Femur strength index versus bone mineral density: new findings (Slovak epidemiological etudy)

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Summary: *Patients and methods:* We analysed the data in the sample (n = 3,215) of East Slovak women with a primary or secondary osteopenia, osteoporosis and with risk factors for osteoporosis, aged 20–89 years, median 59 years, 95% C. I. (59.31; 60.07) obtained from dual energy X-ray absorptiometry device (Prodigy-Primo, GE, USA). Measured variables: 1. left proximal femur: T-score total hip, FSI (femur strength index), 2. lumbar vertebrae L_1–L_4: BMD (bone mineral density). *Objectives:* 1. To estimate and to compare an expected frequency of pathological FSI < 1 and T-score total hip ≤ –2.5 SD values in the East Slovak female population. 2. To estimate expected frequency of women with: FSI < 1 and T-score total hip ≤ –2.5 SD (Group A), FSI < 1 and T-score total hip from interval from –1,0 till –2.5 SD (Group B), FSI < 1 and T-score total hip > –1.0 SD (Group C) in the East Slovak female population. 3. To determine, if FSI variable value is a significant predictor of BMD variable values in lumbar vertebrae. *Results:* 1. In the East Slovak female population we can expect 14.54% of women with FSI values < 1 and 6.25% of women with osteoporosis in the total hip area according to T-score. 2. For the group A we can expect the mean value (μ) from interval (1.41; 2.36)%, for the group B from interval (4.50; 6.03)% and for the group C from interval (6.76; 8.55)%. 3. Between FSI and BMD L_1–L_4 variable values there is not a statistically significant dependence, because FSI variable is quantitative and qualitative different variable from BMD variable. *Conclusion:* The measurement of FSI variable values may discover a higher percentage of women with a probability of femoral neck fracture by fall than the measurement of BMD variable value in the total hip area. Patient with osteopenia or normal BMD measured in the total hip area may sustain a femoral neck fracture by fall, when she has pathological value of FSI, i.e. she has adverse values of geometric variables of proximal femur (biomechanically unfavourable proximal femur configuration). FSI variable value is not a significant predictor of BMD variable values in lumbar vertebrae L_1–L_4.

Key words: osteoporosis – femur strength index (FSI) – bone mineral density (BMD) – femoral neck fracture – dual energy X-ray absorptiometry (DXA) – lumbar vertebrae

Index pevnosti femuru versus hustota kostného minerálu: nové poznatky (Slovenská epidemiologická štúdia)

Súhrn: *Pacienti a metódy:* Analyzovali sme hodnoty premenných získaných meraním na kostnom denzitometri (DXA, Prodigy Primo, GE, USA) vo výberovom súbore žien (n = 3 215) s osteopéniou, osteoporózou a rizikovými faktormi pre osteoporózu z oblasti východného Slovenska vo veku od 20 do 89 rokov, s mediánom veku 59 rokov. Populáciu definujeme ako všetky ženy z východného Slovenska s osteopéniou, osteoporózou a rizikovými faktormi pre osteoporózu. Sledované premenné: 1. ľavý proximálny femur: T-score total hip, FSI (femur strengt index), 2. lumbálne stavce L_1–L_4: BMD (bone mineral density). *Ciele:* 1. Stanoviť a porovnať očakávané početnosti patologických hodnôt premenných FSI < 1 a T-skóre total hip ≤ –2,5 SD v populácii žien z východného Slovenska. 2. Stanoviť očakávané početnosti žien v populácii, ktoré majú patologické hodnoty FSI < 1a zároveň T-skóre total hip ≤ –2,5 SD (skupina A), T-skóre total hip z intervalu –1,0 až –2,5 SD (skupina B), T-skóre total hip > –1,0 SD (skupina C). 3. Zistiť, či je FSI štatisticky významným prediktorom pre odhad hodnôt BMD v lumbálnych stavcoch. *Výsledky:* 1. V populácii môžeme očakávať 14,54% žien s patologickými hodnotami FSI < 1 a 6,25% žien s osteoporózou v oblasti total hip na základe meraných hodnôt T-skóre. 2. V skupine A môžeme očakávať, že stredná hodnota (μ) bude z intervalu (1,41; 2,36)%, v skupine B z intervalu (4,50; 6,03)% , v skupine C z intervalu (6,76; 8,55)%. 3. Medzi hodnota premenných FSI a BMD L_1–L_4 sa nezistila štatisticky významná závislosť. *Závery:* Meranie hodnôt premennej FSI odhalí v populácii väčšie percento žien s pravdepodobnosťou pre vznik zlomeniny krčka femuru pri páde ako meranie BMD v oblasti total hip. Pacientky s ostepéniou alebo normálnymi hodnotami BMD v oblasti total hip môžu utrpieť zlomeninu krčka femuru pri páde, ak majú patologické hodnoty FSI, t.j. ak majú nepriaznivé hodnoty geometrických premenných proximálneho femuru (tzv. biomechanicky nepriaznivú konfiguráciu proximálneho femuru). Pomocou hodnôt premennej FSI nie je možné robiť predikciu hodnôt premennej BMD v stavcoch, pretože je to kvalitatívne aj kvantitatívne iná premenná ako BMD.

Kľúčové slová: osteoporóza – index pevnosti femuru (FSI) – hustota kosného minerálu – zlomeniny krčka femuru – kostná denzitometria (DXA)

Introduction

With the development of clinical osteology, spheres of interest, objectives and directions of epidemiological studies have been changing. Rising costs of complex treatment of fractures and social care of patients with permanent consequences of fractures (reduced work skills, reduced self-sufficiency, disability) brought to attention the precise assessment of bone quality, fracture risk and the prevention strategy of osteoporotic fractures [1,2]. The treatment costs of fractures caused by falls represent still an economic burden for the health care system [3–7]. Therefore, the search continues to find more precise variables in densitometric methods (DXA and QCT – quantitative computed tomography) to determine patients with a fracture risk by fall.

In this clinical study we were interested in comparison of two densitomeric variables measured by DXA and their possibility to discover the female patients at high risk of proximal femoral fracture by fall.

Objectives of the study

1. To estimate an expected frequency of the occurrence of pathological FSI < 1 variable values and pathological BMD (T-score total hip ≤ –2.5 SD) variable values in the East Slovak female population and to compare them.
2. In the East Slovak female population to estimate expected 95% C.I. for percentage of women with variable values:
   - FSI < 1 and T-score total hip ≤ –2.5 SD (Group A),
   - FSI < 1 and T-score total hip from interval from –1.0 till –2.5 SD (Group B),
   - FSI < 1 and T-score total hip > –1.0 SD (Group C)

   and in the sample to estimate the percentage of women belonging into groups A, B or C.
3. To determine, if FSI variable value is a significant predictor of BMD values in lumbar vertebrae L_1–L_4.

Patients and methods

Characteristics of the sample

Using a DXA bone densitometer (Prodigy – Primo, GE, USA) we analysed the data in the sample of East Slovak women (n = 3,215) aged 20–89 years, median 59 years, 95% C. I. (59.31; 60.07):

1. without case – history of femoral neck fracture,
2. with risk factors for the development of osteoporosis,
3. with a primary or secondary osteopenia,
4. with a primary or secondary osteoporosis.

Tab. 1. The WHO criteria of osteoporosis or osteopenia.

Classification of bone density	T-score
normal	> –1.0 SD
osteopenia	from –1.0 till –2.5 SD
osteoporosis	≤ –2.5 SD

All women were examined with the same bone densitometer DXA. The BMD was determined in the standard region of interest (ROI) – total hip left. BMD values were given in absolute numbers in g of Ca-hydroxyapathite crystals for cm^2 (g/cm^2), as well as in relative numbers as T-score (the number of standard deviations from the reference group of young healthy women). Osteoporosis or osteopenia were diagnosed in accordance with the WHO criteria (tab. 1).

To achieve the measurement quality (QA), only two operators alternated in measuring with the DXA device and all women were measured with the same device. The following variables were measured:

1. Proximal femur left: BMD total hip (T-score total hip), FSI.
2. Lumbar vertebrae L_1–L_4: BMD.

Characteristics of the population

All women of the East Slovakia with osteopenia, osteoporosis and with risk factors for osteoporosis (hereafter East Slovak female population).

Definitions of measured variables and variables describing in the discussion [8]

FSI (femur strength index) – is a biomechanical variable determining whether the bone strength in the femoral neck area endures the load of compressive force impact by fall (normal value: FSI ≥ 1, pathological value: FSI < 1).

It is defined as a ratio of estimated elastic limit in compression of the femoral neck (δ_E) to the expected compressive stress of a fall on the greater trochanter adjusted for the patient's age, height and weight (δ_C).

α angle (α) is an angle formed by the femoral shaft axis and the perpendicular. The α angle can acquire both positive and negative values in the population, depending whether the femur is in a valgus or varus position.

θ angle (θ) is an angle formed by the femoral neck axis and the femoral shaft axis.

HAL (hip axis length) – is a distance (in mm) from the beginning point of the greater trochanter protuberance to the pelvis inner rim, measured in the femoral neck axis.

CSMI (cross sectional moment of inertia) – is defined as the sum of multiplications of elementary areas and the squares of their distances from neutral axis, denoted as I_Y (given in cm^4). The larger the cross sectional area, the higher the number of small elementary areas (A) and so is the bigger the second root of the distance (z^2) of these elementary areas from the neutral axis. The enlargement of the cross sectional area is accompanied by the enlargement of the cross sectional moment of inertia.

Statistical analysis [9–13]

To analyse the data of the sample, statistical methods were applied using statistical programme systems Statgraphics Centurion XV.

1. We tested the character of the distribution of FSI, T-score total hip and BMD L_1–L_4 variable values in the sample.
2. Using the Goodness-of-Fit Test χ^2 and coming from the character of empirical distribution of the frequencies (probability) of FSI variable values in the sample, we estimated the expected frequencies of FSI variable values in the East Slo-

Tab. 2. Observed and expected frequencies of FSI variable values in East Slovak female population (χ^2 Test, Goodness-of-Fit Test).

	FSI					
	lower limit	upper limit	observed frequency	expected frequency	expected freqency in %	χ^2
at or below		0.5	6	5.77	0.18	0.01
	0.5	1.0	465	461.44	14.36	0.03
	1.0	1.5	1,614	1,644.68	51.17	0.57
	1.5	2.0	859	812.14	25.27	2.70
	2.0	2.5	191	202.48	6.30	0.65
	2.5	3.0	45	55.46	1.73	1.97
	3.0	3.5	17	18.37	0.57	0.10
	3.5	4.0	6	7.12	0.22	0.18
	4.0	4.5	3	3.12	0.10	0.00
above	4.5		8	3.42	0.11	6.13

χ^2 = 12.3499 with 6 d.f. P-Value = 0.0546021
Goodness-of-Fit Tests, χ^2 Test
Sample: n = 3 214 (from the sample n = 3 215 one error value FSI = 0 was excluded)

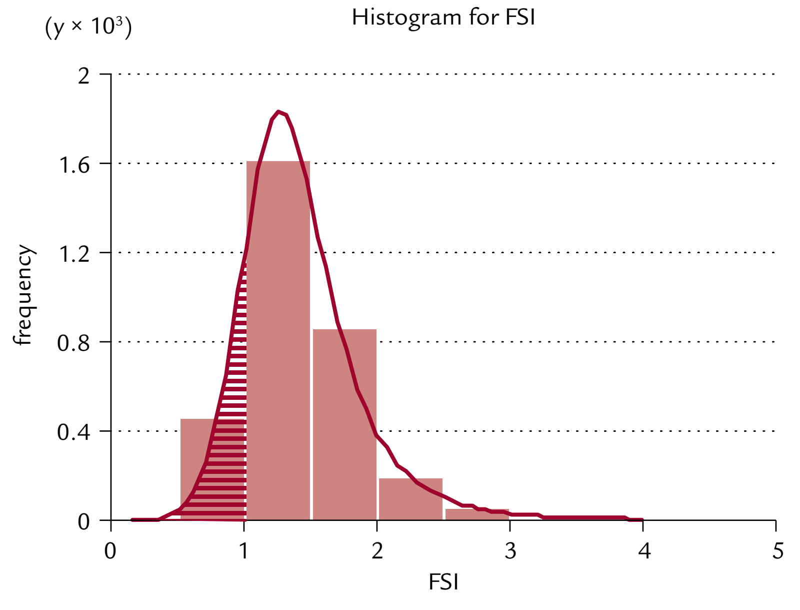

Fig. 1. Expected distribution of frequencies for FSI variable values in the East Slovak population of osteopenic, osteoporotic women and women with risk factors for osteoporosis. Hatched field represents an expected number of frequencies for FSI < 1.

vak female population at the significance level α = 0.01 We tested the character of the distribution of variable values in the sample and using the Goodness-of-Fit Test χ^2 and coming from the character of empirical distribution of the frequencies (probability) of T-score total hip variable values in the sample, we estimated the expected frequencies of T-score total hip variable values in the East Slovak female population at the significance level α = 0.05.

3. In the sample we calculated percentage of women, which belong into group A, B or C.
4. In the East Slovak female population, we calculated the 95% C.I. (confidence interval) for expected percentage frequencies of women, which belong into group A, B or C.
5. Linear regression analysis: To estimate the Pearson's correlation coefficients between FSI and BMD L_1–L_4 variable values. The coefficients verify the linear association and measure the intensity of association between variables FSI and BMD L_1–L_4.
6. To illustrate the results we used the following statistical graphs: histograms, circle diagram.

Results

Age Variable

The median ($\tilde{x}$) for age is 59 years, 95% C. I. (59.31; 60.07).

FSI Variable

The table 2 brings an empirical distribution of FSI variable values frequencies in the sample and the expected distribution of the FSI values frequencies in the East Slovak female population. In the East Slovak female population we can expect 0.18% of women with the FSI values < 0.5 and 14.36% of women with the FSI values from the interval (0.5; 1.0). It means that we can expect 14.36% + 0.18% = 14.54% of women in the East Slovak female population with FSI values < 1. At the significance level α = 0,01 it can be assumed that the probability distribution for FSI variable values in the East Slovak female population is loglogistic with the parameters derived on the basis of values found in the sample. One patient with faulty measurement FSI = 0 was excluded from sample n = 3,214 (fig. 1).

T-score Total Hip Variable

In the East Slovak female population according to values measured in the total hip area we can expect 6.25% of osteoporotic women with the T-score values ≤ 2.5 SD and 34.94% of osteopenic women with T-score values from the interval from –1.0 till –2.5 SD. At the significance level α = 0.05 it can

Tab.3. Observed and expected frequencies of T-score total hip variable values in East Slovak female population.

T-score total hip left (SD)	Observed frequency in the sample (total numbers)	Observed frequency in the sample in %	Expected frequency in population in %
(from ∞ till –2.5)	196	6.10	6.25
(from –2.5 till –1.0)	1.142	35.52	34.94
(–1.0–0.0)	1.089	33.87	34.59
(0.0–+∞)	788	24.51	24.22
Sample: n = 3,215			

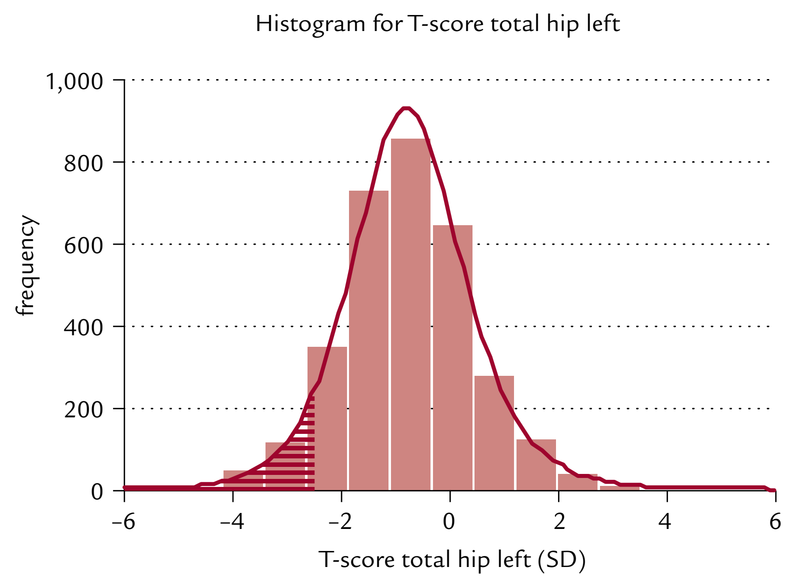

Fig. 2. Expected distribution of frequencies for T-score total hip left variable values in the East Slovak population of osteopenic, osteoporotic women and women with risk factors. Hatched field represents an expected number of frequencies for T-score ≤ –2.5 SD.

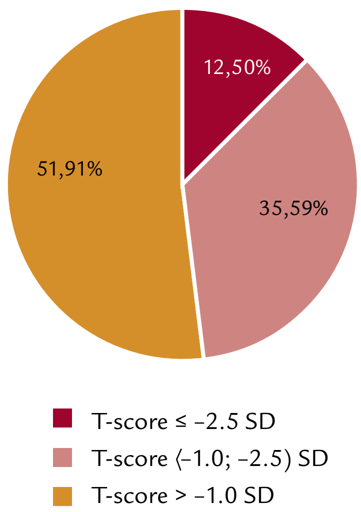

Fig. 3. Observed frequencies of T-score total hip left variable values in percentage for female patients with FSI left < 1 (n = 471) in the sample.

Tab. 4. Comparison of expected frequency of pathological FSI variable values and T-score total hip values in East Slovak female population.

Variable	Observed frequency in the sample (total numbers)	Expected frequency in population (%)
FSI left < 1	471	14,54
T-score ≤ –2.5 SD (total hip left)	196	6,25

Tab. 5a. Frequencies of FSI variable values in the sample.

sample: n = 3 214		
Variable	**Total frequency**	**Frequency in %**
FSI < 1	471	14.65
FSI ≥ 1	2 743	85.34

be assumed that the probability distribution for T-score total hip variable values in the East Slovak female population is loglogistic with the parameters derived on the basis of values found in the sample (tab. 3, fig. 2).

The expected frequency of the incidence of pathological FSI values of the East Slovak female population is 2.33 times higher as the expected frequency of the incidence of pathological T-score for osteoporosis measured in the total hip area (tab. 4).

FSI and T-score Total Hip Variables

In the sample, from total number of women with FSI < 1 (n = 471), there were 51.91% women with FSI < 1 and with T-score total hip > –1.0 SD, 35.59% women with FSI < 1 and with T-score total hip from interval from

Tab. 5b. Table with observed and expected frequencies of categorized FSI and T-score total hip.

		Observed frequencies in the sample and expected frequencies in the population			
variable		T-score ≤ –2.5 SD	T-score from –1.0 till –2.5 SD	T-score > –1.0 SD	Total
FSI < 1	observed frequencies	59	168	244	471
	observed frequencies in %	1.84	5.23	7.62	14.65
	expected frequencies in % (95% C.I.)	1.41–2.36	4.50–6.03	6.76–8.55	–

–1.0 till –2.5 SD and 12.50% women with FSI < 1 and with T-score total hip ≤ –2.5 SD (fig. 3, tab. 5b).

In the sample from total number of women (n = 3 215) there were 7.62% women with FSI < 1 and with T-score total hip > –1.0 SD, 5.23% women with FSI < 1 and with T-score total hip from interval from –1.0 till –2.5 SD and 1.84% women with FSI < 1 and with T-score total hip ≤ –2.5 SD (tab. 5b).

In the East Slovak female population it can be expected with the probability of 0.95 (95%), that the mean value (μ) of percentage (%) will be from:

- interval (1.41; 2.36) for women with FSI < 1 and simultaneously with T-score total hip ≤ –2.5 SD,
- interval (4.5; 6.03) for women with FSI < 1 and simultaneously with T-score total hip from interval from –1.0 till –2.5 SD,
- interval (6.76; 8.55) for women with FSI < 1 and simultaneously with T-score total hip > –1,0 SD (tab. 5a, 5b).

FSI and BMD L_1–L_4 Variables

Linear regression analysis: At the significance level α = 0.05 there is a very low direct dependence between FSI and BMD L_1–L_4, the Pearson's correlation coefficients are near to the zero. Variable FSI explains the variability of BMD L_1 variable values only in 0.250%, of BMD L_2 only in 0.230%, of BMD L_3 only in 0.380% and of BMD L_4 in less than 0.0% (tab. 6).

Tab. 6. Pearson's coorelation coefficinets (k) for linear direct dependence between FSI and BMD L_1–L_4 variable values at the significance level α = 0.05 (n = 3 353).

Lumbar vertebrae	Pearson's correlation coefficients (k)	p – value
L_1	0.05000	0.0038*
L_2	0.04858	0.0049*
L_3	0.06168	0.0004*
L_4	0.03348	0.0526

Discussion

At present, FSI is one of a few available variables, corresponding to biomechanical criteria of loading the bone by fall, whose values can be determined by DXA in a routine ambulatory practice. FSI integrates in itself three important bone characteristics:

1. BMD,
2. bone geometry: HAL, angle α (α), angle θ (θ), CSMI in the minimum cross sectional area of femoral neck (see definitions),
3. elasticity and strength.

Whether the FSI variable value is calculated from the two-dimensional bone measurement by DXA, which in comparison with three-dimensional measurement has some inaccuracies, it is a value determining the bone quality much more precisely than BMD. Clinical importance of the FSI variable value lies in the fact that it enables to determine an individual forecast for femoral neck fractures by fall. The forecast of femoral neck fractures by fall on the basis of BMD is markedly limited, as BMD characterises only one physical value-density, which determine only a part of bone quality.

Authors of some clinical retrospective or prospective studies [14–20] agree that the increase of the values of geometric variables of proximal femur

- HAL,
- θ angle,
- d (average width of femoral neck) over the mean value in the population is a risk factor for femoral neck fractures.

Faulkner et al [20] compared BMD, HAL, and CSMI in femoral neck area and FSI obtained from DXA measurements in a group of women with and without hip fracture. Femoral neck BMD and FSI were significantly lower and HAL significantly higher in fractured group compared with controls. Mean CSMI was not significantly different between fracture patients and controls. After adjustment of these variables in regression model, the authors conclude that BMD, HAL and FSI are significant independent predictors of hip fracture. Crabtree et al [20] concluded in their work, that the geometric variation of proximal femur may contribute to the large variations in hip fracture risk across Europe.

In our clinical study we were interested in percentage comparison of pathological FSI < 1 and T-score total hip ≤ –2,5 SD variable values in the same sample of East Slovak women and to estimate the expected frequencies of this variable values in the East Slovak female population. The expected percentage of FSI pathological variable values occurrence (14.54%) is 2.33 times higher than the expected percentage of osteoporosis occurrence in the total hip area (T-score ≤ –2.5 SD) in the East Slovak female population.

It is evident from such a simple comparison that BMD and FSI variables are two different characteristics of bone quality. FSI, which characterizes the bone quality by means of several integrated biomechanical variables, including in itself the BMD variable, discovers a higher percentage of women at risk for femoral neck fracture by fall than BMD. The results show that even a patient with osteopenia or normal BMD measured in the total hip area may sustain a femoral neck fracture by fall, in case she has pathological value of FSI variable, i.e. she has adverse values of geometric variables of proximal femur HAL, angle α, angle θ (so-called biomechanically unfavourable proximal femur configuration).

In our previous published studies [23,24], we have estimated from predictive logistic regression model, created from East Slovak female data, that the rise of HAL, angle α, angle θ variable values by one unit statistically significant raises the odds for femoral neck fracture by fall. It verifies that the variation of HAL, angle α, angle θ variable values significant influences the risk of femoral neck fracture by fall.

The measurement of FSI value in clinical practice enables to improve the strategy of treatment in the prevention of femoral neck fractures.

The FSI value < 1 could therefore be used as a criterion for the initiation of preventive therapeutic interventions in order to avoid femoral neck fractures. These interventions may include:

1. drug therapy,
2. wearing a hip joint protector,
3. kinesitherapy:
   - coordination exercises,
   - exercises to remove the muscular dysbalance in the mm. coxae area [24],
   - training of techniques how to fall correctly.

FSI variable is quantitative and qualitative different variable from BMD variable, what shows a little portion of variability of FSI variable values on the variability of BMD L_1–L_4 variable values according to linear regression analysis in our study. Prediction of BMD variable values by the help of FSI variable values is unreliable and therefore impossible in practice.

Methods of measurement and determination of bone quality have been constantly improving. As demonstrated by the latest clinical studies, the future of bone densitometry lies in a three-dimensional measurement of FSI an other new progressive biomechanical variables and also in high resolution QCT [26–30].

Conclusion

New types of DXA and QCT densitometers provide programs for clinical and ambulatory practice enabling to measure different biomechanical and geometric variables of proximal femur. Regrettably, these programs are utilized minimally in practice and osteologists are still rigidly adhering to BMD values. Offered programs overrun the "guidelines" of international and national osteological societies, which still have not included the criteria for the evaluation of new biomechanical variables.

Summing up

1. The measurement of FSI variable values may discover a higher percentage of women in the population with a risk of femoral neck fracture by fall than the simple measurement of BMD variable values in the total hip area.
2. Patient with osteopenia or normal BMD measured in the total hip area may sustain a femoral neck fracture by fall, when she has pathological FSI value i.e. she has adverse values of geometric variables of proximal femur (so-called biomechanically unfavourable proximal femur configuration).
3. Between FSI and BMD L_1–L_4 variable values there is not a statistically significant direct dependence, because FSI variable is quantitative and qualitative different variable from BMD variable. FSI variable value cannot be a predictor of the BMD variable values in lumbar vertebrae L_1–L_4.
4. The study investigated East Slovak women. Although it can be supposed that similar results will be found in the whole Slovak female population and in other female populations at least in central Europe, further studies will have to verify this.

Declaration – conflict of interests

The author declares, that she has no competing interests (financial or non financial).

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