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The reaction of the pelvis to the implantation of the acetabular component of the hip endoprosthesis – initial tests with the use of computerized tomography

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Among the population over the age of 65 years joint diseases constitute more than 50% of chronic diseases and most often apply to the hip. Endoprosthetics is one of the methods for treating this condition and is considered one of the best – clinically and economically – interventions of the modern medicine. However, it is not free of complications among which the loosening of the endoprosthesis is commonest. In publications, a full discussion has been going on arguing whether the complication is caused by biological or mechanical factors. The authors – aiming to answer this question based on CT – tested the influence of the implantation of the acetabular component on the pelvic bone density in Hounsfield units within a 6-month period after the operation. The test results indicate the bone density decrease. The statistical analysis shows, however, that the changes are not statistically significant.

Key words: *hip endoprosthesis, computed tomography, bone density, loosening of endoprosthesis*

1. Introduction

Among the population over the age of 65 years joint diseases constitute more than 50% of chronic diseases [24]. Considering the vertical position of the body this condition most often applies to the spine and the hips. In 2000, 1,183,000 total hip joint arthroplasties were performed worldwide. These days the number increases by about 2% every year [26].

First news on this medical procedure come from the mid-nineteenth century when pseudoarthrosis was supposedly made below united joints [3], [12]. Since the 1960's an excessive development has continued up to now. Nowadays, the procedure – considering a change in the quality of life – is one of the best, both clinically and economically, interventions of the modern medicine.

Modern hip endoprostheses – due to their connection to the bone – can be divided into two groups: cemented and cementless. In the cemented endoprosthesis, the joining material is polymethylmethacrylate – commonly known as bone cement. It is not glue because it does not have adhesive qualities. It is a material filling space and weight-bearing, technically described as mortar or putty [3]. The other type is the cementless endoprosthesis, where we deal with two-stage bonding. During the operation you get a mechanical stability which due to the porous surface of the endoprosthesis and bone tissue in-growth becomes a biological stability.

A typical cemented endoprosthesis consists of a polyethylene acetabular component, a steel head and a steel stem implanted into the femur. A cementless endoprosthesis consists of a metal covering, a poly-

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ethylene insert, a metal head and a stem. Steel elements are alloys of various precious metals and show various durability and flexibility qualities. Movement as in an anatomical joint takes place between a polyethylene acetabular body and a metal head. This is where friction between moving surfaces takes place and scratching of the materials is observed. That is why now materials are being searched for that have high tribological quality. New kinds of polyethylene are being developed, or other kinds of materials are being used as friction surfaces. And that is why there are now endoprostheses made of metal, ceramic or polyethylene acetabular components with metal or ceramic heads [1], [21], [22].

2. Loosening of the endoprosthesis elements

The purpose of endoprosthetics is pain relief, restoring a proper function of the joint, protection of the bone, correction of deformations, and maintaining the stability of the implant. The operation is to restore a range of movement in the joint, proper functions of the muscles, ligaments, and other soft tissue affecting the hip joint. With a proper qualification, proper surgical technique, and conducted rehabilitation programme we can gain a significant improvement in the life quality of the patients who are practically disabled before the operation. But arthroplasty, as every surgical procedure, is endangered with various complications. We can divide them into: intraoperative (early) and postoperative (late). The early ones are: nerve, vessel, bladder damage, haemmorhage, and postoperative hematoma. The late ones are: limb-length discrepancy, luxations, subluxations, heterotopic ossification, thromboembolism, periprosthetic fractures, infections, osteolysis, stem damage, and finally loosening of the endoprosthesis elements [6].

Despite constant improvements in the endoprosthesis construction, using better and better materials, and the improvement in the surgical techniques, still the main problem of the total endoprosthetics remains aseptic loosening, especially of the acetabular component [16].

In publications, there has been a discussion whether the loosening of the endoprosthesis elements is caused by biological factors, the reaction of the body to particles, or is a primary mechanical cause resulting from the reaction of the live bone to the implant.

At the beginning CHARNLEY assumed that it was a condition caused by infection [7], [20]. Further research proves that it is a more complex process and still not entirely understood. It is reported that out of over a million cases of hip endoprosthetics performed each year, about 1 per cent requires revisions, and another 0.5 to 1% has clinical and radiological symptoms of loosening [16], [26]. Because the number of primary procedures are increasing, the number of revisions are increasing as well and at the moment they constitute about 10–20% of primary operations [10], [17], [26]. The differences in the reported number of revision operations depend mainly on the definition of loosening and the observation period as well as the kind of prosthesis and surgical techniques [11], [16]. According to the Swedish National Arthroplasty Register aseptic loosening is in 73% the cause of a revision procedure [8].

As MORSCHER specifies the main distant problem in total cemented hip arthroplasty remains aseptic loosening, especially of the acetabular component. As long as the percentage of stem loosening is steady, the complication rarely applies to the acetabular component in the first 6–8 years. However, it increases significantly after 10 years. MULROY and HARRIS specify a 20-time increase of the acetabular component loosening between 5 and 11 years from the primary implantation [13], [16], [27]. The introduction of new cementing techniques remarkably decreased the stem loosening. However, they have not affected or only slightly improved the results for the acetabular component [8], [15], [16], [18].

After introducing new cementing techniques the frequency of stem loosening decreased and reached a plateau after about 5 years and the acetabular component loosening is still increasing [7], [14], [18], [19], [26].

As MANTLEY et al. state the frequency of cemented stem loosening decreases with time. It is quite the opposite with the acetabular component [2], [11], [13].

Roder et al. analysed the results of 24,889 cases of endoprostheses no less than 15 years from the operation. The average age on the operation day was 65. 85% of the patients were happy with the procedure result. The clinical result was gradually improving after the operation to reach its best between 2 and 5 years. Later the results were gradually lower. The authors connect that observation with the aging process, diseases of other joints and damage to the endoprosthesis [9].

After a year-long activity of the Removed Implant Register, WALL and DRAGAN specify the increase of loosening 4.7 and 13.5 years after the primary operation. They observed the highest increase of this complication after 7 years. They stated the cemented cap loosening 3 times more often than that of the stem. But in the cementless prosthesis the cap was loosened two times more often than the stem. However, the average survival time of the cap was by 3.5 years longer than that of the stem (cemented endoprosthesis). Whereas for cementless endoprosthesis the stem survival was longer by 1 year [5], [23].

According to the Swedish National Arthroplasty Register (database since 1979) in revision procedures due to loosening, in 48.2% both elements of the endoprosthesis are loosened, the stem in 30.4%, and the cap in 15.5%. The frequency of revisions due to improvement in cementing techniques decreases from 8% in 1979 to 6% in 1981 and to 4.3% in 1985 [8]. But MULROY and HARRIS specified the radiological symptoms of the cemented cap loosening in as many as 42% of their cases [18].

3. Materials and methods

The empirical material was the group of patients to whom hip joint endoprosthesis was implanted. For further research a group of 19 patients was selected randomly with diversified age, sex, and the endoprosthesis type. Clinical evaluation after hip arthroplasty was based on radiographic measurement of bone density. The research was performed by a single slice Siemens CT scanner. The experiment covered three measuring time periods: directly before the operation, after three and six months after the operation.

During the tests patients were positioned on their backs. Scanning started from lesser trochanter up to 3 cm above the roof of the acetabulum in a spiral sequence of every 2 mm. Bone density was measured in Hounsfield units, within an average distance of 12 mm from the acetabulum (10–15 mm), in the average area of 0.8 cubic cm (0.6–1.3 cubic cm). The measured area covered the center of a given zone which made it possible to avoid bone cysts. The measurements were taken at three points in the area over the acetabular body in frontal and diagonal planes. We did not manage to take measurements in the zones specified by DELEE and CHARNLEY due to interferences in zone III caused by metal parts of the endoprosthesis during the test and unreliable data or even lack of data. That is why zone I corresponds with DeLee's zone I, zone II in our tests is borderline of zones I and II, and zone III corresponds with zone II according to DELEE and CHARNLEY [4]. Exploration of a given characteristic was performed in frontal and sagittal planes (figure 1).

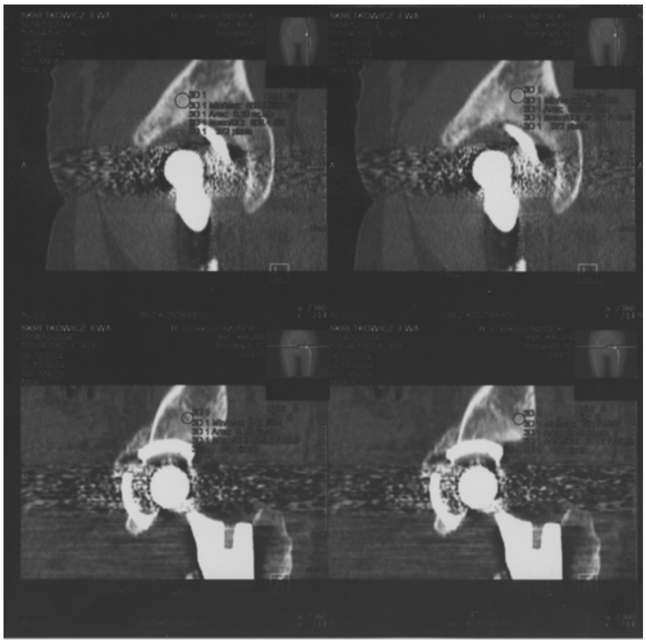

Fig. 1. Measurement areas selected

4. Test results

The test results of bone density in frontal planes are collected in table 1. The results cover all the differentiating factors described above.

5. Variance analysis

Patients examined were divided according to the age (up to 60, 60–70, over 70). The basic statistical results in subgroups for individual measuring zones and post-implantation periods are given in table 2.

In order to perform the variance analysis, it is necessary to verify the statements regarding normal distribution of a given statistical characteristic as well as equality of variances. Levene's test was used to evaluate equality of variances. The test results for all the groups cannot be a basis (at a significance level $\alpha = 0.05$) to reject the null-hypothesis for equality of variances. The lowest significance level ($p = 0.077$) was reached for measuring zone II and the age group of over 70 (table 3).

Table 1. Bone density (HU) in the frontal plane (prosthesis types:
C – cemented, B – cementless; sex: M – male, F – female)

Ordinal	Prosthesis type	Sex	Age	Zone I			Zone II			Zone III		
				0	3	6	0	3	6	0	3	6
1	C	M	over 70	322	308	286	318	330	320	518	505	520
2	B	M	50–60	98	200	212	208	129	148	254	152	155
3	C	F	over 70	665	652	645	324	306	279	357	322	285
4	C	F	over 70	47	52	54	105	114	119	152	163	174
5	C	M	60–70	574	293	304	270	244	253	258	128	132
6	C	M	over 70	483	419	411	255	250	237	139	151	144
7	B	F	40–50	662	666	675	412	378	386	110	94	103
8	C	F	over 70	214	202	211	74	120	126	28	53	68
9	C	M	60–70	508	443	472	601	423	448	526	436	452
10	B	F	50–60	705	470	520	481	320	332	430	714	442
11	C	F	over 70	128	117	96	119	121	197	102	130	212
12	C	M	over 70	431	356	143	457	287	220	203	155	128
13	C	M	60–70	645	649	596	420	407	402	436	519	469
14	C	M	60–70	522	641	511	494	334	377	639	575	624
15	C	F	over 70	101	149	128	184	313	338	278	199	184
16	C	M	over 70	411	381	278	512	266	290	379	487	333
17	B	M	50–60	306	114	88	57	158	128	120	110	62
18	C	F	60–70	579	484	294	406	527	181	426	374	310
19	B	F	40–50	598	604	612	650	662	669	703	708	713

Table 2. Selected basic statistical data for each age group

Age	Zone	Number of months after operation	Bone density (HU), sagittal plane Mean	Bone density (HU), sagittal plane Samples	Bone density (HU), sagittal plane Std. deviation
Over 70	I	0	311.33	9	204.97
Over 70	I	3	292.89	9	185.33
Over 70	I	6	250.22	9	185.07
Over 70	II	0	260.89	9	155.75
Over 70	II	3	234.11	9	90.07
Over 70	II	6	240.67	9	82.00
Over 70	III	0	239.56	9	156.14
Over 70	III	3	240.56	9	161.16
Over 70	III	6	229.78	9	134.31
60–70	I	0	565.60	5	54.25
60–70	I	3	502.00	5	148.67
60–70	I	6	435.40	5	132.39
60–70	II	0	438.20	5	121.73
60–70	II	3	387.00	5	105.54
60–70	II	6	332.20	5	111.16
60–70	III	0	457.00	5	140.44
60–70	III	3	406.40	5	173.59
60–70	III	6	397.40	5	185.43
Up to 60	I	0	453.80	5	242.61
Up to 60	I	3	410.80	5	244.17
Up to 60	I	6	421.40	5	257.57
Up to 60	II	0	381.60	5	202.13
Up to 60	II	3	329.40	5	213.67
Up to 60	II	6	332.60	5	219.06
Up to 60	III	0	323.40	5	248.59
Up to 60	III	3	259.60	5	264.48
Up to 60	III	6	295.00	5	277.08
Total			330.55	171	186.11

Table 3. Levene's test – equality of variances (variable: bone density in sagittal plane)

Variable	Levene's test – equality of variances Marked effects are significant at $p < .05000$							
	SS Effect	df Effect	MS Effect	SS Error	df Error	MS Error	F	p
Bone density, sagittal plane	18044.009	2.	9022.005	75855.739	24	3160.656	2.854	0.077

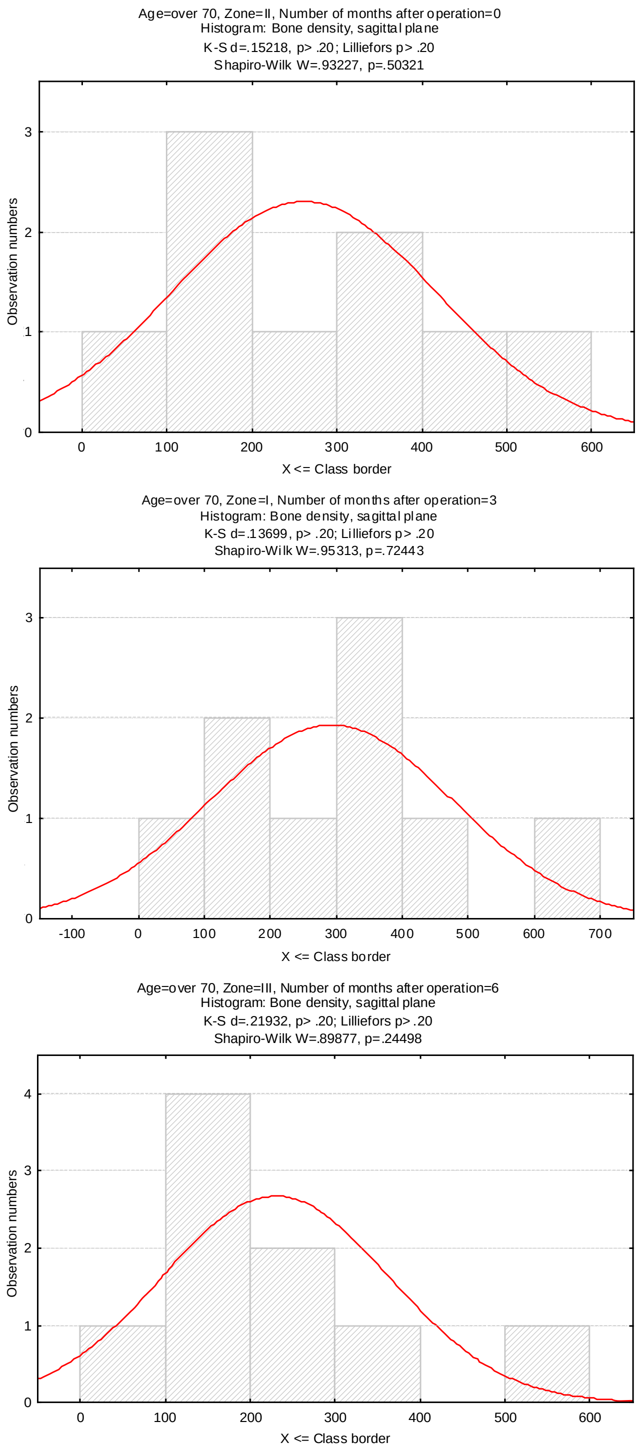

Fig. 2. Histograms of bone density in sagittal plane and results of normality tests. Grouping variable: measuring zones and number of months after operations

In order to evaluate normal distribution, Kolmogorov–Smirnov's, Lillefors' and Shapiro–Wilk's tests were used. Practice shows, however, that if the sample is fewer than 2 thousand cases, the last test is worth recommending the most. At an accepted significance level ($\alpha = 0.05$) the normal distribution hypothesis cannot be rejected. Example test results are shown in figure 2.

The variation analysis of bone density in individual measuring zones was done for all age groups. The results of the analysis at the significance level of 0.05 do not provide any basis to reject the null-hypothesis for equality of variances. This means that there is no significant differentiation in bone density in the patients examined in any measuring zone which applies to all three test periods (figure 3).

The division of the population into age groups allows a more detailed differentiation analysis. The highest differentiation in bone density was observed in two age groups: 60–70 and over 70. The highest differentiation in bone density in each measuring zone could be observed directly after the operation. In next periods the differentiation is lower, but at the same time bone density levels decrease in general. We observe here the effect of cooperation between the bone and the foreign body – the endoprosthesis. Example analysis results are shown in figure 4.

In order to test the bone reaction to the endoprosthesis, variance analysis was carried out in each age group (up to 60, 60–70, and over 70) as well as in each measuring zone after three test periods (0 – directly after operation, 3 months after, and 6 months after the operation). The results of the analysis for each age group are shown in figures 5–7.

The values of significance levels p allow the conclusion that bone density in the period right after the operation decreases slightly in each measuring zone analyzed. The biggest decrease was observed in age groups: 60–70 and over 70 in measuring zone I. The condition also maintains after 6 months although it is smaller. But in age group up to 60 after a decrease in bone density in the 3rd month, there is a slight increase in the 6th month after the operation.

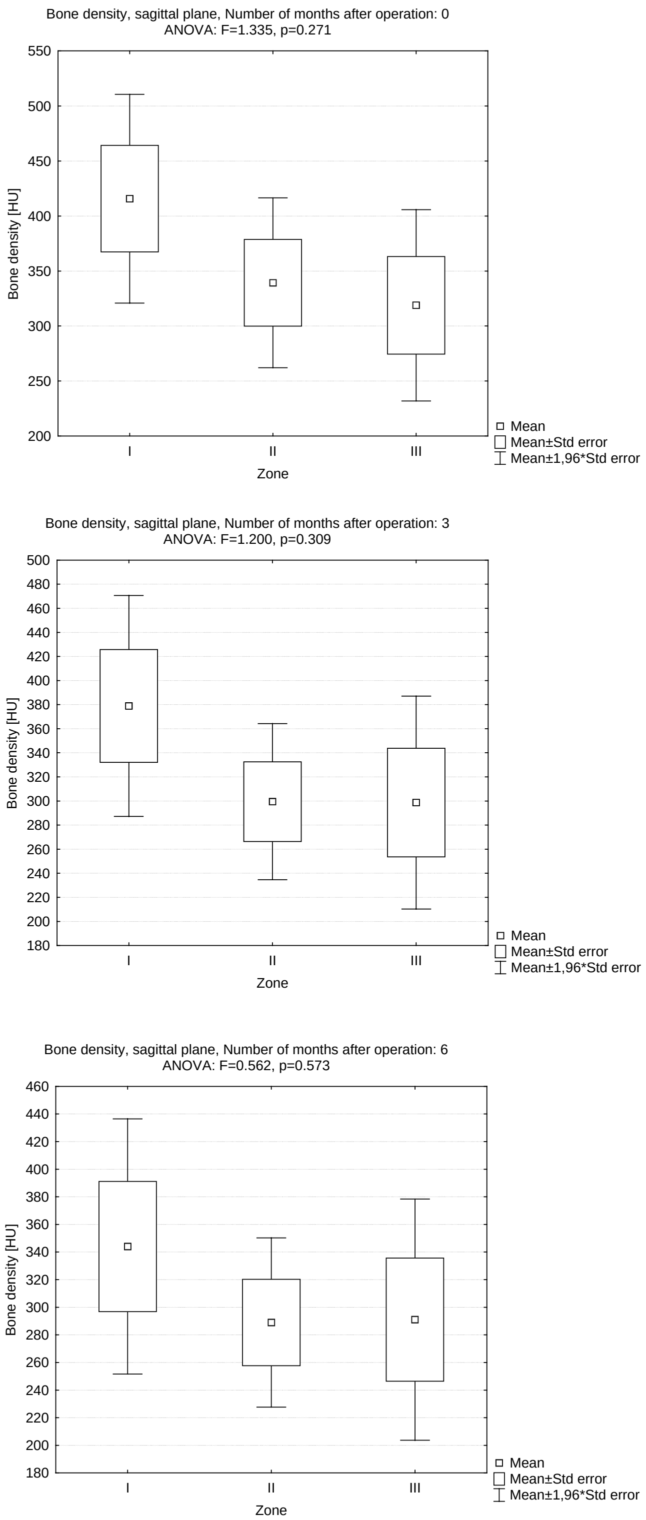

Fig. 3. Bone density measurement results in sagittal plane, in all age groups for three test periods

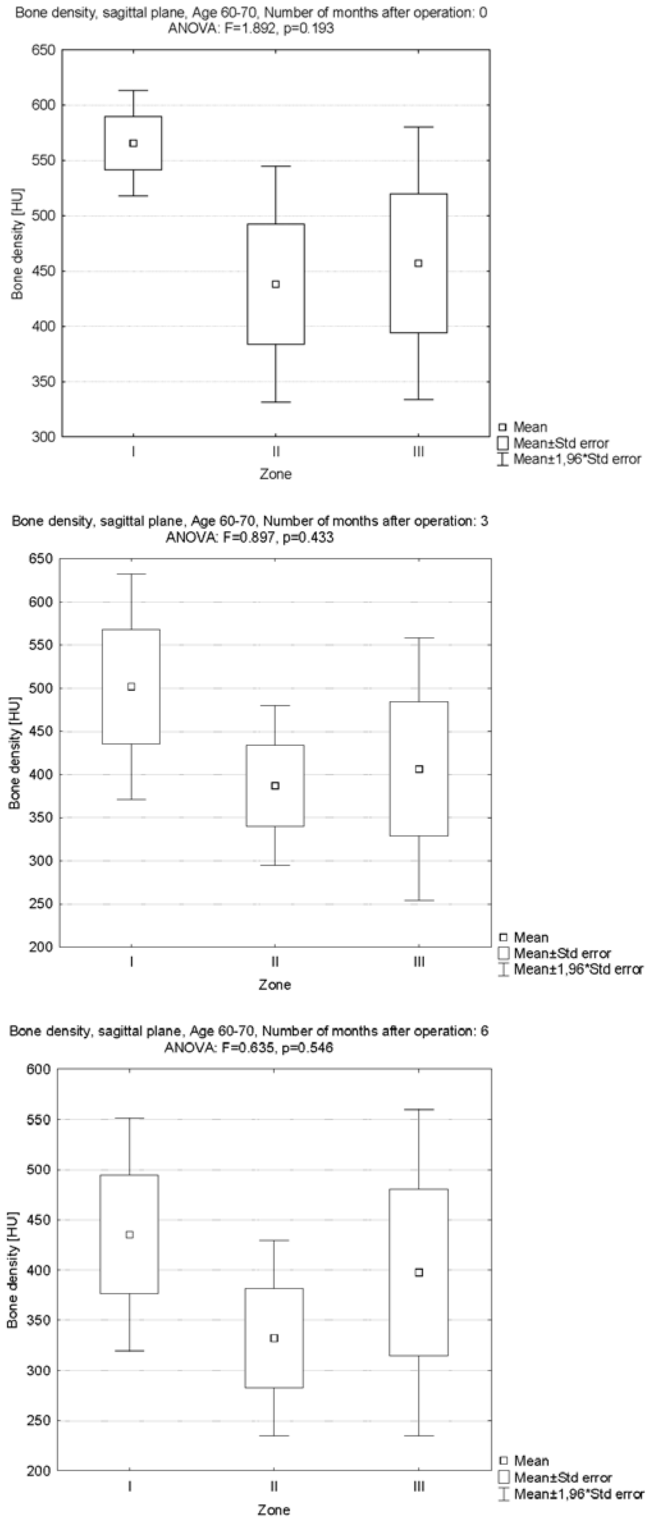

Fig. 4. Bone density measurement results in sagittal plane, in age group 60–70 for three test periods

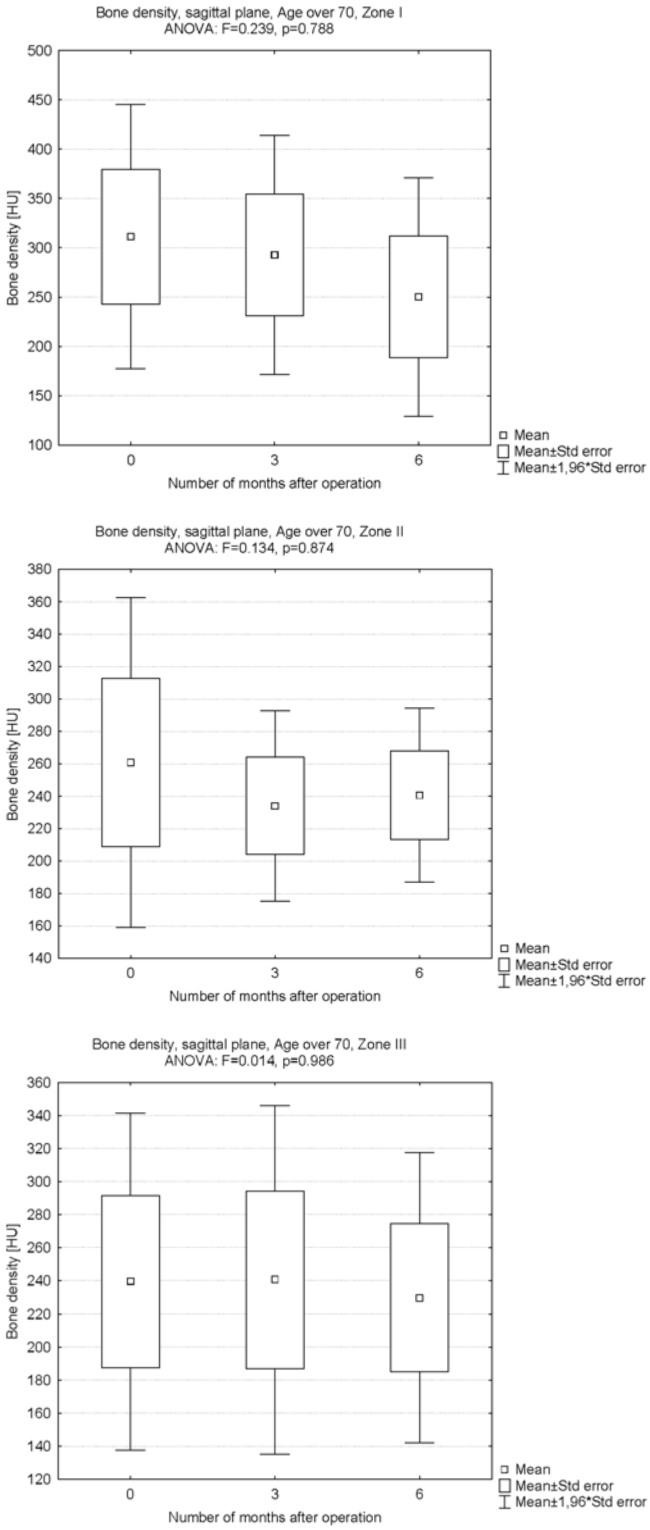

Fig. 5. Bone density measurement results in frontal plane, in age group over 70 for three test periods

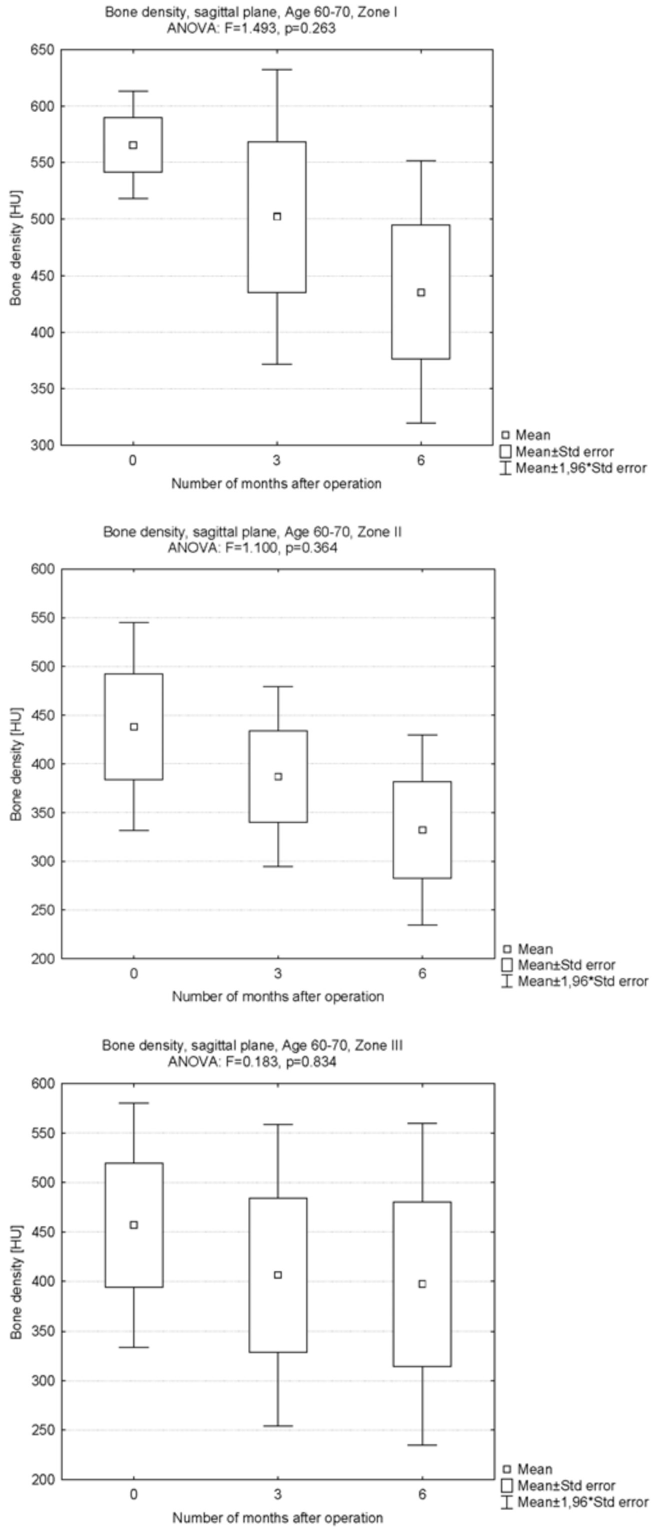

Fig. 6. Bone density measurement results in frontal plane, in age group 60–70 for three test periods

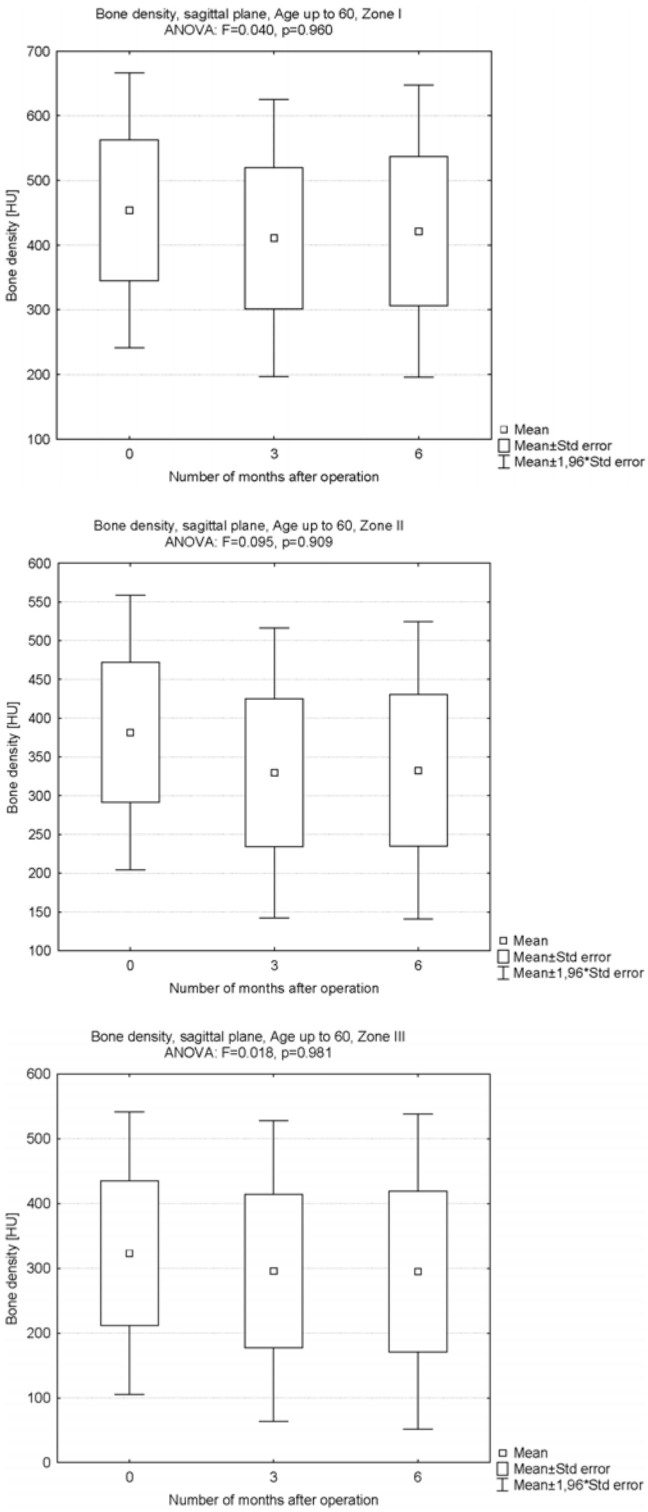

Fig. 7. Bone density measurement results in frontal plane, in age group up to 60 for three test periods

In order to complete the analysis, a non-parametric variance analysis was done and Friedman's test was used. The results of the analysis for each measuring zone are shown in figure 8. At an accepted significance level (0.05) no significant differences in bone density were observed in patients within three consecutive empirical periods (directly before, 3 months after, and 6 months after the operation).

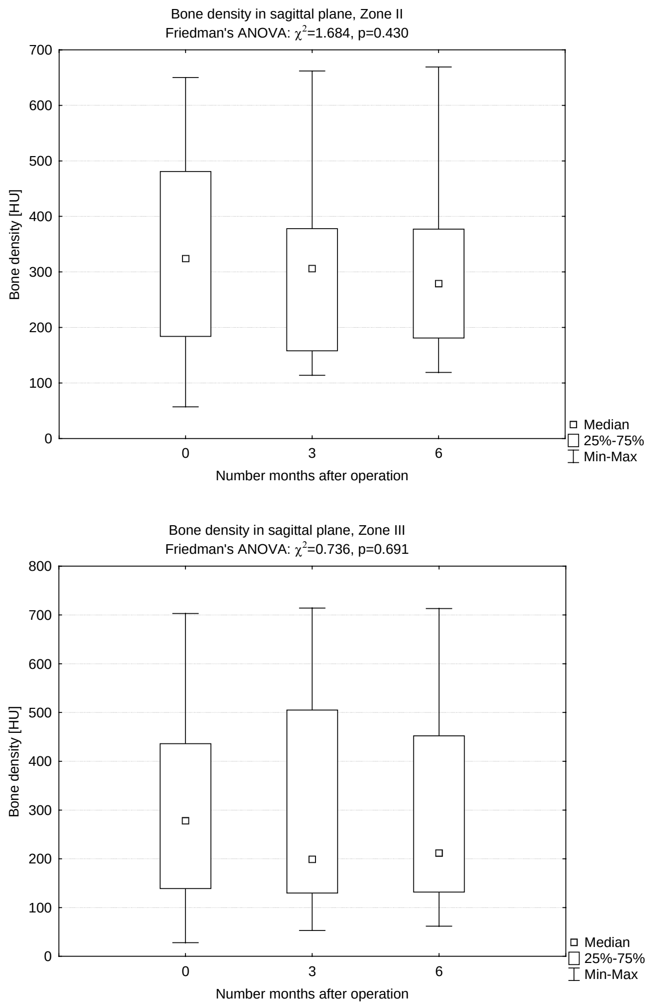

Fig. 8. Results of Friedman's non-parametric variance analysis for bone density measurements in sagittal plane, in each measuring zone for three test periods

6. Discussion

Total hip arthroplasty is an invasive procedure which consists in inserting into the human body a foreign body of the movable pair: an acetabular component with a head and a stem. Due to a commonly described in literature process of loosening endoprosthesis as a result of its wear it is extremely important to learn the factors that affect the process. A very important factor is certainly bone density in the implant area. Several authors [6], [7], [10], [13], [18], [19], [22] point out the fact that the highest dynamics of the bone structure remodelling and therefore the highest change in the bone density follow the period of the first few months after the procedure. This initial period – which can be called adaptive – is related to a dual remodelling: firstly – the bone structure adjusts to the inserted foreign body of the acetabular component and the stem, secondly – the abovementioned elements of the prosthesis – according to the wear rules – have to run in together and that results in the introduction of particles coming from collaborating surfaces of the tenon and the acetabulum (particles of metal, polyethylene and other). Migration of these substances to synovial cavity and to periarticular space stimulates the appearance and reproduction of macrofags which – as a consequence – are responsible for the process of osteolysis of the bone tissue around the implant [29]. According to YANG and others bone tissue resorption followed by activities of proteolitical enzymes – including lysosomal cathepsins – plays an important role in endoprosthesis loosening. They are liberated from macrofags, mainly from histiocytes and neutrophil granulocytes [31].

In order to thoroughly evaluate in vivo the remodelling of the bone structure, histopathologic tests should be done. These tests cause some discomfort to patients and besides are other forms of physical interference in the body. That is why efforts are made to evaluate the remodelling process of the bone tissue adjoining the stem or the cap based on the test results with the use of spiral computerized tomography. The tests performed by the authors give volumetric values of bone density expressed in Hounsfield units. The tests were carried out subsequently in three time periods: right before the operation, 3 months after, and 6 months after the operation. Bone density before the operation which was measured in three zones according to DeLee-Charnley constituted the reference level in relation to bone density in structural remodelling after the arthroplastic procedure [4].

The biggest differentiation in bone density was observed directly before the operation in all measuring zones. The differences were due to the age (ranging from 40 to over 70) and sex. Elderly people had lower bone density which is a physiological phenomenon. Also lower bone density was observed in woman in all measuring zones in relation to the same zones in men. However, the differences disappear along with time passing after the operation.

Another factor which significantly affects the initial differentiation in bone density in the persons examined is undoubtedly their lifestyle that decides how the hip joint is weighed down. Because of a very limited range of the article that factor was not taken into account.

Having observed clinical cases we may conclude that implantation of an artificial cap does not markedly affect bone density within 6 months after the operation. It causes neither violent reaction, radical decrease nor increase of the pelvic bone density. However, especially in the group of 60–70-year-olds, we can notice a significant decrease in density. Nevertheless, it decreases within 6 months after the operation which could be caused by bone tissue resorption described by YANG and others [31]. But what is interesting – in the group of patients under 60 years of age we can observe a slight increase in bone density. We can see it especially in the patients who were allowed to weigh down the operated hip joint quite early. Clearly a correlation was observed here between the amount of burdening and the increased bone density. The phenomenon is most probably based on Wolff law ("trabecular structure of bone tissue in balanced conditions adjusts to directions of main stress") [30]. Similar observations were also made by other authors, including DRAGAN [5], SCHMALZRIED, JASTY, HARRIS [20], VASU, CARTER, and HARRIS [22], WALL, DRAGAN [23], and WALL [24]. The adaptive modelling theory of bone structure is based on local mechanical stimulation. Contemporary endoprostheses are stiffer than the core bone and that is why they induce *stress shielding*, depriving certain areas of bone tissue of proper stress that is a mechanical stimulator of bone adaptation to changing environmental conditions. A physical symptom of a low level of reduced stress in the adaptation period (after the operation) is bone resorption especially visible in zone I.

Differences in bone density in the periods tested (after the operation) are not however statistically vital and that is why we should assume that the cap implantation itself does not interfere in physiological processes occurring in the pelvic bone tissue surrounding the artificial cap. To sum up, we can say that in the initial period (up to 6 months) we cannot notice a clear response of the bone tissue to the implant. The test results show that the body in the period within the first few months "mildly" models the bone structure around the prosthesis, restoring a stable value of bone density in the zones under analysis. In relation to prosthesis loosening, we should stress – after Harris – that we cannot explain all reactions only in terms of mechanical changes on the bone–implant joint (or bone–cement–implant). The condition of bone tissue around the endoprosthesis is determined by several factors of genetic nature, metabolic, endocrinological nature or its local personal qualities.

7. Conclusions

1. Tests carried out by spiral CT scan enable quantitative evaluation of structural changes around the cap–cement–bone layer.

2. An initial decrease of bone density in all the zones tested is strongly correlated with joint-burdening changes (bone tissue remodelling takes place at this time and is a response to stress values).

3. A few-month convalescence period and rehabilitation burdening the operated joint allow reconstruction of trabecular structure.

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