

Results of total ankle replacement in 71 patients with a follow-up period 6 month to 7 years

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The purpose of this study was to analyse the results of treatment in patients with arthritis of the ankle joint (AJ) based on analysis after surgery involving total ankle arthroplasty. We evaluated the efficiency of AJ replacement (71 patients). All patients were divided into two groups: prospective (6, 12 and 24 months) and retrospective (3, 5, and 7 years). The results were evaluated with the help of a visual analogue scale (VAS) and the 100-point AOFAS scale; we also performed X-ray examinations. With regard to AJ replacement, we identified a significant risk factor for the most frequent complication, which was aseptic instability of the implant components. Total ankle replacement (TAR) provides good or satisfactory treatment results in the vast majority of patients examined in the absence of complications: 100% on the VAS and 96% on the AOFAS scale after 2 years; 100% on both scales after 3 years; 92.3% on both scales after 5 years; and 85.7% on both scales after 7 years. At the same time, the dynamics of the various indicators studied were generally similar, but there were also some differences.

Keywords: ankle joint, arthrosis of the ankle joint, ankle arthroplasty, risk factors for poor treatment outcomes

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The improvement of methods of surgical treatment for patients with late stages of deforming arthrosis of the ankle joint (AJ) is one of the priority goals of modern traumatology and orthopaedics [1, 2]. Currently, patients with the specified pathology undergo two main types of surgery: the first is AJ arthrodesis, which has been used since the beginning of surgical orthopaedics, and the second is total ankle replacement (TAR), which has been used in clinical practice since the 1970s [3, 4] and quickly became an accepted method. According to the literature, both specified methods of surgical treatment have advantages and disadvantages and also show different results in the present day compared with the past.

Therefore, the choice of one of these methods presents certain difficulties. Indications and contraindications for performing either of these surgeries are discussed in the following articles [5, 6, 7, 8, 9]. Surgeries of each type are quite often followed by complications and pathological states that substantially worsen the result of treatment in both the short- and long-term. In particular, after AJ fusion, patients often develop degenerate and dystrophic changes in joints of the middle part of the foot, and in addition, compensatory loads of the overlying large joints of the lower extremity lead to increased development of a pain syndrome [7].

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Figure 1 a. Deformities of the bones forming the ankle joint in patients of the consequences of ankle joint injuries subgroup: a-radiographs of patient S, 53 years old, with the consequences of a fracture of the distal metaphysis of the tibia; b. X-ray of patient SH, 36 years old, with a consequence of fractures of both ankles.

Operations involving TAR increase the risk of future development of a number of pathological states, such as destruction of the established prosthesis designs, aseptic instability of their components and a deep periprosthetic infection [10, 11, 12]. Therefore, the introduction of TAR has been approached cautiously in clinical practice around the world. Indeed, according to the German register of operations, arthrodesis of the AJ is carried out approximately three times more often than its endoprosthesis replacement; the number of annually established endoprostheses of the AJ is about 1300 [13].

On the other hand, the relevant literature also has suggestions from some orthopaedists to greatly expand the indications for arthroplasty of the AJ [14, 15]. In particular, there are publications describing operations with the angles of varus or valgus deformations in this joint over 200 [16, 17, 18], at the site of tumoural damage of the tibia or talus [19], at defects of the talus [20] and also at the fracture of an earlier arthrodesis of the AJ [21, 22, 23]. The analysis of literature on this subject has convinced us that the comparative efficiency of ankle fusion and TAR operations, especially regarding long-term performance, and also risk factors for the development of a number of pathological states are insufficiently studied and need to be further investigated.

Materials and Methods

We performed an analysis of 71 patients who underwent TAR using three third-generation implants: Mobility (DePuy) 27, Hintegra (NewDeal) 37, and STAR (Waldemar Link) 7. The gender and age characteristics of patients are provided in Table 1 for comparison. Radiological examination showed that most patients had late-stage arthritis of the ankle and was based on the classification of Kellgren et al. [24]. It was found that 15 (21.1%) patients had stage II AJ arthrosis, 41 (57.8%) patients had stage III arthrosis, and 15 (21.1%) patients had stage IV arthrosis (Table 2).

It should be noted that pathological changes in the articular parts of the bones that form the AJ were found mainly in patients with the consequences of injuries to this joint. Thus, 10 (11.5%) patients had deformities of the distal metaphysis of the tibia after fractures (Figure 1 a) and 27 (51.9%) patients had ankle deformities (Figure 1 b), with 5 (9.6%) patients having significant deformities of the talus bone in this clinical subgroup. Among patients with AJ diseases that led to the development of deforming arthrosis, there were only two such observations: one patient (5.3%) with deformation of the distal metaphysis of the tibia and another (5.3%) with significant deformation of the talus bone.

For all patients, we carried out an objective and radiological inspection of the feet, including an X-ray analysis with the necessary projections, and patients also completed visual analogue scale (VAS) and American Orthopaedic Foot & Ankle Society (AOFAS) scores. Of note, all patients included in the research underwent surgery in the clinic by one team of surgeons in order to avoid differences in the result of treatment due to different operational techniques and equipment. It should be noted that, in general, all patients in the considered clinical group had VAS scores ranging from 6 to 10 and AOFAS scores ranging from 12 to 34, which corresponds to poor evaluation categories. In addition, they had pronounced restrictions on the amplitude of movement in the affected AJs (from 16° to 27°), which was significantly worse than normal indicators (on average 39±5°). All these changes are typical for the later stages of development of deforming ankle arthrosis (Table 3).

Average age (years)	Sex		Total
	M	F	
48.1±4.2	29 (40.9%)	42 (59.1%)	71 (100%)

Table 1 Age and sex of patients of the first clinical group.

II		III		IV		Total	
n	%	n	%	n	%	n	%
15	21.1	41	57.8	15	21.1	71	100

Table 2 Ankle arthrosis stages.

AOFAS	VAS	Movement amplitude
25.0±2.0	8.5±0.7	24.0±3.4°

Table 3 Preoperative clinical and functional indicators in patients.

Results

The most frequent reason for unsatisfactory treatment results from 6 months until 7 years after surgery was aseptic instability of components of the AJ. Therefore, special attention was paid in our work to the detection of significant risk factors of this emerging pathological state. We found that, in the prospective group of patients, radiological signs of instability of the established designs were observed 2 years after the surgery in 6 (19.4%) of 31 patients under clinical supervision. However, the presence of a severe pain syndrome and essential decrease in functionality, which necessitated carrying out a repeat operation (fusion), was reported only by one (3.2%) patient of the prospective group.

In the retrospective group from 3 to 7 years after treatment, radiological signs of instability of the components of the AJ were recorded for 16 (40%) of 40 observed patients. In addition, using VAS and AOFAS scores, patients with this complication had worse average values of these indicators ($R < 0.01$) than other patients of the group. However, the revised procedures, including removal of unstable implants with subsequent biarticular fusion of the ankle and subtalar joints were only carried out by interlocking intramedullary nails in 7 (43.8%) of 16 patients, as the other 9 patients preferred to keep the established endoprostheses. It should be particularly noted that these nine patients had only radiological signs of instability of the endoprosthetic components

without essential migration of the bone bed, and they had a satisfactory functional result.

An example of a satisfactory functional result can be observed (Figure 2) 5 years after TAR with the presence of radiological signs of instability of the established construction. However, it is necessary to note that the patient did not demand a high functional load from the operated AJ.

Special attention in our research was paid to the detection of risk factors for developing aseptic instability of endoprostheses of the AJ. A search was carried out concerning two groups of factors noted in the relevant literature [4, 15, 17, 22, 25, 26, 27, 28]. The first group of risk factors included various deformations of the bones forming the AJ. The second group included the age of patients, related physical activity, and functional loads of the operated joints as significant factors. It should be noted that such analyses were carried out separately in the prospective group (31 patients) and in the retrospective group (40 patients). The results are presented in Tables 4 and 5.

The analysis showed that the risk of aseptic instability of the endoprosthetic components of the AJ during all periods of observation was clearly associated with previous fractures of the bones forming the joint. As can be seen, such fractures occurred in 5 of 6 patients with this pathological condition in the prospective group and in 13 of 16 patients in the retrospective group. In addition, we observed that the vast majority of these states (21 of 22 or 95.5%) occurred in patients under the age of 55 years. The proportion of patients with aseptic instability of the implant in the group of patients younger than 55 years was 34.4% (21 of 61) and only 10% (1 of 10) in the group of patients 55 years and older. It should also be noted that, in 19 (86.4%) of the 22 cases of aseptic instability of the endoprosthetic components, these patients performed activities involving high functional loads on the AJ in the postoperative period.

Analysis of the models installed as AJ implants in patients diagnosed with aseptic instability of the implant did not reveal any significant advantages for any one of the three used structures.



Figure 2 The result 5 years after total ankle replacement (left side) in a 42-year-old patient with the use of a Hintera implant (NewDeal). a) Radiological signs of instability of an endoprosthesis: the slight shift backwards of the tibial component and sagging of the talus component due to decreased height of the talus; b) Satisfactory functional result: 3 points on the VAS and 69 points on the AOFAS scale.

The third-generation implants studied implants had similar clinical effectiveness with respect to the development of the discussed pathological conditions. The analysis revealed the following significant risk factors of aseptic instability of the endoprosthetic components of the AJ: previous fractures of bones forming the joint, age of up to 55 years, and high

functional load on the operated joints in the postoperative period.

Discussion

A comprehensive study of the results of ankle replacement of up to 7 years conducted in the prospective (31 people) and retrospective (40 people) subgroups of patients allowed us to make some generalizations presented in this section.

First of all, it was shown that operations with the AJ endoprosthesis in the absence of complications provided good or satisfactory treatment results in the vast majority of the examined patients: 100% on the VAS and 96% on the AOFAS scale after 2 years; 100% on both scales after 3 years; 92.3% on both scales after 5 years; and 85.7% after 7 years. At the same time, the dynamics of the various indicators studied were generally similar, but there were also some differences.

In particular, the severity of pain in the area of the operated joint, estimated by VAS, was minimal 2 years after the operation and gradually increased in the future, reaching a maximum by the 10-year follow-up. The functional capabilities of the AJs, determined on the AOFAS scale, reached the maximum average value 6 months after surgical treatment, remained at this level until 3 years, and then gradually decreased over the next 7 years of follow-up. Various indicators of gait biomechanics on the side of the operated joints gradually improved during the first 3 years after implantation of artificial AJs and then gradually deteriorated by the 7-year follow-up period. The amplitude of movements in the AJ (flexion/extension) increased after endoprosthesis on average only by 3–40° and reached the maximum average values, corresponding to about 75% of the norm, after 6 months. In the future, the volume of such movements gradually decreased and was an average of 46% of the norm 7 years after surgery.

However, it should be especially noted that, in the examined patients who did not show signs of aseptic instability of the established AJ components, the average values of almost all the studied parameters (except for the amplitude of movements) even 7 years after the performed operations were significantly better ($P < 0.05$) than the corresponding preoperative values.

Anamnesis	Age of patients, years		Total
	20–39	40–54	
Change of a distal metaphysis of tibia	–	3 (50%)	3 (50%)
Fracture of ankle bones	–	1 (16,7%)	1 (16,7%)
Fracture of a collision bone	1 (16,7%)	–	1 (16,7%)
Deforming ankle joint arthrosis	–	1 (16,7%)	1 (16,7%)
Total	1 (16,7%)	5 (83,3%)	6 (100%)

Table 4 The anamnesis and age of patients who had aseptic instability of ankle joint endoprostheses 2 years after surgery.

Anamnesis	Age of patients, years			Total
	20–39	40–54	55 and older	
Change of a distal metaphysis of tibia	–	3 (18,8%)	–	3 (18,8%)
Fracture of ankle bones	2 (12,5%)	2 (12,5%)	–	4 (25%)
Fracture of a collision bone	–	6 (37,5%)	–	6 (37,5%)
Deforming ankle joint arthrosis	1 (6,3%)	1 (6,3%)	1(6,3%)	3 (18,7%)
Total	3 (18,8%)	12 (75%)	1(6,3%)	16 (100%)

Table 5 The anamnesis and age of patients who had aseptic instability of ankle joint endoprostheses from 3 to 7 years after surgery.

The above results of our research generally coincide with similar data in the literature. In particular, it is known that the analysis of the outcomes of the Hintegra (NewDeal) endoprosthesis in the period from 1 year to 5 years showed an increase in the AOFAS score on the average from 40.3 to 85.0 points [24]. Another publication presents the results of the Mobility (De Puy) endoprosthesis in 233 patients with an average follow-up period of 32.8 months [25]. It was noted that the function of the joints after the installation of this endoprosthesis improved on the AOFAS scale from an average of 48.2 to 84.1 points, and the pain syndrome on the VAS regressed from an average of 7.7 to 1.7 points. However, the volume of movement in the AJs that were operated on improved on average only by 2.1° (from 19.8° to 21.9°), which is quite consistent with the data we received.

A purposeful comparative analysis of our clinical data allowed us to conclude that, in the long-term postoperative period (3–7 years after the performed operations), there are no significant and reliable ($P < 0.05$) differences in the values of clinical and functional indicators (according to the VAS and AOFAS scales) when using three different models of AJ implants: Hintegra (NewDeal), Mobility (De Puy) and STAR (Waldemar Link). Thus, it was shown that the third-generation implants studied have quite comparable clinical effectiveness in those patients

who do not have aseptic loosening of the installed structures.

The analysis of models of installed AJ implants in patients with diagnosed aseptic instability of implants also did not reveal any significant advantage of any of the three designs used. However, in the prospective group, 2 years after surgery, instability of the Mobility (De Puy) endoprosthesis was observed in 3 (30%) of 10 cases, and a similar condition after installation of the Hintegra (New Deal) structure was recorded in 3 (14.3%) of 21 patients. Despite the revealed differences, in our opinion, these data are not enough to make a clear judgment about the advantages of one of these endoprosthetic models of over the other.

Our research has shown that aseptic instability of various components of AJ endoprostheses is a frequent unsatisfactory outcome of operations. In particular, it occurred in 6 (19.4%) of 31 patients of the prospective clinical subgroup by the 2-year follow-up period after surgical treatment. In the retrospective subgroup, 16 (40%) of 40 patients had this pathological condition in the long-term period (from 3 to 7 years) after surgical treatment. In our opinion, the proportion of patients with this condition in the retrospective clinical subgroup was so high, because patients with aseptic instability of implants purposefully went to the hospital, where they performed the primary implant of the AJ endoprosthesis. At the same time, patients with good

clinical and functional results did not always agree to undergo additional examination in the long term after surgical treatment. It is likely that if the survey was not 40 patients, but all 116 patients operated on in RNIITO n.a. R. R. Vreden in 2003–2011, the proportion of patients with the discussed unsatisfactory outcomes would have been significantly lower.

The information we received generally coincided with those given by other researchers. Thus, according to various foreign authors, the percentage of patients with aseptic instability of AJ endoprosthetic components varies from 3% to 13.7% in the first 5 years after the surgery [26-27] and from 16% to 32% within 5 to 10 years after the surgery [28-29].

In a retrospective subgroup of our patients, the analysis of cases of aseptic instability of the components of the AJ endoprostheses showed that the largest number of them and, accordingly, the highest proportions of the number of examined patients were recorded within 3 years (5 cases or 17.2%) and 5 years (10 cases or 43.5%) after the performed operations. By the 7-year follow-up period, these indicators decreased (one case or 12.5%), and three patients examined after 10 years showed no signs of aseptic instability of the implants. In addition, it was noted that 3 years after the surgical treatment, X-rays of patients with the considered pathological condition showed signs of loosening only in the tibial components, and in later periods of observation (after 5 and 7 years), signs of instability of both the tibial and talus components were recorded. Thus, based on the data obtained, it can be assumed that usually the tibial components of endoprostheses are loosened first, and then, over time, instability also develops in the talus components of the implants.

It should be noted that the presence of radiographic signs of aseptic instability of AJ endoprosthesis, reducing the functionality of the operated joints (by AOFAS scale) and increasing pain intensity (by VAS), have significant individual differences. Therefore, patients with aseptic instability do not always agree to repeat the operation, which involves the removal of implants and arthrodesis of the AJ. In particular, such revision operations were performed only in 1 (16.7%) of 6 patients in the prospective subgroup and in 7 (43.8%) of 16 patients in the retrospective subgroup. Thus, most of our patients with aseptic instability of

the components of the installed endoprosthesis preferred to keep the installed implants and refused arthrodesis of the AJ.

The facts described above indicate that X-ray signs of instability of AJ components do not always have pronounced clinical manifestations. In our opinion, this feature explains the large variation in the numbers of unsatisfactory results discussed in the publications of various authors. It should also be noted that our work took into account the X-ray signs of aseptic instability of the installed implants, which determined a fairly high percentage of patients with such negative results.

Special attention in our study was paid to determining the risk factors for the development of aseptic instability of AJ endoprostheses. The following factors were identified: technical errors in positioning the endoprosthetic components, the young age of patients (up to 55 years) and the associated high functional loads on the operated joints, as well as deformities of the tibial and talus bones that form the articular surfaces of the AJ that occurred as a result of previous injuries. Taking this into account, it is clear why the proportion of patients with the considered pathological condition was higher in the subgroup of patients with the consequences of ankle joint injuries (CAJI) than in the subgroup with diseases of this joint (DAJ). However, the analysis showed that the risk factor for developing this condition is not so much the presence of a history of AJ injuries as it is the existing deformities of the tibia and talus bones.

It should be noted that, according to the special literature, technical errors of implantation are considered an important cause of aseptic instability of AJ endoprostheses, which predetermine up to 15% of unsatisfactory results. Some authors noted that the positioning ratios of the tibial and talus components had a direct effect on the occurrence of pain and instability of implant components. Correct surgical technique and correct positioning of endoprosthetic components relative to the mechanical axis helped to increase the durability of the installed structures [30-32].

Some authors have developed their own classifications of the unsatisfactory results discussed. For example, Glazebrook and co-authors (2009) proposed dividing negative outcomes into high-value,

moderate-value, and low-value outcomes. At the same time, infection in the area of surgical approach and aseptic instability of the prosthesis were highly significant; errors during implantation were moderately significant; and difficulties during the healing of postoperative wounds were insignificant. It should be noted that, due to the technical difficulties of installing AJ endoprostheses and ensuring good integration with bone tissue, the problem of aseptic instability of such implants has not yet been completely eliminated. It continues to be actual. The associated severe pain syndrome and reduced functionality are common causes of revision operations.

Also, it should be noted that there are publications in the special literature with indications of a direct link between the development of aseptic loosening of the AJ components and causes of pronounced deformities of the articular surfaces of the tibia and talus bones [33-34], as well as the young age and high physical activity of patients, which determine the increased functional workloads on the operated joints [35].

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