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# Impact of Zweymüller Stem Modification on Clinical and Radiological Outcomes

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### **Abstract**

**Background.** According to the analysis of large arthroplasty registers we have noted the increase in the use of noncemented implants, because the latter shows the same results of implant survival as well as cemented implants. On the other hand, they can affect the quality of the bone around the implant in different ways. These components differ in shape, length, and surface properties. According to the analysis of the arthroplasty register of the Vreden National Medical Research Center of Traumatology and Orthopedics, a significant decrease of the Alloclassic femoral stem using can be noted. In parallel the use of its SL-PLUS MIA modification has increased significantly.

**Aims of the study:** 1) to determine the influence of changes in the design of the Zweymüller-type femoral stem on midterm and long-term outcomes and its survival; 2) to identify the characteristics of adaptive remodeling of periprosthetic bone tissue around these femoral stems; 3) to determine risk factors for aseptic loosening of these femoral stems.

**Methods.** 492 cases of hip arthroplasty using the Alloclassic and SL-PLUS MIA femoral stems were observed, with an average follow-up 78.6 months. The patients were divided into 2 groups according to the type of femoral stem. The assessment the hip articulation condition was carried out using the HHS and OHS. The intensity of the pain syndrome was assessed by VAS, and the level of patient's satisfaction. The dynamic analysis of X-rays was also performed visually.

**Results.** A significant improvement in clinical and functional results was observed according to the HHS and OHS in both groups of patients, regardless of the type of femoral stem. Analysis of X-rays over time showed differences in the behavior of these two femoral component models. The radiolucent lines around the femoral stem are absent in SL-PLUS MIA group, in Alloclassic stem group radiolucent lines are present even at a minimal period (12 months). We also found that a tight fit of Zweymüller femoral stems in the distal shaft is a risk factor for severe stress-shielding syndrome, especially in the funnel channels. But ceteris paribus, a distal tight fit of SL-PLUS MIA stems despite similar geometry of the distal part does not lead to such frequent manifestation of severe stress shielding. **Conclusion.** The change in Zweymüller stem design from Alloclassic to SL-PLUS MIA improved the nature of adaptive remodeling in the periprosthetic area of the femur. It may improve the long-term results of primary hip arthroplasty, but these differences require closer observation.

**Keywords:** hip arthroplasty, Zweymüller-type femoral stems, stress-shielding syndrome, radiolucent lines, aseptic loosening.

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# Что изменила модификация бедренного компонента Zweymüller?

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#### Реферат

**Актуальность.** Анализ крупных регистров артропластики показывает, что наблюдается значительный рост использования бесцементных бедренных компонентов, так как современные конструкции показывают схожие результаты выживаемости как при цементной, так и при бесцементной фиксации. Однако эти компоненты различаются по форме, длине и свойствам поверхности, поэтому могут по-разному влиять на качество кости вокруг имплантата. Согласно данным регистра эндопротезирования НМИЦ ТО им Р.Р. Вредена, отмечается значительное уменьшение доли использования бедренного компонента Alloclassic, в то время как доля использования его модификации SL-PLUS МІА значительно увеличилась.

**Цели исследования:** 1) определить, влияет ли изменение дизайна бедренного компонента типа Zweymüller на среднесрочные и отдаленные результаты и его выживаемость; 2) определить особенности адаптивного ремоделирования перипротезной костной ткани в области имплантации этих бедренных компонентов; 3) определить факторы риска асептического расшатывания данных бедренных компонентов.

*Материал и методы.* Выполнен анализ 492 случаев энодопротезирования тазобедренного сустава с использованием компонентов Alloclassic и SL-PLUS MIA. Средний срок наблюдения — 78,1 мес. (МКИ 36,0–132,0). Пациенты были разделены на две группы в зависимости от типа бедренного компонента. Проведена клиническая оценка состояния тазобедренного сустава по шкалам Harris и OHS, дополнительно оценивались интенсивность болевого синдрома по VAS и уровень удовлетворенности пациентов результатами лечения. Также выполнен анализ рентгенограмм в динамике.

**Результаты.** Значительное улучшение клинико-функцональных результатов наблюдалось по шкалам HHS и OHS в обеих группах пациентов независимо от типа бедренного компонента. Анализ рентгенограмм в динамике по-казал различия в поведении этих двух моделей бедренного компонента. Линии рентгеновского просветления вокруг бедренного компонента отсутствовали при использовании бедренного компонента SL-PLUS MIA, а при использовании ножки Alloclassic присутствовали даже при минимальном сроке наблюдения (12 мес.). Фактором риска развития тяжелого стресс-шилдинг синдрома при использовании бедренных компонентов типа Zweymüller является плотная посадка в дистальной части ножки, особенно в воронкообразных каналах. Но при прочих равных условиях плотная дистальная посадка ножек SL-PLUS MIA, несмотря на схожую геометрию дистальной части, не приводит к столь частому проявлению тяжелого стресс-шилдинга.

**Заключение.** Изменение дизайна ножки типа Zweymüller из Alloclassic в SL-PLUS MIA позволило улучшить характер адаптивного ремоделирования перипротезной зоны бедренной кости, что, возможно, улучшит отдаленные результаты первичного эндопротезирования ТБС. Но данные различия требуют дальнейшего наблюдения.

**Ключевые слова:** эндопротезирование тазобедренного сустава, выживаемость эндопротеза, линии рентгеновского просветления, асептическое расшатывание бедренного компонента.



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# **BACKGROUND**

One of the trends in modern arthroplasty is the increasing frequency of using non-cemented implants in hip replacement, which is confirmed by the data of numerous arthroplasty registers<sup>1-6</sup> and scientific publications [1, 2, 3, 4, 5]. On the one hand, this is due to the fact that existing non-cemented prostheses show similar or even better survival results than cemented ones [4, 6, 7, 8]. On the other hand, the use of cemented implants, despite their relative cheapness, is associated with an increase in the surgery duration, which levels their economic attractiveness [6, 9].

Nowadays, there is a huge number of noncemented femoral stems of different geometry, which, due to their design features, transfer the load to the underlying bone in different ways, leading to formation of specific adaptive remodeling response [10, 11]. In some cases, the normal process of adaptive bone remodeling becomes negative, and leads to bone weakening and implant loosening [10, 12].

Analysis of hip arthroplasty register of the Vreden National Medical Research Center of Traumatology and Orthopedics has revealed a tendency towards gradual decrease in the proportion of straight wedge-shaped stems with a rectangular cross-section compared to proximally curved wedge-shaped stems fully coated with hydroxyapatite. In particular, the most commonly used Zweymüller (Alloclassic) femoral stems have become five and a half times less frequently used, with their share decreasing from 42.4% of all non-cemented stems in 2007 to 7.7% in 2018-2020. At the same time, the SL-PLUS MIA modification of this stem was used in only 0.8% of cases in 2014 (at the beginning of use) and in 2018-2020 - in 14,0% [5].

Aims of the study: 1) to determine the influence of changes in the design of the Zweymüller-type femoral stem on midterm and long-term outcomes and its survival; 2) to identify the characteristics of adaptive remodeling of periprosthetic bone tissue around these femoral stems;

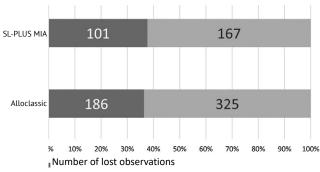
3) to determine risk factors for aseptic loosening of these femoral stems.

# **METHODS**

Hip arthroplasty register database contained 1580 cases of primary arthroplasty using two Zweymüller stem models: Alloclassic (Zimmer-Biomet) and SL-PLUS MIA (Smith+Nephew). Of these, only 779 observations had both pre- and postoperative X-rays. Of these cases, some observations were lost to complete analysis: 9 patients (11 observations) had died by the time of the study, and 269 patients (276 cases of hip arthroplasty) could not be contacted. Therefore, assessment of functional results and analysis of X-rays in dynamics were performed in 492 (63.2%) observations out of 779 at a mean time of 78.1 months (IQR 36.0-132.0; Me = 60.0: 12.0 to 180.0) (Fig. 1). Patients were operated by different surgical teams using different approaches and were divided into two groups according to the type of the stem.

Alloclassic stem was used in 37.3% of cases in men and 62.7% of cases in women, whereas SL-PLUS MIA stem was used in 25.3% of cases in men and 74.7% of cases in women (p = 0.012).

There was also a statistically significant difference in the frequency of stem use in complex cases of primary hip arthroplasty: Alloclassic stems were used in 80.3% of complex cases and 19.7% in stan-



Number of observations available for subsequent analysis

**Fig. 1.** Distribution of observations by the type of femoral stem

<sup>&</sup>lt;sup>1</sup> American Joint Replacement Registry, Annual report 2020, Available from: http://www.ajrr.net/publications-data/annual-reports.

<sup>&</sup>lt;sup>2</sup> Australian Orthopaedic Association. National Joint Replacement Registry, 2022 Annual Report. Available from: https://aoanjrr.sahmri.com.

<sup>&</sup>lt;sup>3</sup>National Joint Registry for England, Wales, Northern Ireland and the Isle of Man 19<sup>th</sup> Annual Report 2022. Available from: https://www.njrcentre.org.uk.

<sup>&</sup>lt;sup>4</sup>Norwegian Hip Arhtroplasty Register Annual Report 2021. Available from: http://nrlweb.ihelse.net.

<sup>&</sup>lt;sup>5</sup>Swedish Hip Arthroplasty Register. Annual Report 2021. Available from: https://registercentrum.blob.core.windows.net/slr/r/SAR-Annual-Report-2021-SJIAFmIRI5.pdf.

 $<sup>^6</sup> The German Arthroplasty Registry (EPRD-Endoprothesen register Deutschland). Annual Report 2020. Available from: \\https://www.eprd.de.com/error.de/error$ 

dard cases, while SL-PLUS MIA stems were used in 93.2% and 6.8%, respectively (p<0.001) (Tab. 1).

Follow-up period was statistically significantly longer when Alloclassic stems were used (p<0.001). Patients operated with SL-PLUS MIA stems had a follow-up period of 37.6 months (IQR 24.0-48.0: Me = 36.0: 12.0 to 84.0), while patients operated with Alloclassic stems had a follow-up period of 99.4 months (IQR 60.0 to 144.0; Me = 96.0: 24.0 to 180).

Clinical outcomes of hip arthroplasty were assessed according to the Harris Hip Score (HHS), the Oxford Hip Score (OHS) and the satisfaction index on a 10-point scale. Pain syndrome intensity was assessed by 10-point VAS.

To achieve the goals, we processed and analyzed X-rays of all patients before and after surgery using the "mediCAD® Classic" software (Sante Medical Systems, Russia).

The following quantitative parameters were measured on preoperative and postoperative pelvic X-rays:

- femoral offset,
- difference in limb length,
- Dorr index [13],
- degree of prosthetic filling in the three Gruen zones [13],
  - prosthesis axis/femoral axis angle.

Qualitative X-ray parameters were also evaluated:

- presence of stress-shielding syndrome and its severity according to the C. Engh classification [14],
- presence of radiolucent lines around the stem along the Gruen lines,
- presence of the cortical layer hypertrophy of the bone,
  - presence of pedestal [15].

Table 1 Distribution of observations by etiologic diagnosis, n (%)

		•	-	
Etiologic diagnosis		Alloclassic	SL-PLUS MIA	Total
Standard cases of arthroplasty	PHOA	105 (20.5)	16 (5.9)	121 (15.5)
	AONFH	20 (3.9)	10 (3.7)	30 (3.8)
	PFF	4 (0.7)	0 (0)	4 (0.5)
	Total	129 (25.1)	26 (9.6)	155 (19.8)
Complex cases of arthroplasty	DHOA	283 (55.3)	189 (70.5)	472 (60.6)
	Arthritis	25 (4.8)	12 (4.4)	37 (4.7)
	PTHOA	67 (13.1)	29 (10.8)	96 (12.3)
	Ankylosis	7 (1.7)	12 (4.7)	19 (2.6)
	Total	382 (74.9)	242 (90.4)	624 (80.2)
Total		511 (100)	268 (100)	779 (100)

PHOA — primary hip osteoarthritis; AONFH — aseptic osteonecrosis of the femoral head; PFF — proximal femur fracture; DHOA — dysplastic hip osteoarthritis; PTHOA — post traumatic hip osteoarthritis.

# Statistical analysis

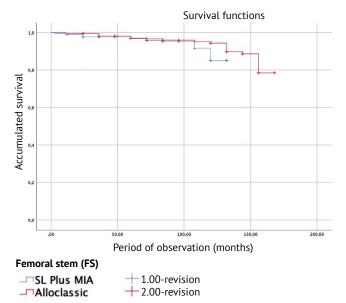
Statistical calculations were performed using the SPSS Statistic v. 26 (IBM) software. Methods of descriptive statistics were used. Taking into account the non-normal data distribution, in addition to mean values, the median (Me) was used to measure the central tendency for the studied parameters, and the lower (Q1) and upper (Q3) quartiles (25-75% IQR) were used as measures of dispersion. Minimum and maximum values in the data series were also indicated. Quantitative parameters in groups and

subgroups were compared using the Mann-Whitney U-test, and for multiple comparisons the method of single-factor analysis of variance (ANOVA test) was used. Comparison of the frequency characteristics of the parameters was performed using the nonparametric chi-square test, in case of a small number of observations with the Yates correction. Prediction methods were used for a number of parameters — calculation of odds ratios (OR). Survival rates for each type of the stem were determined using the Kaplan-Meier method.

# **RESULTS**

# Number of revisions and time of surgery

Twenty-eight out of 492 observations (64.1% of 779 observations included in the study) were performed between 2007 and 2020, representing 5.7% with an overall mean follow-up period of 7.7 years (IQR 3.5-11.5; Me = 7.5: 1.0 to 14.0). There were 23 revisions in the Alloclassic group (mean follow-up period was 93.3 months (IQR 36.0-132.0; Me = 108.0: 12.0 to 156.0), and 5 cases were noted in the SL-PLUS MIA group (mean follow-up period was 31.2 months (IQR 12.0-



**Fig. 2.** Survival of endoprostheses according to the Kaplan-Meier method

54.0; Me = 24.0: 12.0 to 60.0). Despite the higher number of revisions in the group of patients with the Alloclassic stem, this difference was not statistically significant (p = 0.095) (Table 2). The 10-year Kaplan-Meier prosthesis survival rate with the endpoint "revision for any reason" was 92.8% (Fig. 2).

Given the difference in the follow-up periods, the structure of reasons for revision differed between the patient groups (Table 2). When using the SL-PLUS MIA stem, there were no revisions associated with aseptic loosening of the components, and aseptic loosening of the Alloclassic stem was noted in 6 (1.8%) cases.

# **Functional state of patients**

The vast majority of patients had a significant improvement in hip function after surgery, expressed in an increase of the HHS compared to the preoperative level. Preoperatively, the mean HHS was 42.0 points (IQR 36.0-46.0; Me=43.0:24.0to67.0), and after surgery-93.1 points (IQR 91.5-96.0; Me = 94.0: 72.0 to 98.0) (Fig. 3).

Patients with the Alloclassic stems had a mean HHS of 93.1 (IQR 92.0-96.0; Me 94.0: 72.0 to 98.0) and those with the SL-PLUS MIA stems had a mean HHS of 93.3 (IQR 91.0-97.0; Me = 95.0 (72.0 to 98.0; p = 0.001).

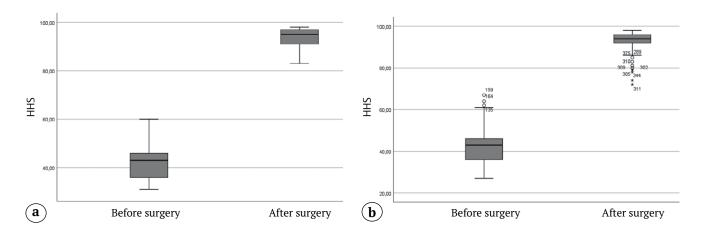
Distribution of the OHS was similar: patients operated with the Alloclassic femoral stem had a mean score of 44.7 (IQR 43.0-47.0; Me = 46.0: 36.0 to 48.0), and patients with the SL-PLUS MIA femoral stem had a mean score of 44.3 (IQR 42.0-47.0; Me = 46.0: 35.0 to 48.0; p<0.001).

Reasons for revision in groups with different stems

Table 2

Cause of revision	Alloclassic (n = 325)	SL-PLUS MIA (n = 167)	Всего (n = 492)
FS aseptic loosening	6 (1.8)	0 (0)	6 (1.2)
AC aseptic loosening	4 (1.2)	0 (0)	4 (0.8)
Prosthesis dislocation	5 (1.5)	2 (1.2)	7 (1.4)
Infection	6 (1.8)	1 (0.6)	7 (1.4)
Periprosthetic fracture	0 (0)	0 (0)	0 (0)
Muscle weakness	1 (0.3)	1 (0.6)	1 (0.2)
Pain syndrome	1 (0.3)	1 (0.6)	1 (0.2)
Total	23 (7.1)	5 (3.0)	28 (5.7)

FS – femoral stem; AC — acetabular component.



**Fig. 3.** Average score on the HHS before and after surgery: a - Alloclassic; b - SL-PLUS MIA

Despite statistically significant differences in functional scale scores, there was no significant difference in clinical outcomes. A high level of patient satisfaction index was obtained in both groups with no statistically significant difference between the groups (p = 0.059). Patients operated with the use of the Alloclassic femoral stem had a mean satisfaction index of 9.0 (IQR 8.0-10.0; Me = 10.0: 4.0 to 10.0) and with the use of the SL-PLUS MIA - 8.6 (IQR 8.0-10.0; Me = 9.0:3.0 to 10.0). The mean VAS pain score of the patients with the Alloclassic femoral stem was 1.0 points (IQR 0.0-2.0; Me = 0: 0 to 8.0) and that of the patients with the SL-PLUS MIA stems was 1.6 points (IQR 0.0-2.0; Me = 1.0: 0 to 8.0; p = 0.404).

# X-ray signs of adaptive bone tissue remodeling around femoral stems

During the studied period of observation when Alloclassic femoral stem was used in 108 (33.2%) cases, hypertrophy of the cortical layer was detected in the Gruen zones 2-6. The most pronounced changes were observed in the zones 3 and 5. Pedestal formation in the distal part of the stem was observed in 101 (30.1%) cases. When the SL-PLUS MIA stem was used, hypertrophy of the cortical layer around the implant was observed only in 24 (14.3%) cases, and the pedestal was formed only in 28 (16.7%) cases. However, this discrepancy may be accounted for the differences in the follow-up time, as the degree of adaptive remodeling of the bone around the prosthetic stem became more distinct over time (Pearson's positive correlation R = 0.470; p<0.001).

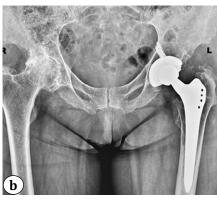
At the long-term follow-up, rather significant stress shielding (3-4 degrees) was detected in 39 cases. The third degree was detected in 27 cases out of 325 (8.3%) in patients with the Alloclassic stems (mean follow-up period 74.4 months (IQR 63.0-97.0), in patients with the SL-PLUS MIA stems — in 2 cases out of 167 (1.2%) (mean follow-up period 55.5 months). In other 10 (3.1%) observations, grade 4 stress shielding was noted when the Alloclassic stems were used (Fig. 4, 5).

In these cases, the mean follow-up period was 117.0 months (IQR 96.0-138.0). No significant bone remodeling was observed in our study when using the SL-PLUS MIA femoral stem, probably due to considerably shorter follow-up periods (Table 3).

The time since surgery was the most significant factor in the development of stressshielding syndrome. Odds ratio for detecting grade 2-4 stress-shielding syndrome at followup of 48 months or more was OR 5.662 (95% CI: 3.171-10.113; p<0.001). However, there are other factors, including anatomical features of the femur and technical details of the femoral stem implantation. A funnel-shaped canal (Dorr type A) has been found to be a risk factor for the development of more pronounced stress-shielding syndrome (grades 2-4). Correlation between the canal type and the severity of stress-shielding syndrome is demonstrated using the chisquare test. Chi-square value is 55.853, which indicates a highly statistically significant correlation (p<0.001) (Table 4).

Another factor affecting the development of stress-shielding syndrome is the way the femo-







**Fig. 4.** A 66-year-old patient in 2008 underwent left THA for primary idiopathic hip arthritis. The canal fill index in the  $1^{st}$  zone was 0.63, and in the  $2^{nd}$  and  $3^{rd}$  zones, it was 1.0 (a).

At the time of the survey, the patient's satisfaction was 10 points, and VAS pain score was 0. X-rays taken 13 years later show signs of stress shielding syndrome of the 4th degree, characterized by thinning of the inner and outer cortical layers to the femoral diaphysis (b).

X-rays also reveal areas of osteolysis in the proximal part of the femur, especially clear up to the level of the lesser trochanter, and osteolysis areas in the screw region in the retroacetabular zone, as well as heterotopic ossification in the area of the greater trochanter (Brooker 1-2). The enlarged X-ray visualizes bone loss (atrophy) without clear boundaries, while preserving the trabecular structure, especially at the border with the implant. The bone in this case does not exhibit focal deformations typically seen in osteolytic changes. This is because the mechanism of bone loss is related stress bypass in the distal direction, consequently resulting in reduced loading bone in the proximal regions (c)





**Fig. 5**. A 40-year-old patient in 2014 underwent left THA for dysplastic hip arthritis, with a canal fill index of 0.63 in the 1<sup>st</sup> zone, 0.79 in the 2<sup>nd</sup> zone, and 1.0 in the 3<sup>rd</sup> zone (a). At the time of the survey, the patient was satisfied with 10 points, and VAS pain score was 0. X-rays taken 6 years later show signs of stress shielding syndrome of the 3<sup>rd</sup> degree, characterized by thinning of the inner cortical layer below the level of the lesser trochanter (b)

ral stem fills the canal. Tighter fit in the distal third of the stem is a risk factor for the development of more severe stress-shielding syndrome. If the canal filling index with Zweymüller stems (Alloclassic and SL-PLUS MIA) is greater than the mean value for the respective component type, the risk of grade 2-4 stress-shielding syndrome is higher than that with a filling index less than the mean value (OR = 3.166; 95% CI: 2.02-4.96; p<0.001) (Table 5).

In 49 (15.1%) observations when the Alloclassic femoral stem was used, the presence of radiolu-

cent lines along the stem of the prosthesis, more pronounced in the proximal region, was detected. No such lines were found when using the SL-PLUS MIA stem.

In our study, we could not detect the intensity and localization of radiolucent lines depending on the varus-valgus position of the stem (Table 6). However, the presence of radiolucent lines may be a sign of gradual loosening of the femoral stem. Odds ratio for aseptic loosening of the Alloclassic stem in the presence of radiolucent lines is OR 12.178 (95% CI: 2.167-68.446; p = 0.003) (Fig. 6).

 ${\it Table~3}$  Severity of stress-shielding syndrome depending on the femoral stem and its position

Femoral stem	Position in the canal		Tatal				
		0	1	2	3	4	Total
Alloclassic	Varus	9	55	20	8	3	95
	Neutral	12	108	17	12	7	156
	Valgus	8	47	12	7	0	74
	Total	29	210	49	27	10	325
SL-PLUS MIA	Varus	6	31	12	0	0	49
	Neutral	10	48	20	2	0	78
	Valgus	5	23	12	0	0	40
	Total	21	102	42	2	0	167
Total		50	312	91	29	10	492
Follow-up period	, mos.	17.2 28.1 65.7 95.9 103.1					

 ${\it Table~4}$  Severity of stress-shielding syndrome depending on the Dorr index

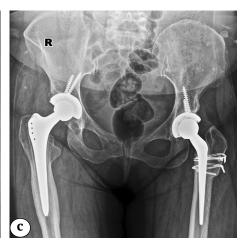
	D .		m . 1				
Femoral stem	Dorr type	0	1	2	3	4	Total
Alloclassic	Dorr A	1	65	28	17	6	117
	Dorr B	10	126	20	8	4	168
	Dorr C	18	19	1	2	0	40
	Total	29	210	49	27	10	325
SL-PLUS MIA	Dorr A	3	23	26	2	0	54
	Dorr B	6	70	15	0	0	91
	Dorr C	12	9	1	0	0	22
	Total	21	102	42	2	0	167
Total		50	312	91	29	10	492

Table 5
Localization of stress-shielding syndrome depending on the degree
of canal filling at different levels

Femoral stem	Zono Dogress of gonal filling		Se	m 1				
	Zone Degree of canal filling	0	1	2	3	4	Total	
Alloclassic	1	<0.6	6	36	11	14	6	73
		≥0.6	23	174	38	13	4	252
	2	<0.79	19	99	29	11	2	160
		≥0.79	10	111	20	16	8	165
	3	<0.92	32	91	13	4	0	140
		≥0.92	7	109	36	23	10	185
SL-PLUS MIA	1	<0.6	4	36	7	2	0	49
		≥0.6	17	66	35	0	0	118
	2	<0.79	12	65	20	2	0	99
		≥0.79	9	37	22	0	0	68
	3	<0.90	19	42	15	0	0	76
		≥0.90	2	60	27	2	0	91
Total			50	312	91	29	10	492









**Fig. 6.** A 49-year-old patient: bilateral hip dysplasia with high dislocation of the left hip (C2 according to Hartofilakidis) and low dislocation of the right hip (B2 according to Hartofilakidis). In June 2011, left THA was performed with a shortening osteotomy according to Paavilaainen. In March 2012, right THA was performed (a).

On follow-up X-rays in February 2014, radiolucency lines are already detected in zones 1, 2, 6, and 7 of Gruen (b). However, until the beginning of 2020, there were no clinical manifestations of femoral component loosening. On X-rays in September 2020, the radiolucency lines became more pronounced (c), and the patient complained of hip pain after loading. Revision of the femoral component was performed (d)

Table 6 Localization of radiolucent lines around the femoral stem depending on its position in the canal and possible association with aseptic loosening

Femoral stem		No	Localizat	m . 1			
	Position in the canal	lines	1 zone	2 zones	3 zones	4 or more zones	Total
Alloclassic	Varus	79	6	4	4	2	95
	Neutral	137	2	10	1	6	156
	Valgus	60	1	6	1	6	74
	Total	276	9	20	6	14	325
Revision due to F	Revision due to FS aseptic loosening		1	0	0	3	6
SL-PLUS MIA	Varus	49	0	0	0	0	49
	Neutral	78	0	0	0	0	78
	Valgus	40	0	0	0	0	40
	Total	167	0	0	0	0	167
Revision due to FS aseptic loosening		0	0	0	0	0	0

# Correlation between radiologic signs, functional scale scores and patient satisfaction

Presence of radiolucent lines in case of patients with the Alloclassic stem was accompanied by reduced functional scores according to all scales compared to patients who did not have radiolucent lines. The average level of pain syndrome in these patients was higher, and the degree of satisfaction with the results of the surgery was lower. This difference was highly statistically significant for all parameters (Table 7).

Table 7
Correlation between the presence of radiolucent lines, patients' functional state according to the OHS and HHS scales, VAS pain score and satisfaction index in the Alloclasic group

Scale	Radiolucent	Statistical values						
	lines	Mean value	Me	IQR 25-75%	Min–Max			
HHS	Yes	87.8	89.0	87.0-90.0	72.0-97.0			
	No	94.3	94.0	94.0-95.0	87.0-97.0			
OHS	Yes	41.9	42.0	40.0-43.0	36.0-48.0			
	No	44.9	46.0	45.0-47.0	36.0-48.0			
VAS	Yes	3.1	3.0	2.0-4.0	0.0-7.0			
	No	0.4	0.0	0.0-0.0	0.0-6.0			
Satisfaction index	Yes	7.9	8.0	7.0-9.0	6.0-10.0			
	No	9.3	10.0	9.0-10.0	6.0-10.0			

Group values for all scales are highly statistically significantly different in all groups (p<0.001).

# **DISCUSSION**

This retrospective study showed that the wedge-shaped non-cemented rectangular stems developed by Karl Zweymüller provide reliable long-term results. Survival rate for revision for aseptic loosening of the Alloclassic stems was 98.2% at a mean follow-up period of 166.3 months and 100% for the SL-PLUS MIA stems at 37.5 months. Both types of stems had high HHS and OHS values and high patient satisfaction index independent of the stem design. This is consistent with the generally accepted notion of a high efficacy of primary total hip arthroplasty using non-cemented rectangular wedge-shaped stems [16, 17, 18, 19].

Analysis of X-rays in dynamics showed that the development of the classical phenomenon of stress-shielding syndrome (as described by C. Engh [14]) depended on the time elapsed since the arthroplasty, but was observed in a number of patients already 12 months after surgery. Similar changes were observed by other researchers [20, 21]. According to our data, the risk factor for

the development of severe stress-shielding syndrome when using Zweymüller stems is a tight fit in the distal part of the stem (canal filling index in the Gruen zone 3 is 0.98 and more), especially in combination with a funnel-shaped canal (Dorr type A). However, all other things being equal, the tight distal fit of the SL-PLUS MIA stems, despite the similar geometry of the distal part, does not lead to such a frequent manifestation of severe stress-shielding syndrome. According to S. Nakamura et al., bone loss around the Zweymüller stems does not depend on the peculiarities of the femoral anatomy, but the follow-up period in their work did not exceed 12 months. [21].

Other unfavorable variants of bone remodeling are radiolucent lines at the prosthesis-bone interface [22]. Appearance of this phenomenon also depended on the follow-up period, but it was observed only in patients with the Alloclassic stem. Mean follow-up period in the group with the presence of radiolucent lines was 103.5 months in patients with the Alloclassic stem,

with a minimum follow-up period of 12 months, and 76.2 months in patients with no radiolucent lines. Mean follow-up period with the SL-PLUS MIA stem was 35.4 months, which is significantly shorter than the mean period with the Alloclassic stem and does not exclude the development of this phenomenon in the future. At the same time, the minimum term at which the lines are detected is 12 months. It is possible that the absence of this phenomenon in the group with the SL-PLUS MIA stems is due to the peculiarities of its design, in particular, the presence of hydroxyapatite coating in the proximal part, especially since the maximum follow-up period of these stems in our study is 60 months. Probable influence of the hydroxyapatite coating in the proximal part of the stems is also confirmed by a comparative study by A. Tanaka et al. in which they found radiolucent lines when using the SL-PLUS MIA stems with hydroxyapatite in comparison with the SL-PLUS MIA stems without hydroxyapatite, in which lucent lines were found in 6% of cases [23]. On the other hand, D. Hoornenborg et al. did not observe a positive effect of hydroxyapatite coating on Zweymüller stems with regard to their possible migration [24, 25].

In our study, we have found out that the presence of radiolucent lines can negatively affect the functional outcome and postoperative patient satisfaction, but the presence of radiolucent lines in three or more Gruen zones is an independent risk factor and an important predictor of aseptic loosening of the stem.

It appears that despite the high survival rates, Alloclassic stems are less predictable in terms of stress remodeling of the periprosthetic femoral region, and under unfavorable circumstances (funnel-shaped canal and tight distal fit) there is an increased risk for aseptic loosening in the distant period. According to the results of our study, the redesign of the proximal part of the Zweymüller stem implemented in the SL-PLUS MIA stem improved the nature of adaptive remodeling in the periprosthetic zone of the femur, possibly improving the long-term results of primary hip arthroplasty. However, longer follow-up periods are required to make a definitive judgment about the possible benefits of the SL-PLUS MIA stem.

#### **DISCLAIMERS**

# Author contribution

*Shubnyakov I.I.* — study concept and design, drafting the article.

*Riahi A.* — study concept and design, data collection and processing, writing the article.

*Sereda A.P.* — data analysis and interpretation, drafting the article.

*Cherkasov M.A.* — data collection and processing. *Khujanazarov I.E.* — study concept and design, drafting the article.

*Tikhilov R.M.* — study concept and design, drafting the article.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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