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## **Comparative Evaluation of Custom-made Components** and Standard Implants for Acetabular Reconstruction in Revision Total Hip Arthroplasty

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CLINICAL STUDIES

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#### Abstract

*Background.* The use of custom-made acetabular components is one of the promising methods for reconstruction of the acetabulum in cases of significant defects, including those associated with pelvic bone dissociation. It allows achieving stable fixation and restoring the biomechanics of the hip joint.

*Aim of the stud*y - to compare the results of individually designed components, supportive antiprotrusion rings, augments, and hemispherical components in revision total hip arthroplasty for type IIIB bone defects according to Paprosky classification.

*Methods.* The study analyzed the treatment outcomes of 90 patients with type IIIB bone defects who underwent revision total hip arthroplasty between 2017 and 2022. Patients were divided into three groups: the first group received individually designed acetabular components, the second group received augments with hemispheres, and the third group had antiprotrusion cages implanted. The analysis included the reasons for revision surgery, operation duration, blood loss volume, and type of revision procedure. Pain and functional outcomes were assessed with WOMAC, Harris Hip Score, and VAS.

**Results.** Constructs were more frequently implanted in patients with pelvic bone dissociation. The first group showed a significantly positive dynamic in functional outcomes. Complications were diagnosed in 27 (30%) cases: joint instability (dislocation) in 10 (11.1%) patients, periprosthetic infection in 8 (8.8%), aseptic loosening in 4 (4.4%), and sciatic nerve neuropathy in 5 (5.5%) patients. The number of these complications was higher in the second and third groups of patients.

*Conclusion.* Custom-made implants using 3D technologies are a preferable option for revision total hip arthroplasty in patients with type IIIB defects according to Paprosky classification, especially in cases of pelvic discontinuity.

**Keywords:** revision total hip arthroplasty, acetabular defects, pelvic discontinuity, custom-made acetabular components, 3D printing.

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## Сравнительная оценка использования индивидуальных 3D-компонентов и стандартных имплантатов для реконструкции вертлужной впадины при ревизионном эндопротезировании

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#### Реферат

*Актуальность.* Использование индивидуальных вертлужных 3D-компонентов является одним из перспективных методов реконструкции вертлужной впадины при ее значительных дефектах, в том числе сопровождающихся диссоциацией костей таза, позволяет добиться стабильной фиксации и восстановить биомеханику тазобедренного сустава.

**Цель исследования** — сравнить результаты применения индивидуально изготовленных 3D-компонентов, опорных антипротрузионных колец, аугментов и гемисферических компонентов в ревизионном эндопротезировании тазобедренного сустава при костных дефектах типа IIIB по классификации W.G. Paprosky.

*Материал и методы*. Проведен анализ результатов лечения 90 пациентов с костными дефектами типа IIIB, которым выполнялось ревизионное эндопротезирование тазобедренного сустава в период с 2017 по 2022 г. Пациенты были разделены на три группы: в первой группе имплантировали индивидуальные 3D-компоненты вертлужной впадины, во второй группе — дефекты компенсировали аугментами и/или гемисферическим компонентом, в третьей группе устанавливали антипротрузионные кольца. Анализ был выполнен по следующим параметрам: причины ревизионного вмешательства, продолжительность операции, объем кровопотери, тип ревизионного вмешательства. Оценку выраженности болевого синдрома и функциональных результатов проводили с помощью шкал WOMAC, Harris Hip Score, BAШ.

**Результаты.** 3D-конструкции чаще импланировали пациентам с диссоциацией костей таза. Установлена выраженная положительная динамика функциональных результатов в первой группе. После выполненных ревизионных вмешательств диагностировано 27 (30%) осложнений: нестабильность в суставе (вывих) у 10 (11,1%) пациентов, перипротезная инфекция — у 8 (8,8%), асептическое расшатывание компонентов — у 4 (4,4%), нейропатия седалищного нерва — у 5 (5,5%) пациентов. Количество осложнений было больше во второй и третьей группах пациентов.

*Заключение.* Изготовленные с использованием 3D-технологий индивидуальные компоненты являются приоритетным вариантом при ревизионном эндопротезировании у пациентов с дефектами типа IIIB по классификации W.G. Paprosky, особенно с диссоциациями костей таза.

Ключевые слова: ревизионное эндопротезирование тазобедренного сустава, дефекты вертлужной впадины, нарушение целостности тазового кольца, индивидуальные вертлужные компоненты, 3D-печать.

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### BACKGROUND

Over the last two decades, there has been a significant increase in the number of primary large joint arthroplasties, leading to an escalated need for surgical revision [1, 2, 3, 4]. The reconstruction of the acetabulum in defects IIC, IIIA, and IIIB according to the W.G. Paprosky classification, especially when accompanied by disruption of the pelvic ring, poses a complex challenge [5, 6]. A wide range of standard implants is necessary to restore the acetabular area with substantial bone defects [7]. Currently, numerous surgical options and techniques for utilizing standard revision implants exist; however, achieving their prolonged survival is not always successful [8]. The use of individually customized acetabular components stands out as one of the most effective approaches for reconstructing the acetabular defect with significant bone loss [9, 10, 11]. The application of 3D-printed components in cases of extensive bone defects, coupled with pelvic bone dissociation, not only ensures stable fixation but also restores the biomechanics of the hip joint [12, 13].

*The aim of this study* was to compare the outcomes of using customized components, supportive antiprotrusionn rings, augments, and/or hemispherical components in revision total hip arthroplasty for type IIIB bone defects according to the Paprosky classification.

## **METHODS**

## Study design

A prospective cohort study was conducted from 2017 to 2022. The treatment outcomes of 90 patients with type IIIB bone defects who underwent revision total hip arthroplasty were analyzed.

Inclusion criteria:

• loosening of the acetabular component of the hip joint replacement with a type IIIB bone defect according to the Paprosky classification;

• second-stage treatment of periprosthetic infection (PJI) (spacer removal, implantation of prosthetics components).

Exclusion criteria:

• HIV infection, drug addiction, mental disorders;

• deep PJI of the hip joint;

• severe somatic pathology requiring active correction and contraindicating for surgical treatment or significantly increasing operative risk;

• patients with PJI and presence of the sinus tract;

• decompensation of somatic pathology before surgical treatment.

All patients were divided into three groups. The first group comprised 30 (33.3%) individuals who received individually customized acetabular components; the second group included 30 (33.3%) patients in whom defects were compensated with augments and/or hemispherical components; the third group consisted of 30 (33.3%) patients who received antiprotrusion supportive rings.

The indication for revision total hip arthroplasty was aseptic loosening of prosthetics components or the second stage of revision surgery for PJI.

Comprehensive preoperative assessments of all patients were conducted in accordance with the recommendations of the II International Consensus Meeting on Musculoskeletal Infection, including:

• clinical examination;

• evaluation of pelvic and hip joint x-rays;

• assessment of blood parameters: ESR and C-reactive protein;

• joint aspiration for microbiological and cytological analysis [4].

# Customized acetabular component manufacturing

For 3D reconstruction of the pelvis and its defects, a three-dimensional CT scan with slices no thicker than 0.6 mm and taken within two weeks was used. Subsequently, the CT scans were sent to a design engineer, who generated a 3D model of the pelvic defect and created a trial component model using PME Planner software (MEDTEK, Russia) (Fig. 1a, b).

Collaboratively with the surgeon, a 3D model of the component was created to assess potential implant-bone contact, determine directions for fixing screws, and identify the center of hip rotation. An anteversion angle of 25° and an inclination angle of 45° were chosen (Fig. 1c). To better comprehend existing bone defects within the acetabular area, tactile 3D pelvic models were created in a 1:1 scale. These models allowed analysis of the patient's pathological hip joint anatomy, accurate classification of bone defects, and more precise positioning of the implant (Fig. 2).

To enhance osteointegration, a porous structure was applied at the "implant-bone" interface, with beam thickness ranging from 0.45 to 0.50 mm. Additional recesses were created on the inner surface of the acetabular compo-

nent to accommodate the caps of 6.5 mm diameter cancellous bone screws, with a depth not exceeding 0.2 mm. To monitor the lower edge of the acetabulum and facilitate positioning of both the trial model and the actual component, a depression up to 1.5 cm in diameter was requested from the manufacturers at the "6 o'clock" position (Fig. 3). The inner part of the component was designed for implanting the acetabular cemented component. We used personalized implants customized by LLC "TIOS" (Russia).

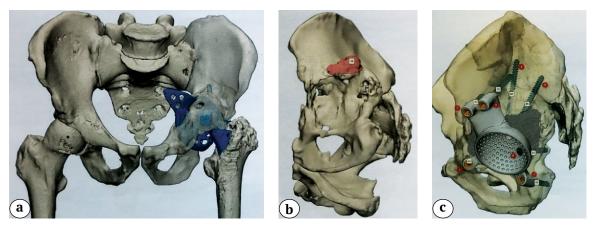


Fig. 1. Preoperative digital planning based on 3D visualization:

a – evaluation of acetabular bone defect before component removal;

b - evaluation of acetabular bone defect after component removal (the red area indicates the portion

to be removed for accurate positioning of the implant component);

 $\mathbf{c}-\mathbf{fixation}$  of the custom-made acetabular component with screws



Fig. 2. Tactile 3D model of the pelvis at a 1:1 scale



**Fig. 3.** Custom-made pelvis fragment, component, and trial model of the acetabulum. The red circle indicates an additional recess at "6 o'clock" for optional orientation during implant positioning

## Surgical technique

After preliminary preparation, the operative treatment was carried out. For patients who received individually customized constructs, an anterior-lateral approach to the hip joint was used, but in the absence of proximal femur access, it was shifted to a lateral approach. After removal of the prostetic components, wound debridment was performed using antiseptic solutions delivered through the Pulsavac system (ZimmerBiomet). Subsequently, the acetabular area was prepared, a bed for the personalized component was formed, and the 3D model was tried on using a trial component and within the wound. The congruence and stability were assessed (Fig. 4).

The implantation of the individual acetabular component followed (Fig. 5). The customized implant was secured using 6.5 mm diameter screws, with lengths from 30 to 80 mm, in accordance with preoperative planning results.

It's noteworthy that during model formation, the designers only evaluated the presence of bone tissue. However, often soft tissues act as an interponent, adding difficulties for positioning and installing the 3D model. Therefore, meticulous preparation of the bed is essential for accurate component implantation. Postoperatively, all patients underwent control radiography, and at 3 months, CT scans were performed to assess the stability and positioning of the implanted components (Fig. 6).

At 3, 6, and 12-months post-surgery, radiographic evaluations were conducted in three zones of the acetabulum according to the DeLee-Charnley lines of radiolucency [14], in order to assess stability and potential loosening of the implants.

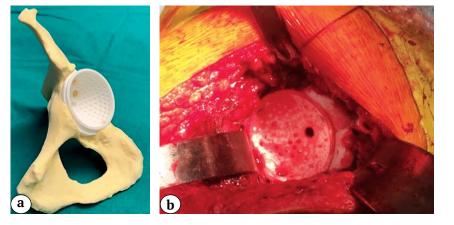
Loosening of the acetabular component was identified based on the following criteria:

• negative progression in radiolucency border expansion;

• fracture of screws fixing the acetabular components or their migration;

• migration of the acetabular component by more than 2 mm and alteration of its inclination angle by more than 4° [15];

• shift of the center of rotation compared to previously taken x-rays [16].



**Fig. 4.** Trial component fitting: a — on the pelvis model; b — in the wound



**Fig. 5.** Implantation of the individually designed acetabular component

#### **Results assessment**

For statistical analysis, the following parameters were chosen: gender, age, patients' body mass index, reason for revision surgery, number of previous surgical interventions, duration of surgery, intraoperative blood loss, partial or complete revision surgery, use of dual mobility systems. Pain syndrome assessment and functional outcomes were conducted before surgery, at 3, 6, and 12 months, and subsequently annually using WOMAC, Harris Hip Score (HHS), and VAS.

After surgical treatment, the frequency and structure of complications were analyzed, including aseptic loosening, implant instability, development of PJI, and sciatic nerve neuropathy.



**Fig. 6.** Evaluation of stability and positioning of the implanted custom-made acetabular component: X-ray images (a) and tomograms (b) of the pelvic bones



#### **Statistical analysis**

Statistical analysis was performed using IBM SPSS Statistics Base 22.0 for Windows. The Kolmogorov-Smirnov test was used to check for normal distribution. HHS, WOMAC, and VAS showed non-normal distribution upon Kolmogorov-Smirnov test. Other parameters were deemed to have a normal distribution. The following non-parametric tests were used for further analysis: Wilcoxon rank-sum test (for before and after surgery parameters) and Mann-Whitney U test (comparative analysis of the first and second groups). Qualitative characteristics were described using relative (%) and absolute frequencies. Pearson's  $\chi^2$  test was used for comparing two independent groups of qualitative characteristics. Continuous variables with normal distribution were presented as M±SD, where M represents the sample mean and SD is the standard deviation. For non-normally distributed data in both groups, median (Me) [Q1, Q3] was used. Differences with p<0.05 were considered statistically significant.

#### **RESULTS**

Our analysis indicated that the study groups were comparable in terms of gender, BMI, and types of acetabular bone defects. However, the first group exhibited more cases of type IIIB bone defects, often combined with pelvic bone dissociation. The average follow-up period was 37 months (range: 26 to 56) for the first group (3D-component application), 42 months (range: 30 to 59) for the second group (augment and/or hemispherical component application), and 40 months (range: 27 to 58) for the third group (support rings application). Notably, the first group of patients had a higher number of revision surgeries in their medical history compared to the second and third groups (p<0.05) (Table 1).

Despite the longer duration and scope of surgical interventions in the first group, the average intraoperative blood loss was greater in the second group by 23.3 ml compared to the first group, and by 98 ml compared to the third group. Out of 22 cases of pelvic bone dissociation, 15 cases involved implantation of individual constructs, 3 cases involved the use of an augment and/or hemispherical component, and in the remaining 4 cases, support rings were used. Complete intraoperative data is presented in Table 2.

Indicator		First group n = 30	Second group n = 30	Third group n = 30	Total n = 90	
Mean age, years		58.6	62.1	72.4		
BMI		29.3	28.7	27.6		
Gender	Male	11	9	8	28	
	Female	19	21	22	62	
Number of previous operations		3.8	2.36	2.1		
Defect type						
IIIB		30	30	30	90	
including pelvic bone dissociation		15	3	4	22	
Reason for revision						
Aseptic loosening		24	24	19	67	
Second stage of PJI treatment		6	6	11	23	

## **Characteristics of the study groups**

#### Table 1

#### Intraoperative indicators

Table 2

Indicator		First group n = 30	Second group n = 30	Third group n = 30	Total n = 90
	Yes	0	2	3	5
Impaction bone grafting	No	30	28	27	85
Operation duration, mins		168.4 (±24.2)	129.2 (±23.1)	134.4 (±12.1)	
Intraoperative blood loss, ml		696.7 (±127.1)	720 (±172.2)	622 (±152.3)	
Average number of screws, pcs.		5.1 (±1.2)	4.6 (±2.1)	4.3 (±2.2)	
Use of dual mobility components, pcs		21	0	8	29
	Partial	6	14	9	29
Revision procedure type	Complete	24	16	21	61

## Complications

After the revision surgeries, 27 (30%) complications were identified, with a higher number of complications observed in the second and third groups (Table 3).

In the first group of patients with 3D constructs, 2 cases (6.6%) of deep PJI were diagnosed, one of which resulted in a fatal outcome. In the second case, successful debridment was performed, resulting in infection control, pain relief, and a positive clinical outcome.

Dislocation of the prosthesis occurred in 2 cases (6.6%): one involving a patient with a dual mobility system and the other with standard components (Fig. 7). Dislocation occurred 4 months after surgery in the patient with a dual mobility

system, and 3 weeks after surgery in the patient with standard components. In both cases, an open reduction was performed with an increase in head size. Another complication occurred 23 months after partial revision arthroplasty of the right hip joint. This complication was diagnosed solely through follow-up X-rays and manifested as a fracture of one flange, but it had no impact on component stability and functional outcomes (Fig. 8).

Evaluation of the outcomes of revision hip arthroplasty involves important indicators such as clinical results and pain intensity. Results assessment are presented in Table 4.

Table 3

Complication	First group n = 30Second group n = 30		Third group n = 30	Total n = 90
Joint instability	2 (6.6%)	4 (13.2%)	4 (13.2%)	10 (11.1%)
Periprosthetic infection	2 (6.6%)	3 (10%)	3 (10%)	8 (8.8%)
Loosening of components	1 (3.3%)	2 (6.6%)	1 (3.3%)	4 (4.4%)
Neuropathy	1 (3.3%)	2 (6.6%)	2 (6.6%)	5 (5.5%)
Total	6 (20%)	11 (36.6%)	10 (33.3%)	27 (30%)

#### Complications after revision in three patient groups

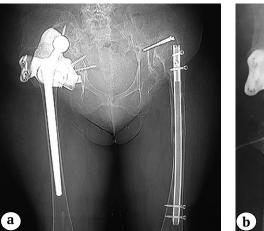




Fig. 7. Pelvis X-rays after revision total hip replacement:

a — dislocation of the prosthesis head (dual mobility system);

b — after open reduction with an increase of the prosthesis head (dual mobility system)



**Fig. 8.** X-ray of the right hip two years after partial revision hip replacement — fracture of one of the flanges of the individual component (indicated by an arrow)

Table 4	
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	Harris hip score		WO	МАС	VAS	
Group	Before surgery	After surgery	Before surgery	After surgery	Before surgery	After surgery
First	27 [25.5;29.2]	78 [36.9;90.1]	76 [34.7;92.2]	7 [2.9;15.1]	9 [8.7;10]	0.5 [0.3;1.2]
Second	32 [24.3;38.2]	72 [38.2;91.7]	68 [31.9;82.1]	14 [7.7;28.5]	8 [7.9;9.8]	1.1 [0.8;2.5]
Third	34 [29.2;39.5]	70 [32.5;85.9]	71 [32.8;85.4]	17 [9.9;32.9]	7 [6.7;8.9]	1.5 [0.7;3.1]

**Results assessment by different scales** 

*p*<0,05.

#### DISCUSSION

As the number of primary hip arthroplasty surgeries in young patients increases, the frequency of revision surgeries steadily rises [17]. In 2017, for instance, more than 8000 revision surgeries on the hip joint were performed in the UK [18].

Each revision surgery is a complex task for the surgeon, particularly when dealing with extensive bone defects of the acetabulum. Surgeons are faced with challenges like ensuring reliable implant fixation and joint stability. Competent preoperative planning is crucial to address these challenges, as accurate interpretation of bone defects minimizes the risk of error and facilitates the surgical procedure [19].

The classification of acetabular bone defects proposed by Paprosky in 1993, based on radiological signs, is convenient for preoperative planning [13]. However, it has limitations in terms of indepth diagnosis, as it does not distinguish between limited and extensive bone defects, nor does it consider acetabular bone dissociation [20]. Therefore, detailed assessment of each acetabular defect requires CT scans followed by 3D visualization.

M.S. Ibrahim et al demonstrated favorable outcomes in revision hip arthroplasty when using impaction bone grafting and uncemented components with porous coating simultaneously. However, the authors emphasize that this method may not provide long-term implant survival for extensive acetabular defects such as type IIIA and IIIB [21]. Other researchers report high complication rates when using impaction bone grafting or allografts to address massive acetabular defects [22, 23]. The primary advantage of impaction grafting is bone mass restoration, particularly in younger patients who may require further revision in the future [24, 25].

Metal augments with tantalum coating are increasingly being used in revision surgery. However, these augments require sufficient existing bone tissue for reliable fixation and subsequent osseointegration. M. Whitehouse et al demonstrated a fairly high survival rate (92%) 10 years after revision hip arthroplasty using augments [26]. While versatile, augments often necessitate additional bone milling, reducing the available bone tissue. Moreover, the orientation of screws in augments is parallel, limiting the possibility of changing screw direction for better fixation. Consequently, in certain cases of revision hip arthroplasty, the use of augments may not adequately address the bone defect [8]. In our study, we observed 6.6% cases of aseptic loosening of components when using augments.

Another treatment option for patients with significant acetabular bone defects is supportive antiprotrusion rings. The main advantage of this method is its cost-effectiveness. However, the absence of biological fixation does not provide long-term stability for the construct [27]. Therefore, this method is not recommended for active and young patients. In our study, the average age of patients who received antiprotrusion rings was 72.4 years, classified by the WHO as elderly.

In cases of combined anterior and posterior column deficiencies of the acetabulum, none of the standard revision implants can restore the true center of femoral head rotation. The only method for reconstructing extensive acetabular bone defects is the use of individually customized constructs with three flanges. This approach enables a personalized solution for each case. While this method is more costly compared to using standard implants [28], it often becomes the only viable treatment option [29]. Additionally, the presence of a porous surface in the implant's contact area with the bone bed promotes biological fixation and osseointegration, directly affecting long-term stability [30]. M.J. Taunton et al demonstrated that the cost of a individually customized component is comparable to that of an uncemented cup with augments [31]. R.M. Tikhilov et al argue that using individual acetabular constructs is a more effective treatment strategy from an economic standpoint for extensive defects, compared to implanting standard acetabular components [32].

A.A. Korytkin and colleagues identified a direct correlation between postoperative center of rotation deviation and subsequent revision of the femoral component, emphasizing the importance of restoring hip joint anatomy [33]. The implanted custom-made component allows to restore a preplanned center of anatomically correct rotation.

The main drawbacks of individually customized acetabular components are complex preoperative planning and the extended manufacturing process [33]. On the other hand, this method simplifies the surgical procedure: there's no need to implant allografts, model support rings, choose augments, cages, or hemispheres for adequate fixation [8, 34]. However, in our study, implanting a personalized component took 39.2 minutes longer than installing an augment with a hemisphere, and 34.0 minutes longer than placing an antiprotrusion ring and cup.

The frequency of complications after revision hip arthroplasty using individual constructs reaches 26% [35]. A.C. Kawalkar et al demonstrated that when using individual three-flange constructs, the incidence of dislocations ranges from 0% to 30% according to different data sources. In our study, the dislocation rate was 6.6% (2 out of 30 patients) [36].

Many authors point out the improvement in HHS results from around 25 points before surgery to 75 or more after the operation when using personalized implants [6, 9, 38, 39]. In our study, the average HHS increased from 27 [25.5; 29.2] to 78 [36.9; 90.1], which is comparable to literature data. The relatively low scores on assessment scales after surgery indicate the initially severe condition of the patients and the extent and complexity of the revision hip arthroplasty performed [6]. In our study, the results for the group of patients who received personalized constructs were 1.08 times higher on the HHS than the group with augments and 1.10 times higher than the group with antiprotrusion rings. Similar results were obtained for the WOMAC scale: the result was 1.95 times better than that of patients with augments and 2.32 times better than that of patients with antiprotrusion rings. The number of postoperative complications in the group of patients with individual constructs was 1.83 times lower than in the second group and 1.66 times lower than in the third group.

## Limitations to the study

This study was limited by a relatively short follow-up, with an average period of 42 months. The postoperative observation periods varied, which could have influenced the comparative results of these three groups as well.

## **CONCLUSION**

Individually customized constructs using 3D technology are a preferred option for revision hip arthroplasty in patients with type IIIB defects according to the Paprosky classification, especially when accompanied by pelvic bone dissociation. However, when utilizing personalized components, a reduction in the duration of the surgical procedure should not be expected.

## DISCLAIMERS

## Author contribution

*Murylev V.Yu.* — study concept and design, literature search and analysis, data analysis and interpretation, writing and drafting the article.

*Kukovenko G.A.* — study concept and design, literature search and analysis, data analysis and interpretation, writing the article.

*Elizarov P.M.* — study concept and design, literature search and analysis, data collection and processing.

*Rukin Ya.A.* — data collection and processing, writing and drafting the article.

Muzychenkov A.V. — data collection and processing, writing and drafting the article.

*Rudnev A.I.* – data collection and processing, drafting the article.

*Zhuchkov A.G.* – data collection and processing, drafting the article.

Alekseev S.S. - data collection and processing, drafting the article.

*Bobrov D.S.* — data collection and processing, drafting the article.

*Germanov V.G.* — data collection and processing, 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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