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Total ankle arthroplasty with the use of Zimmer prosthesis and a review of the results of previous research conducted in this field

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Abstract: The aim of this article is to describe surgical technique and early results of Total Ankle Replacement (TAR) from lateral approach using Zimmer TM prosthesis. The study uses theoretical knowledge which is the result of research conducted by other authors, and practical knowledge due to the fact that our center performs that type of operation. Arthrodesis as the current standard in the treatment of advanced degenerative ankle disease, apart from its advantages, also has many disadvantages. The relative durability and reduction of the patient's pain have been achieved at the expense of the adjacent joints. Their accelerated arthrosis is the result of compensatory loads as a consequence of change in foot biomechanics. That determined implementation of solutions that will guarantee elimination of pain in the ankle joint, preserve its motor function and improve gait, while having no negative impact on the mobility of adjacent joints.

Keywords: ankle arthrodesis, contraindications, total ankle replacement, ankle degenerative disease, lateral access.

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Introduction

The ankle joint is classified as a complex synovial hinge joint formed by three bone structures: distal end of the tibia, fibula and talus bone. Plafond, i.e. the articular surface of the distal end of the tibia together with medial malleolus and the fibula's lateral malleolus form the so-called "articular fork", in which the trochlea of talus is tightly located. The adjustment of individual elements guarantees proper functioning of the ankle joint. Its stability is also determined by the ligament system. The tibia and fibula are connected with each other by the tibiofibular syndesmosis. Stabilization against lateral stresses is ensured by the lateral collateral ligaments which include anterior talofibular ligament, posterior talofibular ligament and calcaneofibular ligament, while from the medial side stability is ensured by the strong deltoid ligament. The ankle joint is subjected to considerable stress when carrying out various daily activities related to movement (walking, running, jumping). It is a perfect example of ligaments, muscles and bone structure cooperation. Biomechanically correct range of motion in the ankle joint is 30 degrees dorsiflexion and 45 degrees plantar flexion, although it is believed that the correct gait can be maintained with a minimum of 10 degrees dorsiflexion and 20 degrees plantar flexion [1].

Any disturbances in the position of joint structures resulting from various types of injuries generate serious side effects for its functionality and contribute to premature degenerative changes. To restore proper anatomical reconstruction surgical intervention is necessary, preferably at an early stage following the injury [2].

Approximately 1% of adults are diagnosed with an advanced painful form of ankle osteoarthritis which, in the first place, requires conservative treatment (physiotherapy, orthopedic supplies). Most cases of ankle arthrosis may be a consequence of a previous injury. The procedure of eliminating the effects of the damage initially comes down to administration of painkillers and anti-inflammatory drugs, lifestyle modification, physiotherapy (gait training, muscle and movement exercises that prevent joint stiffness and influence development of the muscle strength), orthopedic equipment (orthosis); the use of intraarticular injections may also be considered (e.g. hyaluronic acid) [3, 4].

In the event of failure of the already mentioned conservative treatment, in mild degenerative changes, we can use arthroscopy to remove free bodies, perform microfracturation of cartilage and bone defects, remove osteophytes causing conflict [5].

If the above-mentioned conservative treatment fails, ankle arthrodesis and total ankle replacement (TAR) are the standards of conducting in order to improve the quality and comfort of the patient's life. However, recent evidence has shown better clinical outcome and larger patient satisfaction with the use of TAR, especially in those under the age of 50. In general, when TAR is compared to ankle arthrodesis, a similar rate of complications and durability of the prosthesis is observed. A higher reoperation rate is highly probable in younger patients undergoing TAR but without any harm to nearby joints [6]. Observed among general population, osteoarthritis of the ankle is relatively less common than the knee or hip arthritis. However, one should bear in mind that in the long term arthrodesis of this joint shows a number of disadvantages, including, for example, compensatory overload, change in gait profile, non-union, development of arthrosis of the adjacent joints and, above all, a long period of rehabilitation [7]. Due to the above-mentioned, arthroplasty is gaining popularity, thanks to introduction of modern implants that allow for the maintenance of motion rage within the tibiotalar joint and the lack of influence on generating of degeneration of nearby joints [8]. In fact, it is an alternative to arthrodesis in the treatment of the end-stage ankle osteoarthritis. Its undoubted advantage is the preservation of movement functionality which cannot be ensured by arthrodesis [9]. This determines the correctness of gait and the possibility of maintaining an upright position. Any limitations in this regard (degenerative changes) generate posture defects and hinder the foot mobility, which automatically translates into the quality of movement. Ankle arthroplasty has the best prognosis in relatively mobile, middle-aged or elderly patients with correct body-mass index who have the proper bone structure with slight deformations, with multiple arthritis (e.g. rheumatoid arthritis), but a fully functional neurovascular system of the operated limb. There are no such limitations to ankle arthrodesis, which can be performed in severe deformities, neuropathy and aseptic ankle bone necrosis in people of all age and weight [4].

In our trauma-orthopedic surgery center several total ankle replacement surgeries have been performed recently using Zimmer type prosthesis dedicated to lateral access. The need for surgical intervention resulted from extensive damage to the joint as a consequence of post-traumatic degeneration. The aim of the study is to present the results in the short term perspective and to gather up-to-date evidence supporting or threatening against this type of surgical procedure.

Research highlights good results of arthroplasty with the success rate of around 90% in the medium to long term observation. It will not be possible, however, to apply this solution in every case. The following are absolute contraindications:

— acute and chronic leg infections,
— sensory disturbance in the leg,
— Charcot's arthropathy,
— aseptic talus necrosis,
— foot muscle atrophy,
— paralysis and severe misalignment of the tibia and talar bone,
— deformities of the lower limbs.

Relative contraindications include:

— young age,
— hard physical work,
— high body mass index,
— diabetes,
— nicotinism [10].

There are studies showing good results of total ankle replacement regardless of the above-mentioned contraindications [11].

Each surgical operation entails the possibility of complications and similar might refer in that case. Complications include wound healing disorders, osteolysis, subsidence and aseptic loosening of prosthetic components. There have also been reports of fractures of the lateral and/or medial ankle (intraoperative and postoperative), periprosthetic infections, non-union in the area of tibiofibular ligaments, nerve damage, deep vein thrombosis, heterotopic ossification and the formation of osteophytes conflicting with the elements of the prosthesis [5, 12].

Presurgical planning

Qualification for surgery is made on the basis of a physical and radiological examination. The starting point should be a careful analysis of the history of the disease. Its aim is to ascertain the scope and methods used so far in the treatment process. It is important to obtain information on body weight, pain characteristics and the degree of impairment in physical activity caused by the disease. Information on comorbidities (especially diabetes, osteoporosis, polyneuropathy) and the type of drugs used in their treatment are equally important [11].

The clinical examination essentially consists of assessing the foot in different body positions (sitting, standing or walking). The patient's standing position allows the rearfoot (varus, valgus or neutrality) to be assessed from the rear, and the degree of limping and deviation from the correct gait pattern can be assessed while moving. In sitting position, it is possible to test the degree of stability as a result of the ankle bone tilt test and the anterior and posterior drawer test, and to assess the range of motion in the ankle joint [13]. It is extremely important to assess the blood supply and vascularization of the limb, and if any abnormalities are detected in the physical examination, to further the diagnosis. In addition, the remaining joints of the lower limb qualified for surgery (knee and hip joints) should be examined in order to exclude distortions above the ankle joint, which may compensate for ankle joint degeneration; the length of the limbs should also be assessed. The triceps muscle of the calf and the Achilles tendon should also be evaluated clinically to exclude its contracture that will need to be released during surgery [12].

For radiological evaluation a series of X-rays should be taken in dorsolateral and lateral position of the foot, antero-posterior and lateral ankle joint — necessarily standing up (best with a shot of the shin), preferably comparative photos (Fig. 1, exemplary X-ray in the AP and lateral projection) and position of the hindfoot in the Saltzman's projection [14]. Some cases may require additional information to be provided so CT or MRI may be needed. The anteroposterior projection full-length standing radiograph is also helpful and allow to determine the mechanical axis of the limbs.

Surgical technique

The vast majority of ankle prostheses are implanted from the anterior approach. The Zimmer Trabecular Metal Total Ankle prosthesis used by our center is dedicated only and exclusively to lateral access with an oblique fibular osteotomy. It is convenient for

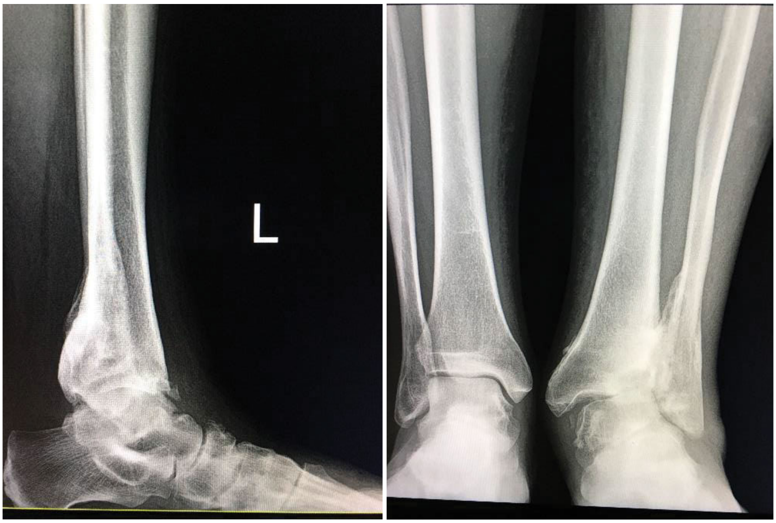


Fig. 1. Advanced post-traumatic ankle arthrosis (AP and lateral projection).

the operator because it shows the center of rotation of the joint more precisely. It also allows for more precise reconstructive positioning of the ankle joint and reduces bone resections with anatomically shaped cuts of the talus and tibia plafond. In addition, this type of access allows the implant to be placed perpendicular to the trabeculae of the tibia and talus. Theoretically, the benefit of this approach may be to reduce the risk of complications in the wound healing due to the fact that the incision takes place between angiosomes. Contrary to the anterior approach, the lateral access has less damage to the soft tissues and nerves, thus achieving a faster recovery and restoration of the proper biomechanics of the ankle joint.

The Zimmer Trabecular Metal Total Ankle system includes a tibial component with an embedded polyethylene insert (made of highly cross-linked polyethylene) and an ankle component (Fig. 2).

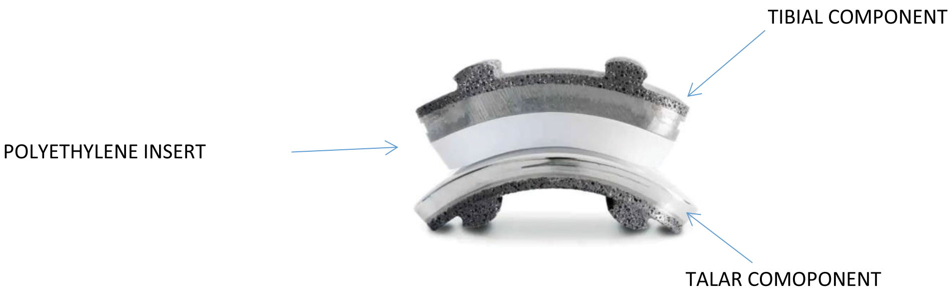


Fig. 2. Zimmer implant.

The patient was placed in the supine position on the X-ray transparent operating table. A thick pad was placed under the hip of the operated limb to make an internal rotation of the lower limb so that toes point towards the ceiling. The inoperable limb was bent at the knee and abducted at the hip to facilitate the necessary lateral projections with the help of an X-ray machine. The operation was performed without ischemia. In patients who underwent previous ankle procedures the fixation material (e.g. screw plate, girth) was removed prior to the target surgery. After removing the material, the area should be rinsed intensively with Microdacin to reduce the risk of infectious complications. According to the primary surgical technique a straight cut of the skin was performed, starting just below the distal end of the fibula and extending proximally over the length of approximately 15 cm. An oblique talus osteotomy was performed starting approximately 50 mm proximally from the ankle joint line and ending 10 mm proximally. A scarred and stretched ATFL was cut. In addition, the interosseous membrane and syndesmosis were cut and the fibula was deviated in the plantar direction, stabilizing it to the calcaneus with Kirschner wire. The anterior-posterior compartment of the joint was developed by removing the osteophytes (Fig. 3).

The medial compartment of the ankle was accessed from a longitudinal approach at the lateral edge of the medial ankle. Numerous osteophytes were removed and the deep part of the ligamentum deltoideum was cut. The range of motion of the ankle joint was 10-0-20. A calcaneus pin and talar pin have been introduced. The lower leg was placed in an operating frame dedicated to this type of prosthesis, which was assembled sterile before the operation started. Calcaneus and talar pins were attached

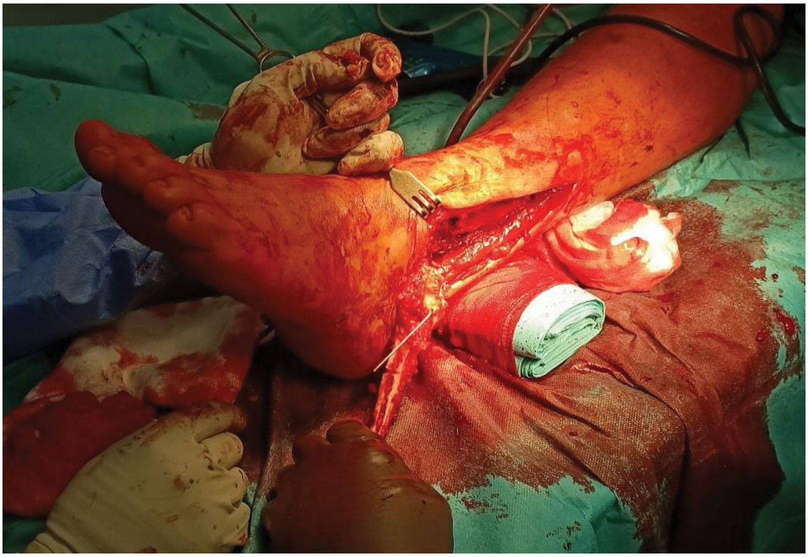


Fig. 3. Lateral approach and visualization of the ankle joint after fibula osteotomy and ligament cutting.

to the frame, correcting the intra-articular varus. Two tibial pins were fitted. Correct axis alignment was confirmed (using X-ray machine) (Fig. 4).

With the help of dedicated gauges, the size of the prosthesis components was determined. The cube milling plane was set appropriately to its size. The milling of the endoprosthesis bed was performed in the copious rinsing of the operating field. Trial pieces were attached and following stability and range of motion of the joint were checked (Fig. 5).

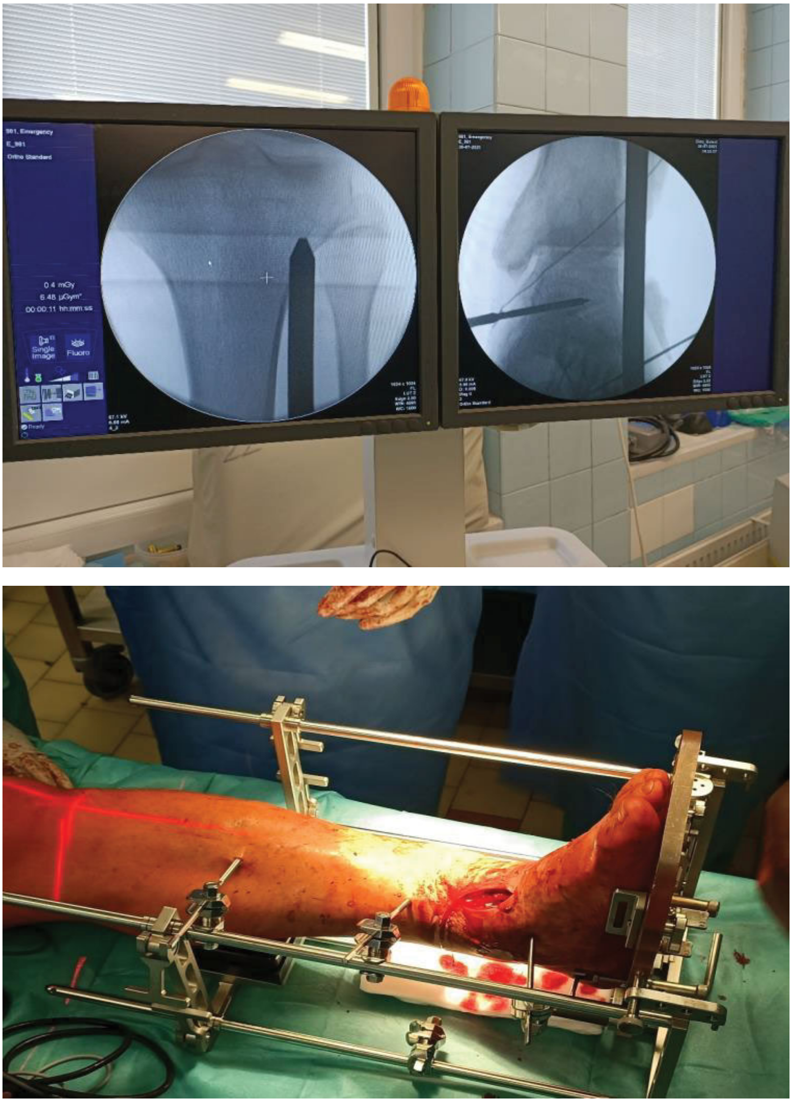


Fig. 4. Confirmation of the correct setting of the frame and the final effect of mounting the operated limb in the frame — two tibial pins, calcaneus and talar pins are visible.

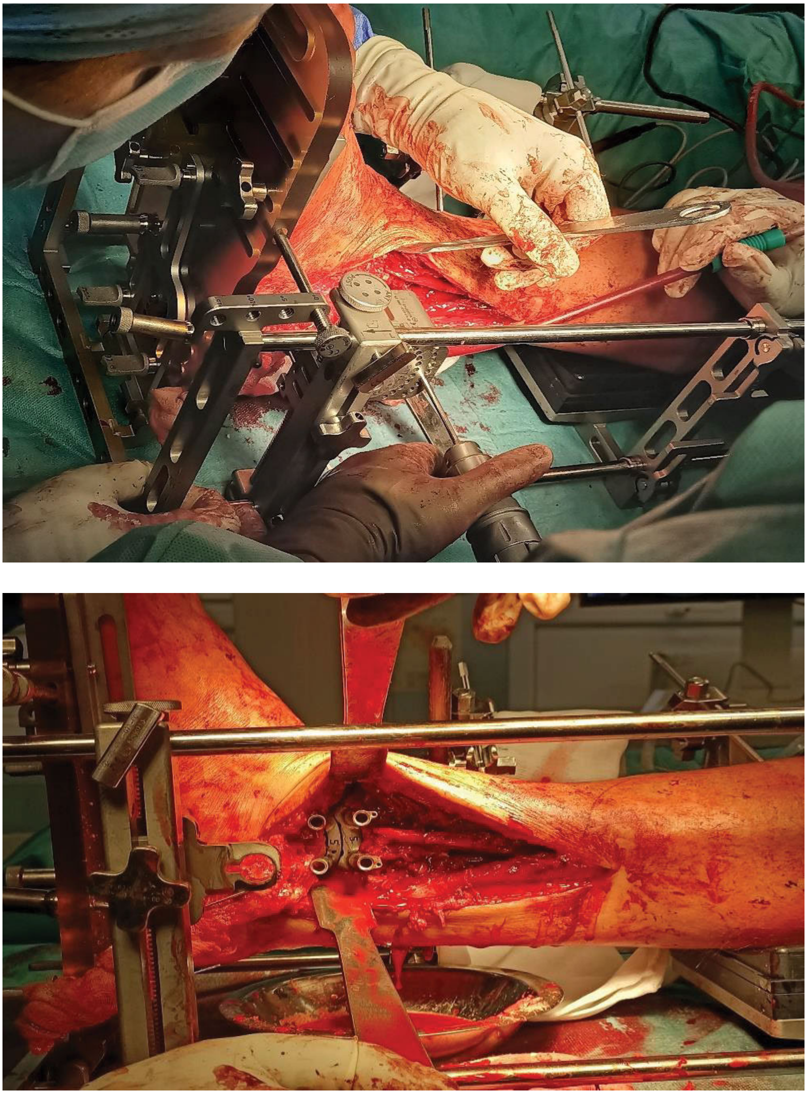


Fig. 5. Milling the bed for endoprosthesis and prosthesis measuring elements.

The sample elements were removed, the bed was rinsed and the final components of the prosthesis were placed (Fig. 6).

The foot platform was removed from the frame and ankle mobility and medial stability reassessed. Because of increased tension of the Achilles tendon at the end of the procedure, the tendon was lengthened with a few point cuts, thus obtaining an increase in flexion. In order to improve stability of the anastomosis the lateral malleolus was repositioned and internally stabilized, in our case with cortical screws (a plate dedicated to lateral malleolus anastomosis can also be used) and one syndes-

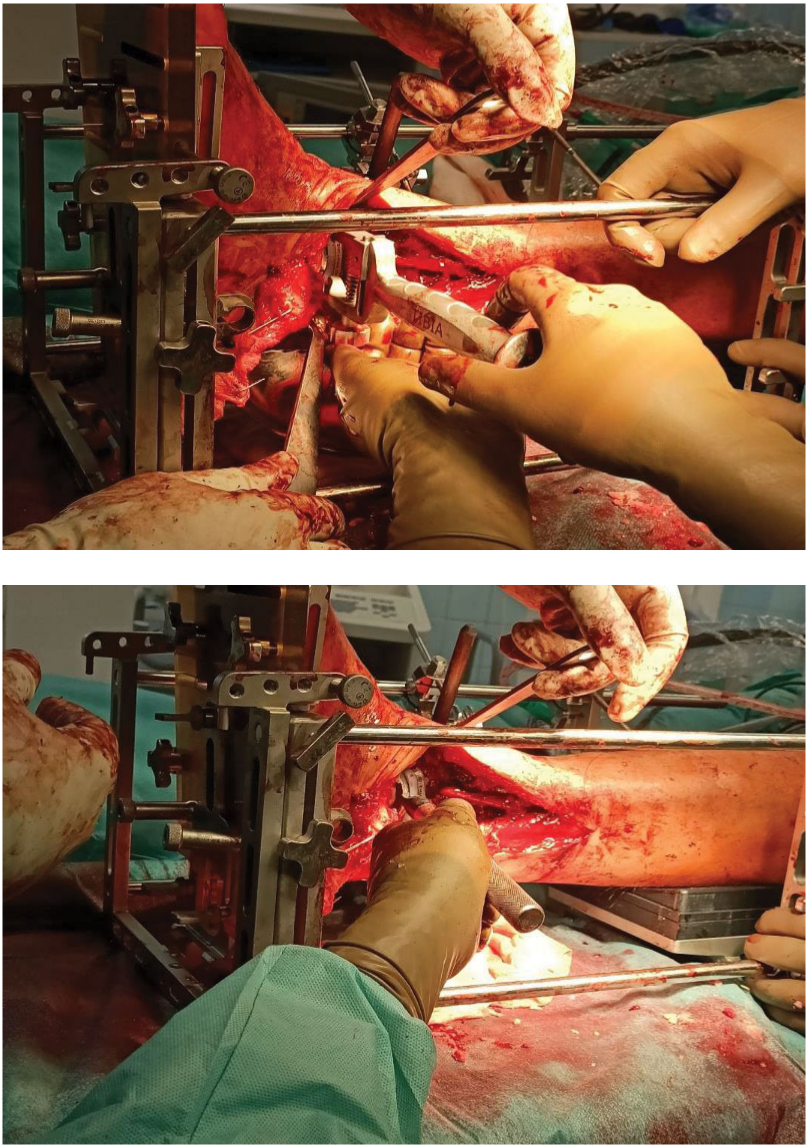


Fig. 6. Placement of the final tibial and talar component of the prosthesis.

mosis screw. The ATFL's cut at the beginning of the operation were reconstructed with transosseous sutures (Brostroom), obtaining lateral stability of the ankle joint. Then the joint capsule, subcutaneous tissue and skin were sutured. A sterile dressing and shin plaster were put on, which were cut after solidification.

Postoperative management (physiotherapy and rehabilitation)

It was recommended to the patient to walk with the help of two elbow crutches without burdening the operated limb for two weeks in a shin cast. Since the third week, the patient was told to walk in a Walker type brace with a gradual increase in the load to full load after six weeks. Since the fifth week it was advised to walk with one elbow crutch on the side opposite to the operated one. Ankle flexion and extension exercises were recommended since the third week, after removing the plaster cast. Exercises were recommended to be performed in 5–6 series, starting from 5 minutes and gradually extending their duration. During rest, elevation of the operated limb is required. Stationary bike exercises were advised since the sixth week after the procedure with a gradual increase in the load depending on the effort tolerance.

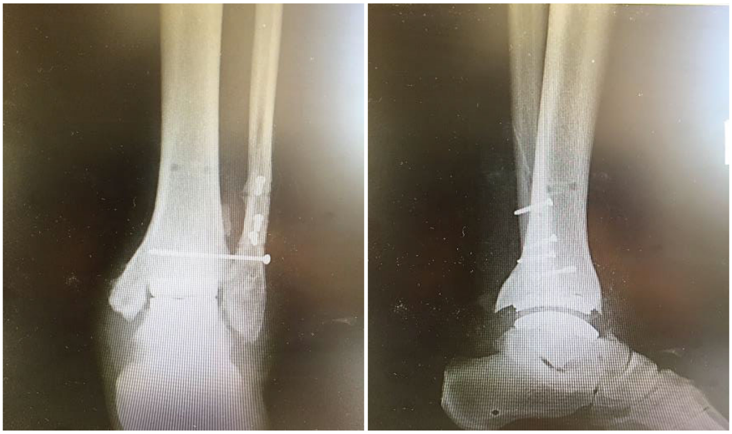
In order to evaluate the patient after the procedure a series of X-ray control images were taken: on the first postoperative day, after two weeks and after 6 weeks — below are the results obtained from two patients of different age groups (Fig. 7, 8).

Discussion

TAR is a widely used method for ankle osteoarthritis following trauma, rheumatoid arthritis, and other conditions that result in progressive loss of ankle integrity. The data collected so far seem to confirm high satisfaction with the improvement of mobility comfort among patients operated with the Zimmer Trabecular Metal Total Ankle Replacement (Zimmer TM TAR) prosthesis. It is a relatively new design solution used in the USA and Europe. Many reports on its effectiveness are based on the accounts of people directly involved in the research project and therefore there is a natural suspicion as to their objectivity [15]. On the other hand, a relatively small number of prosthetic implantations have a negative impact on the level of experience

A

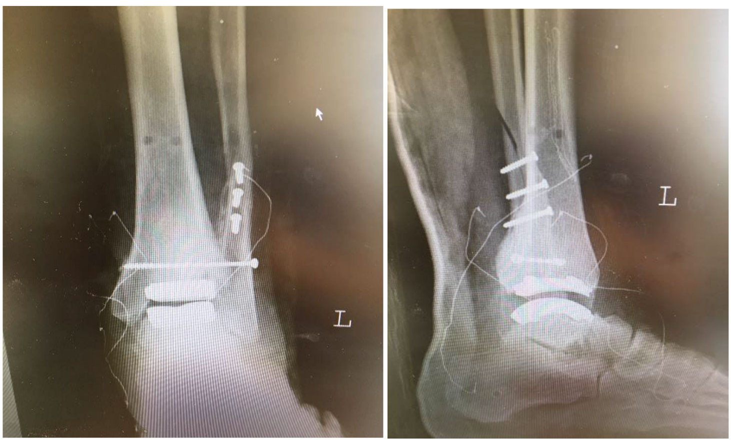
B



C

Fig. 7. A 50-year-old patient after TAR. **A** — the first postoperative day, **B** — after 2 weeks, **C** — after 6 weeks.

A



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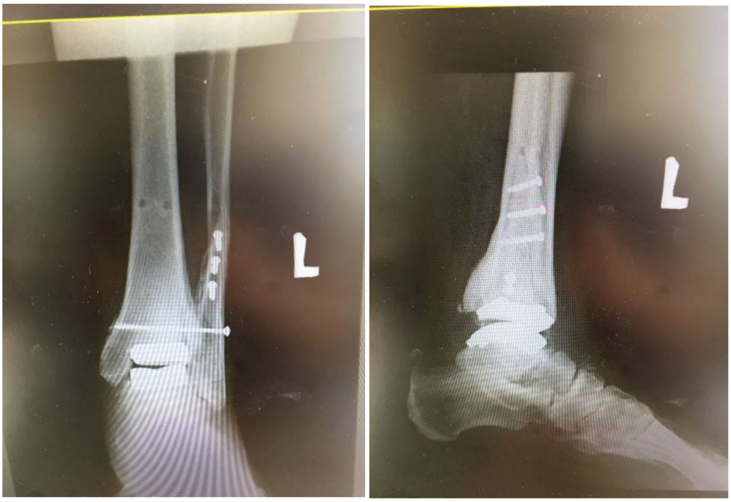

Fig. 8. A 67-year-old patient after TAR. **A** — the first postoperative day, **B** — after 2 weeks, **C** — after 6 weeks.

and knowledge of surgeons, which may result in drawing not entirely correct conclusions. The main purpose of implementation such a solution was to learn about a new surgical access for ankle arthroplasty, as well as to reduce complications in the field of postoperative wound healing (the risk is 2-40% in anterior approach) [16, 17]. For example, Usuelli *et al.* showed a higher rate of complications caused by both superficial and deep infection in the case of anterior approach, but without statistical significance [18]. Lateral approach should theoretically be more favorable in the healing process due to the incision between the two angiosomes, resulting in less damage to the cutaneous vessels. Usuelli *et al.* proposed a certain modification of the incision — they led it along the lateral ankle, curved under its apex. It was aimed at better access to the joint, which allowed for more effective removal of osteophytes [19]. Moreover, the use of the surface imitating a spongy bone resulted in more permanent fixation, and thus its greater stability [20].

The complication rate according to Bianchi *et al.* in their study was 23.3 and is similar to those reported in other studies with different TAR solutions. The major complication of lateral access is related to fibula osteotomy which can affect the quality of the union, the length of the fibula, and can contribute to the damage of vessels (e.g. the peroneal artery) and nerves. In addition, the need for revision surgery may result in the necessity to perform another osteotomy, which further increases the risk of complications. Precise knowledge of the instrumentation, biomechanics of the ankle and the operator's overall experience in the lateral approach procedure is the key to success of the operation [21].

There are several studies on the durability of Zimmer TM TAR prosthesis. However, they are still not very reliable, due to the short observation time. Barg *et al.* report the value of 93% after three years of observation [22]. Our annual follow-up is consistent with the findings of Tan *et al.*, no failures were recorded [15]. As a rule, younger patients enrolled in the TAR are at greater risk of revision surgery. It is caused by greater physical activity, and therefore faster wear rate of surfaces covered with polyethylene. There are no long-term studies confirming the durability of the prosthesis in this group of patients.

The main problem with TAR from lateral access is related to fibula osteotomy and ligament cut [23]. An undoubted advantage is the good visualization of the joint, however, one must bear in mind the possible risk of delayed union or lack of union, and thus instability of the fibula.

When it comes to contraindications, we decided to refer in particular to age, high BMI and diabetes as a comorbid disease. The age range of patients operated on in our center was 36 to 67 years of age. So far, no side effects attributable to this factor have been observed. Due to life expectancy and undertaken physical activity, young age may be, obviously, a burden for the long-term success of the operation, however, there is no clear evidence confirming this statement. For example, Schmalzried *et al.* noted a faster wear rate of polyethylene prosthetic surfaces in young people [24]. Spirt *et al.* report that each additional year of life reduces the risk of failure of the Agility prosthesis operation by 3.5%, while the majority of other authors do not see significant statistical differences among the analyzed age groups [25–28]. Most of the research on this issue was carried out with the use of second-generation prostheses. New solutions used in third-generation prostheses require repeated long-term observations in order to finally exclude the age factor from the list of contraindications for TAR [6]. The mentioned physical activity assigned to young people, in the light of the available data in short-term observations after TAR, does not constitute a significant burden for the durability of the prosthesis. There was no need for revision after 2.8 years for 152

Hintegra prostheses, similarly reported by Bonnin *et al.* after using Salto prostheses [29, 30]. Despite this, we are fully aware that increased activity in certain circumstances (intensive training) may have an adverse effect on the durability of TAR in the long term. It is recommended to use common sense and adapt the physical load to the current situation. The fact is that obesity (BMI ≥30) is a contraindication to TAR. There are several studies in this area, but with the use of other types of prostheses. Beyond single studies (e.g. Schipper *et al.* — Agility prosthesis), there is a view that obesity is not related to the increased number of failures after TAR [31–33]. However, in our group of obese patients undergoing surgery, we recorded a single case of difficult wound healing. Certainly, in obese patients physical activity and consequently, the degree of load on the prosthesis will be of great importance. Our short-term observations show that mild obesity should not be a factor eliminating from this procedure.

With regard to diabetes, the available field literature does not provide convincing evidence, apart from decompensated diabetes which can have and influence on postoperative complications [34–36]. Nevertheless, we recommend checking blood sugar levels before surgery, and in patients with diabetes, it is essential to optimize it.

There will certainly be more medium to long term analyzes of the Zimmer TAR over time. It is a structurally new solution (lateral access), therefore there is a natural deficit of knowledge as to its effectiveness and the complications generated. As it seems, one of the advantages of our study is the presentation of currently available information, not only about the Zimmer prosthesis, but more broadly, TAR. We perceive many common elements, especially in the context of presurgical qualifications, contraindications and postoperative care. Naturally, this analysis is not without limitations. We do not present detailed studies once we decided that a small number of operations and short observation period might not reflect the actual state of affairs. However, we believe that the collected material may be a stimulus for further research in this area.

Conflict of interest

None declared.

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