutoff TPA of less than 385 mm^2/m^2 in females and less than 545 mm^2/m^2 in males.[16]

osteoporosis and change in pain score following vertebroplasty/kyphoplasty using a large cohort with a wide range of sarcopenia and bone density *t*-score values. The importance of patient selection to optimize the risk-benefit ratio in patients undergoing vertebroplasty/kyphoplasty is frequently highlighted, and it has been suggested that variability in reported complication rates likely reflects differences in patient selection rather than technical factors.[22] For this reason, a detailed understanding of subpopulations who may benefit more or less from intervention is critical. In particular, sarcopenia is both a risk factor for VCF and a reported relative contraindication in patient selection given its known association with surgical complications. Our study demonstrates that patients receive the same degree of benefit from these procedures regardless of the severity of sarcopenia or osteoporosis and thus should not be considered as any sort of contraindication. Sarcopenia and osteoporosis may be associated with higher preprocedural pain, although this did not reach significance in our analysis.

Underlying the importance of patient selection, the effectiveness of vertebroplasty/kyphoplasty in reducing pain related to VCF is complex and multifactorial. In contrast to our findings, Fan et al found increased postprocedural pain was associated with lower bone mineral density, as well as two or more fractured vertebral bodies, maldistribution of bone cement, less than 5 mL of injected cement, and thoracolumbar fascial injury.[23] In addition, Li et al found that intravertebral vacuum cleft, posterior fascial edema, facet joint violations, and a separated bone cement distribution were associated with residual back pain following percutaneous kyphoplasty.[24]

The method of quantifying sarcopenia in this study relied on the TPA. While there are more intensive ways to measure frailty, we chose a method that is practical and applicable for all types of practices. Most patients have some CT imaging readily available and this basic TPA measurement removes the barrier of using often sophisticated and subscription-based segmentation software not available to most practices or referrers.

Our analysis was performed on a relatively large cohort; however, it was limited to a single institution and may not reflect variability in practice patterns and patient presentation across different settings. In addition, the retrospective design limited longer-term follow-up and evaluation for complications. While we attempted to control for confounders in our linear mixed-effects model, given the complexity of factors related to postprocedural pain the presence of unaccounted confounders is possible.

The use of immediate (2-hour) postprocedure pain scores may not reliably capture longer-term outcomes. To illustrate, Fan et al utilized 1 month follow-up to assess pain and this difference may account for their finding; decreased bone mineral density was associated with postprocedural pain, in contrast to our study.[23] However, there is strong evidence that immediate postprocedural pain scores are a reliable and durable measure of longer-term pain outcomes in vertebroplasty/kyphoplasty patients. A meta-analysis by Gill et al found no significant difference between immediate postprocedural VAS pain scores and final follow-up pain scores.[9] A rigorous randomized control trial by Clark et al found patients undergoing kyphoplasty experienced immediate reduction in pain scores compared to patients undergoing sham procedures, and this difference remained significant

Table 2 Demographic and clinical characteristics of all patients in the osteoporosis (bone density t-score) analysis

Age	All ($n = 130$)
Mean (SD)	69.6 (12.2)
Median (min, max)	69.5 (25.0, 93.0)
Sex	
Female	85 (65.4%)
Male	45 (34.6%)
BMI	
Mean (SD)	26.0 (5.34)
Median (min, max)	25.9 (14.5, 42.3)
Diabetes	
No	91 (70.0%)
Yes	39 (30.0%)
Patient type	
Inpatient	13 (10.0%)
Outpatient	117 (90.0%)
Bone density t-score	
Mean (SD)	−2.49 (1.03)
Median (min, max)	−2.60 (−4.90, 1.70)
Osteoporosis classification	
Normal bone density	11 (8.5%)
Osteopenia	47 (36.2%)
Osteoporosis	72 (55.4%)

Abbreviations: BMI, body mass index; SD, standard deviation.

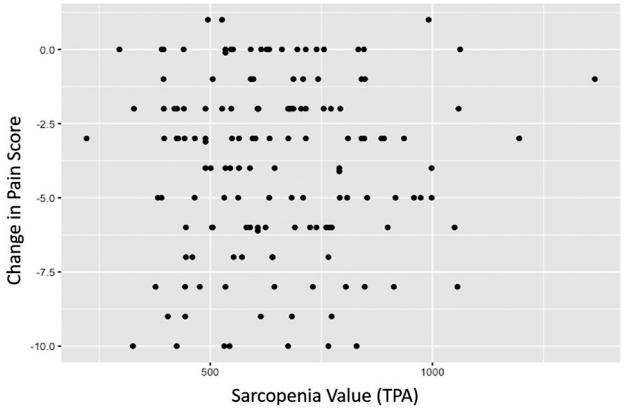

Fig. 3 Univariate scatterplot depicting sarcopenia value (TPA) against change in pain score. There is a relatively uniform distribution with no obvious trend, consistent with the findings of no association on linear mixed-effects model analysis.

over 6 months of follow-up.[6] Acute pain relief and faster functional recovery are primary rationales for performing vertebroplasty/kyphoplasty, and in elderly patients these procedures are associated with earlier hospital discharge, lower readmission, and decreased mortality.[5] For these reasons, postprocedural pain scores are a clinically important and durable outcome metric for study.

Other studies have shown that a minority of patients undergoing vertebroplasty/kyphoplasty report persistent or recurrent back pain on longer-term follow-up, with Kamalian et al reporting this in 23% of vertebral augmentation patients.[25] Notably, most of these patients (25 of 29) reported new pain after being pain-free postprocedurally and this pain was attributable to the sacroiliac and/or facet joints rather than a reflection of procedural failure or inefficacy. This finding highlights the multifactorial nature of back pain and raises the question of whether vertebral augmentation can increase the risk of developing subsequent pain generators; however, without comparison to conservatively managed VCF patients it remains an open question.

Bo et al performed a case–control study on vertebroplasty patients with residual back pain, defined as a VAS pain score of more than 4/10 at 1 year follow-up, and reported a higher rate of sarcopenia in the case group (33.9%) compared to a control group (21.0%) drawn from kyphoplasty patients without residual back pain.[26] This suggests sarcopenia may be associated with worse longer-term postprocedural outcomes. However, the clinical significance of this small (13%) difference in sarcopenia incidence is unclear and the control group incidence suggests that a large proportion of sarcopenic patients have excellent pain relief for up to 1 year. To illustrate this point, if the same incidence of sarcopenia (21.0%) is assumed in the 582 cases the control group was randomly drawn from by Bo et al; only an estimated 13.5% of sarcopenic patients have residual back pain at 1 year follow-up in this cohort. The findings of Bo et al do not indicate that sarcopenic patients benefit less from kyphoplasty but do suggest their underlying disease may contribute to ongoing mechanical back issues, which is likely related to sagittal imbalance parameters.[26] As previously noted, Kamalian et al found most patients with significant pain at longer-term follow-up experienced recurrent pain attributable to other sources.[25] Additionally, higher-level evidence including a meta-analysis by Wu et al suggests that sarcopenia is not an independent risk factor for increased back pain in patients following lumbar spine surgery.[15]

Further analysis is needed to determine whether sarcopenia is associated with increased risk of longer-term complications. In particular, whether there is greater risk for adjacent level vertebral body fracture remains an open question. In addition, sarcopenia is interrelated with other measures of physical frailty and deconditioning, and further evaluation of the effects of frailty on VCF treatments is warranted given its high comorbidity with VCFs and association with other postprocedural complications.[27] It is feasible that patients with sarcopenia and related physical frailty may derive greater benefit from interventions that minimize the morbidity of VCFs, by helping prevent a “downward spiral” of cascading adverse health events which can follow major fractures in the elderly.[28]

Conclusion

Postprocedural pain reduction after vertebroplasty/kyphoplasty is not associated with the presence or severity of sarcopenia or osteoporosis; however, these patients are

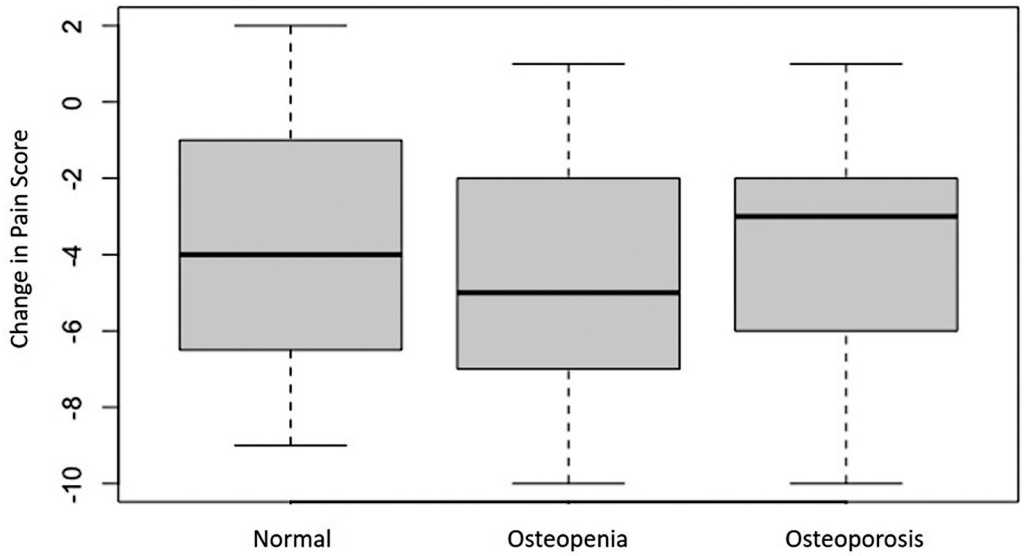

Fig. 4 Box plot of change in pain by bone density status: normal (*t*-score ≥ -1.0), osteopenia (*t*-score < -1.0 and > -2.5), and osteoporosis (*t*-score ≤ -2.5). Central bolded lines reflect the median value of each group, with first through third quartile values within the shaded box. Upper and lower whiskers represent the minimum and maximum values. There is no obvious trend across the box plots, consistent with the findings of no association on linear mixed-effects model analysis.

more likely to require hospitalization in the setting of VCF. The factors relating to outcomes in VCF patients undergoing vertebroplasty/kyphoplasty are complex, and the implications of sarcopenia or osteoporosis for longer-term postprocedural outcomes remain an area for further exploration. Evidence-based patient selection is critical for optimizing the risk–benefit ratio for these procedures.

Ethical Approval

The study was performed after approval of an institutional review board.

Conflict of Interest

None declared.

Acknowledgements

The authors declare no relevant financial support or additional personal assistance for the work being published.

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