



# Risk factors for conservative treatment failure in acute osteoporotic vertebral compression fractures (OVCFs)

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## Abstract

**Summary** This study aimed to identify risk factors for failure of conservative treatment of acute OVCFs. The results showed age, BMD, BMI, mFI, and IVC were high-risk factors for failure of conservative treatment of acute OVCFs.

**Purpose** This study aimed to identify risk factors for failure of conservative treatment of acute osteoporotic vertebral compression fractures (OVCFs).

**Methods** This is a retrospective study of patients presenting with acute OVCFs who were initiated on conservative treatment for 3 weeks. Conservative treatment was considered to have failed if patients were not satisfied with pain relief or there were bed rest-related complications. These patients progressed to operation. Patients were divided into a conservative treatment failure group (group A) and a conservative treatment group (group B). X-ray, computed tomography and magnetic resonance imaging of two groups were performed on the first visit to our department due to OVCFs. Recorded data for comparison among groups included age, gender, fracture level, bone mineral density (BMD), body mass index (BMI), modified frailty index (mFI), whether the fractures were multiple ( $\geq 2$  vertebral bodies was defined as multiple vertebral fractures) or combined with old fractures, and whether intervertebral cleft (IVC) was present.

**Results** We collected data from 173 patients who underwent conservative treatment of acute OVCF in our hospital. Of these, 71 had conservative treatment failure, while 102 patients succeeded in long-term conservative treatment. After logistic regression analysis, age, BMD, BMI, mFI, and IVC were identified as high-risk factors for conservative treatment failure ( $P < 0.05$ ). Age, BMD, BMI, and mFI were included in receiver operating characteristic curve analysis, the result showed that the cutoff value of age was 73.5 years old, of BMI was 23.65 kg/m<sup>2</sup>, of BMD was  $-3.45$ , and mFI was 2.5.

**Conclusion** According to the results of this study, patients with high-risk factors should be actively observed during conservative treatment, especially for patients with all of the above risk factors, but further research would be required before considering early-stage treatment policy change.

**Keywords** Osteoporotic vertebral compression fractures · Conservative treatment · Risk factor · Vertebroplasty · Kyphoplasty

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## Introduction

Osteoporosis has become a global health issue. Osteoporotic vertebral compression fractures (OVCFs) are the third most common fracture in the world, with the annual incidence of new OVCFs being up to 1.4 million [1]. One-third of OVCFs are symptomatic [2], with acute and chronic pain, increased risk of disability and death, and adverse effects on quality of life and mental health [3]. As the population ages, OVCFs become more common with interventions that effectively manage pain and reduce recovery time highly beneficial [4]. In recent years, as two minimally invasive surgeries using bone cement, percutaneous vertebroplasty (PVP) and

percutaneous kyphoplasty (PKP), have been used increasingly to treat OVCFs. Because the bone filler that is primarily used currently cannot be absorbed and it is difficult to reconstruct the bone locally, PVP and PKP is not a common treatment for OVCFs in some countries. Further, most guidelines still do not recommend these two approaches as the primary treatment strategy. So, many scholars believe that PVP or PKP should be provided to patients only when early conservative treatment fails [5–7]. Conservative treatment often includes bed rest, analgesia, muscle relaxants, external back braces, and physical therapy [4]. Although most fractures heal within a few months, many patients fail to respond to conservative treatment, often requiring hospitalization or long-term care, and a previous study showed that as high as 35% of patients failed to respond to conservative treatment [4, 6]. Previous research has suggested that age, bone mineral density (BMD), and body mass index (BMI) are risk factors for failure of conservative treatment [6], however, evaluation of risk factors was not the main research purpose of that study. Further, that work did not consider the overall health of the patient and other potential risk factors. Frailty is a characteristic of human aging and an important indicator for measuring and assessing risk preoperatively [8, 9]. At present, the modified frailty index (mFI) is an effective indicator for assessing the degree of patient frailty, and the mFI is scored by 11 possible comorbidities or deficits assessed [10, 11]. A number of studies have found that this index is associated with postoperative complications, readmission, and death [10, 12–14]. However, we are not aware of any study on the relationship between mFI and conservative treatment failure of OVCFs. We included mFI and intervertebral cleft (IVC) among our evaluation of risk factors for early conservative treatment failure in acute OVCFs, and IVC often indicates severe cancellous bone compression, poor bone healing, and local bone ischemia [15]. This study aimed to identify risk factors for failure of conservative treatment of acute OVCFs.

## Methods

### Selection of patients

This was a retrospective study of prospective data collection. The relevant data of patients were recorded by us in real time and stored in the patient's medical record. At the beginning of this study, we searched and summarized useful data from previous patient's medical records. Patients were eligible for inclusion in this study if they met the following criteria (1) age  $\geq 60$  years; (2) BMD (T value)  $\leq -2.5$ ; (3) OVCFs diagnosis duration  $\leq 2$  weeks. Exclusion criteria were the following: (1) pathological fracture(s) due to factors such as malignancy; (2) infection; (3) nerve injury caused by OVCFs; (4) complications caused by bed rest at admission including deep vein

thrombosis of the lower extremity, pneumonia, or pressure sores; (5) a history of obvious trauma; (6) follow up  $< 6$  months. Our department recommended that patients who were without bed rest-related complications and neurological symptoms receive conservative management of acute OVCFs as the first treatment strategy. All patients were informed about the risks and complications associated with surgery and conservative treatment before commencing the latter.

After conservative treatment for 3 weeks, it was considered to have failed if patients were not satisfied with pain relief or there were bed rest-related complications during treatment. These patients would then undergo PVP or PKP [6]. Inadequate pain relief was defined as a visual analogue scale (VAS)  $\geq 3$ , and pain significantly affecting basic daily life and activities. If the patient had adequate pain control (VAS  $< 3$ ) and could tolerate conservative treatment, they underwent conservative treatment long-term. Patients were divided into a conservative treatment failure group (group A) and a conservative treatment group (group B) according to their results.

### Observation indexes

X-ray (anteroposterior and lateral radiograph of thoracolumbar spine), computed tomography (CT) (1 mm thickness scan, parallel sagittal, coronal reconstruction), and magnetic resonance imaging (MRI) were performed on the first visit to our department due to OVCFs. Age, gender, fracture level, BMI ( $\text{kg}/\text{m}^2$ ), BMD (dual-energy X-ray absorptiometry, lumbar spine, T Value), and mFI (the mFI is scored by assigning 1 point for each frailty component present divided by the 11 possible comorbidities or deficits assessed, for an accumulation of deficits ratio indexed from 0 to 1 to account for missing variables [10]) (Fig. 1), whether there were multiple vertebral fractures ( $\geq 2$  vertebral bodies was defined as multiple vertebral fractures), whether old fractures were combined and whether intervertebral cleft (IVC) were combined and were documented for comparison between the two groups [16]. mFI consisting of 11 preoperative asthenic variables; and it was measured by the data from patient's medical record. IVC was confirmed by CT and MRI, at least one of above radiological examinations showed that there was a vertebral vacuum or liquid. All patients were followed-up at 3 weeks and 6 months after initial conservative treatment or after operation.

### Conservative treatment

All patients underwent conservative treatment with analgesics (celecoxib), bed rest, short-term back brace wear, and anti-osteoporosis treatment (calcitonin + calcitriol + calcium). Patients were not confined to strict bed rest and were encouraged to participate in appropriate activities. They did not wear braces for a long time, with the ideal time less than 4 weeks [7,

**Fig. 1** Modified version of the frailty index (mFI)

The mFI include the following:

1. Nonindependent functional status (partially or totally dependent activities of daily living);
2. History of no diabetes or diabetes controlled by diet alone, diabetes treated with oral antihyperglycemic therapy, or diabetes treated with insulin therapy;
3. History of chronic obstructive pulmonary disease exacerbation or pneumonia within 30 days;
4. History of congestive heart failure exacerbation within 30 days;
5. History of myocardial infarction within 6 months;
6. History of angina within 30 days or any percutaneous coronary intervention or coronary artery bypass grafting;
7. Hypertension requiring medication;
8. History of peripheral vascular disease;
9. Acutely impaired sensorium;
10. Transient ischemic attack or cerebrovascular accident without deficits;
11. Cerebrovascular accident with deficits.

17]. After significant pain relief, patients were encouraged to increase activity. Bed rest–related complications were prevented during conservative treatment period, active expectation (active coughing and pat back to promote sputum excretion), active and passive contraction of lower limb muscles (15 min/h), raise lower limbs while sleeping (higher than the heart level.), prevention of pressure sores (at least turn over one time per 2 h), ensure the enough water intake every day, and wash the perineal region with warm water every night.

### Statistical analysis

Distribution of continuous variables was assessed by the Kolmogorov–Smirnov test, and homogeneity of the variance was assessed by the Levene test. Mann–Whitney *U* test was used for data that were not normally distributed. For non-normally distributed, a median and interquartile range was used to present the descriptive statistics. Student's *t* test for independent samples was used to compare the two sets of data that were normally distributed. Categorical data were compared using chi-square test. For these aforementioned assessments and just in case potential risk factors may be excluded,  $P < 0.1$  was considered statistically significant. Significance of the potential risk factors was assessed using the stepwise logistic regression test,  $P < 0.05$  was considered statistically significant. Receiver operating characteristic curve (ROC) analysis was undertaken a  $P < 0.05$  was considered statistically significant. Statistical analyses were performed with SPSS 22.0 software (SPSS Inc., Chicago, Illinois, USA). The *P* values shown were two-tailed.

### Results

There were 156 patients were excluded. Among them, 68 OVCF diagnosis duration  $> 2$  weeks when they first visit our

hospital, 11 patients had pathological fractures, 13 patients had nerve injury caused by OVCFs, 22 patients had complications caused by bed rest at admission, 16 patients had a history of obvious trauma, and 26 patients lost follow-up. Finally, we collected data from 173 patients, from July 2015 to January 2016, who met the study inclusion/exclusion criteria. These patients underwent conservative treatment of acute OVCFs in our hospital. Among them, 71 patients were classified as conservative treatment failure and assigned to group A. In group A, 27 patients had bed rest–related complications and unsatisfactory pain relief and 42 patients only had unsatisfactory pain relief. The remaining two patients were unsatisfied with their pain relief but still adhered to conservative treatment. After a further 2 weeks of conservative treatment, they still did not obtain satisfactory pain control and proceeded to surgery.

In group B, there were 102 patients who eventually succeeded in long-term conservative treatment. Among them, there were three patients who developed intermuscular venous thrombosis during conservative treatment, but these disappeared after thrombolysis and strengthening walking exercise. The other patients in group B did not have any obvious complications, and bone healing was obtained at the last follow-up in all cases. Six patients had obvious malunion without complaining of obvious back pain.

After univariate analysis, age and other factors were identified as significantly different between the two groups ( $P < 0.1$ ) (Table 1). These potential risk factors were then included in logistic regression analysis, with the results showing age, BMD, BMI, mFI, and IVC to be high-risk factors for conservative treatment failure ( $P < 0.05$ ) (Table 2). After age, BMD, BMI, and mFI were included in ROC survival curve analysis, the results showed that the area under the curve (AUC) of age was 0.755 (95% CI 0.682, 0.828;  $P < 0.001$ ), with the cutoff value being 73.5 years old. The AUC of BMI was 0.615 (95% CI 0.524, 0.705;  $P = 0.010$ ), with the cutoff

**Table 1** Univariate analysis of failure of conservative treatment for acute OVCFs

Variable	Group A	Group B	P value
Case	71	102	N/A
Age (years old)	75.13 ± 7.03	68.91 ± 4.70	<i>P</i> < 0.001 <sup>^</sup>
Sex (male/female)	31/40	39/63	0.474*
BMD (T-score)	3.15 ± 0.33	2.95 ± 0.30	<i>P</i> < 0.001 <sup>^</sup>
BMI (kg/m <sup>2</sup> )	23.94 ± 2.89	22.90 ± 1.35	0.010 <sup>^</sup>
mFI	1.93 ± 1.33	1.22 ± 0.78	<i>P</i> < 0.001 <sup>^</sup>
Multiple fracture (single/double)	61/10	96/6	0.067*
Old fracture	15 (21.13%)	12 (11.76%)	0.095*
Intervertebral cleft	19 (26.76%)	6 (5.88%)	<i>P</i> < 0.001*
VAS	6 (5)	6 (5)	0.306#
Level			0.384*
Thoracic spine (T1~T9)	15	20	
Thoraco-lumbar spine (T10~L2)	51	68	
Lumbar spine (L3~L5)	5	14	

*BMD* bone mineral density, *BMI* body mass index, *mFI* modified frailty index, *VAS* visual analogue scale

\*Chi-square test

#Mann–Whitney *U* test

<sup>^</sup>Student's *t* test

value being 23.65 kg/m<sup>2</sup>. The AUC of BMD was 0.663 (95% CI 0.582, 0.744; *P* < 0.001) and cutoff value was −3.45. Finally, the AUC of mFI was 0.652 (95% CI 0.564, 0.739; *p* = 0.001) and the cutoff value was 2.5. Based on these four indicators, the AUC of the prediction model was 0.884 (95% CI 0.837, 0.938) (Fig. 2).

## Discussion

OVCFs are a common osteoporotic fracture that may present as symptoms of lower back pain or discomfort or limited mobility. Conservative treatment or surgery (PVP or PKP) are common treatment approaches. Many doctors consider that surgery should only be provided to patients when

conservative treatment fails [5, 6]. Previous studies have found that trials of conservative treatment for 3 weeks are meaningful [6, 18]. PVP and PKP are most effective when completed within a few weeks of fracture, a result that has been confirmed by a meta-analysis [19]. Therefore, to ensure an appropriate therapeutic effect, our department also recommended conservative treatment of patients for 3 weeks, with the subsequent treatment plan chosen according to the individual situation. In this study, 173 patients with acute OVCFs were treated conservatively. After 3 weeks of initial conservative treatment, 71 cases failed to continue with this approach giving a failure rate for early conservative treatment of about 41%. Another study found that 35% of patients failed after 3 weeks of conservative treatment without pain relief [6].

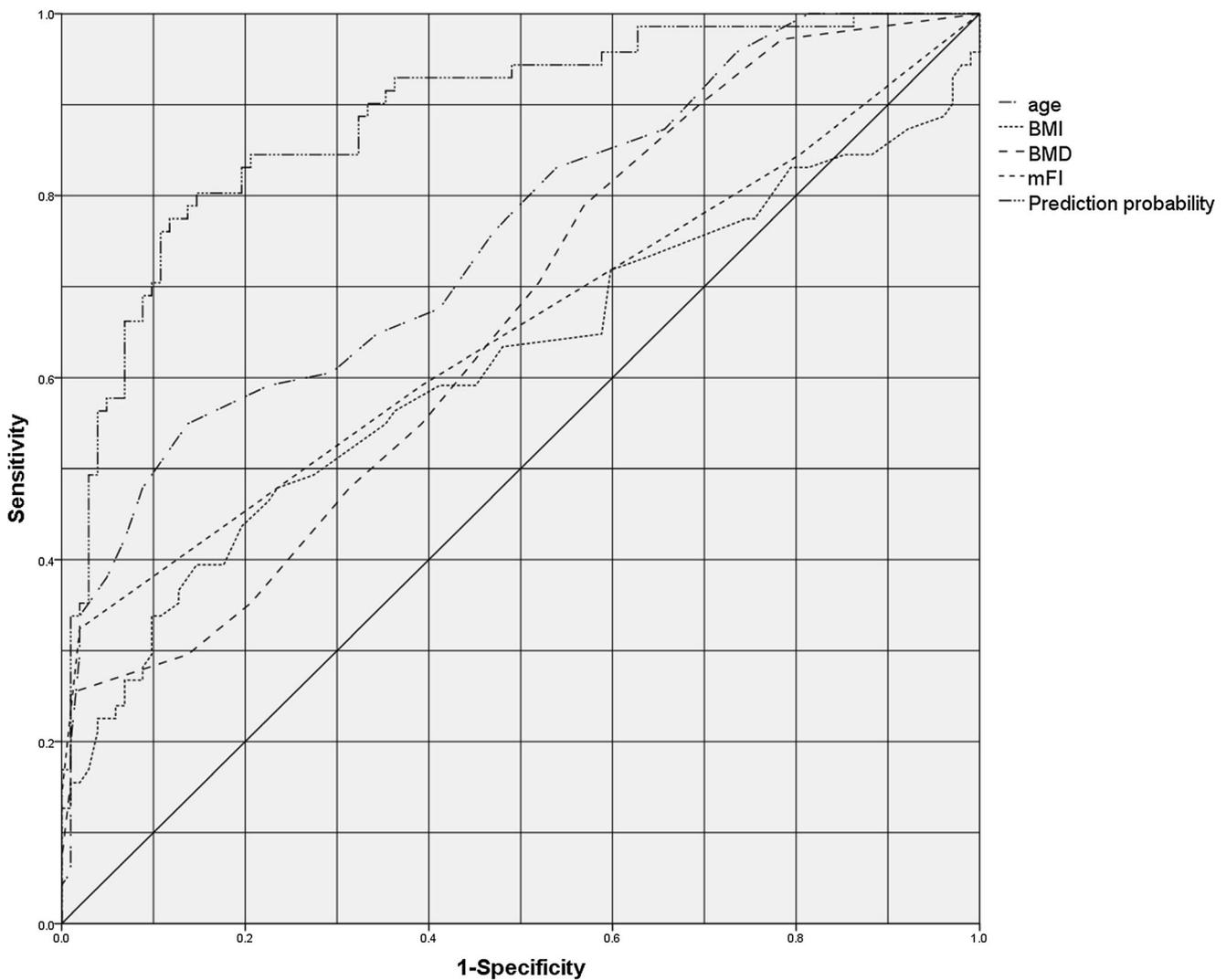
Logistic regression and ROC analyses indicated cutoff values for age (> 73.5 years old), BMD (< −3.45), BMI (> 23.65 kg/m<sup>2</sup>), and mFI (> 2.5), along with IVC, as high-risk factors for failure of conservative treatment of acute OVCFs. Older patients are more likely to fail conservative treatment of acute OVCFs. This is in part because older patients are more likely to have lower bone density, previous experimental data have shown that osteoporosis impairs fracture healing [20, 21]. And they may also have lower tolerance to conservative treatment-related complications and discomfort associated with wearing braces [22]. In most non-developed countries, conservative treatment for elderly patients is typically undertaken at home. In these cases, the supporting partner is often elderly, which greatly increases the risk of conservative treatment failure. A previous study has also reported that age was a risk factor for failure of conservative treatment of acute OVCFs and the cutoff value was 76.5 years old [6]. Our cutoff

**Table 2** Analysis of risk factors by logistic regression test

Variable	OR (95%CI)	<i>P</i> value*
Age	1.27 (1.15~1.39)	<i>P</i> < 0.001
BMI (kg/m <sup>2</sup> )	1.87 (1.48~2.38)	<i>P</i> < 0.001
BMD (T-score)	6.41 (1.20~34.31)	0.030
mFI	2.17 (1.44~3.28)	<i>P</i> < 0.001
Intervertebral cleft	4.12 (1.03~16.45)	0.046
Multiple fracture (single/double)	1.94 (0.43~8.78)	0.388
Old fracture	1.64 (0.48~5.64)	0.434

*BMD* bone mineral density, *BMI* body mass index, *mFI* modified frailty index

\*Logistic regression



**Fig. 2** Receiver operating characteristic curve analysis of risk factors affecting failure of conservative treatment. BMI, body mass index; BMD, bone mineral density; mFI, modified frailty index

value of 73.5 years old was lower, which may result from a lower average life expectancy in our country compared with the country (Republic of Korea) in the former work [6].

In our study, severe osteoporosis was also an important risk factor for conservative treatment failure. The World Health Organization (WHO) defined osteoporosis as a T value less than or equal to  $-2.5$ . This is the most important parameter for development of osteoporotic fractures [23, 24]. BMD is an important index of bone strength that reflects the degree of osteoporosis and is an important basis for predicting fracture risk. The cutoff value for BMD (T value) in our study was  $-3.45$ . We believe that low-bone density affects bone healing and remodeling. Additionally, severe osteoporosis often leads to pain, and bone density may further decrease with prolonged bed rest.

The WHO international standard defined a  $\text{BMI} \geq 25$  as overweight. However, in China, overweight is defined as a  $\text{BMI} \geq 24$ . This study showed that a BMI greater than 23.65 was an

important risk factor for failure of conservative treatment of acute OVCFs, which is similar to what was reported in a previous study [6]. Nielson et al. [25] revealed that obesity was associated with an increased risk of fractures because of poorer physical activity. Obesity may also be associated with poor compliance with the brace used in conservative treatment because it is very difficult to install a back brace in obese patients.

Frailty is a characteristic of human aging and an important indicator for measuring and assessing risk preoperatively [8, 9]. Evaluation using the frailty index includes data such as patient history, physical examination, and physical and functional status. However, this early comprehensive evaluation is time-consuming and labor intensive [26, 27]. Velanovich et al. [11] developed a modified version of the frailty index (mFI) consisting of 11 preoperative asthenic variables. The advantages of mFI lie in its low cost, easy calculation, and ability to be used for prospective or retrospective research. A number of studies have shown a correlation between mFI and adverse

clinical outcomes after spinal surgery including postoperative complications, hospital stay, and mortality [13, 28]. However, we are not aware of any study on the relationship between mFI and conservative treatment failure of OVCFs. This study was the first to evaluate mFI in patients with OVCFs and to use it in the assessment of risk factors for conservative treatment failure. Our results showed that  $mFI \geq 3$  ( $mFI > 2.5$ ) was a risk factor for conservative treatment failure of OVCFs. We consider that the mFI can, to some extent, reflect the ability of an individual to tolerate fracture-related discomfort. It may also reflect tolerance to bed rest-related complications, with patients with higher mFI are more likely to have experienced these. In our study, 25 of 173 patients had a  $mFI \geq 3$ , with 20 (20/25, i.e., 80%) having bed rest-related complications.

Previous studies have suggested that IVC may indicate the presence of osteonecrosis and that the vertebral body may be prone to obvious collapse [29, 30]. This study found that the presence of IVC was a high-risk factor for conservative treatment failure. We thought that this may relate to poor bone reconstruction and local instability after IVC formation, which is more likely to cause pain.

This study found that gender, multi-vertebral fractures, combination with old fractures, and pretreatment VAS score were not risk factors for failure of conservative treatment. This was similar to what was observed in previous studies [6, 31]. In terms of bone healing, no study has found that the effect of conservative treatment of multiple vertebral fractures is different from single vertebral fractures.

There were some limitations to our study. First, this study was a retrospective, single-center study, which may lead to bias in the results, it is often difficult to recruit large number and representative research subjects from single-center study. A prospective, large-sample, multicenter study is needed to verify the outcomes of this research. Second, this study only evaluated risk factors for early conservative treatment failure in acute OVCFs and did not include long-term conservative treatment failures (including kyphosis and Kummell disease). While we still need a larger investigation with a broader scope, the results of this work are still clear enough to guide early treatment. Finally, the conservative treatment is a complex treatment method that includes bed rest, analgesia, external back braces, and anti-osteoporosis, there were still some differences in patients' actual treatment and different risk factors exist for different types of treatments. However, conservative treatment advised of our study for each patient was basically the same, therefore, we thought that the difference between conservative treatment in this study has a limited effect on the results.

## Conclusion

This study showed that nearly 60% of patients were managed with early conservative treatment, that symptoms were

significantly relieved, and that long-term conservative treatment should be adhered to. Our findings also indicated that patients without IVC who are aged  $< 73.5$  years old, with a  $BMD > -3.45$ ,  $BMI < 23.65$ , and  $mFI < 2.5$  are suitable for conservative treatment. Patients with high-risk factors should be actively observed during conservative treatment, especially for patients with all of the above risk factors, but further research would be required before considering early-stage treatment policy change.

**Disclaimer** The manuscript does not contain information about medical device(s)/drug(s).

## Compliance with ethical standards

**Conflict of interest** None.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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