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TNK Ankle-The Ceramic 2-Component Total Ankle Prosthesis

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Abstract

The TNK ankle is a total ankle prosthesis which was first used in clinical settings in 1980, and which has been used in Japan for more than 30 years. The TNK ankle is only major model made from alumina ceramic materials, and is a 2-component type prosthesis with semi-constrained sliding surfaces. Due to various improvements in the surfaces in contact with the bone, the TNK ankle has consistently shown stable clinical outcomes, mainly in patients with osteoarthritis (OA) and rheumatoid arthritis (RA), although a loosening or sinking of the prosthesis has been found in some cases. In this review, we review the features and clinical outcomes of the TNK ankle, as well as the recently reported biomechanical research studies; in addition, we describe future perspectives pertaining thereto.

Keywords: Total ankle prosthesis; osteoarthritis; Rheumatoid arthritis; Ankle

Features

The TNK ankle (Kyocera medical, Kyoto, Japan) belongs to the category of 2-component fixed type, which is currently a minor type; and in terms of materials, it is a general-purpose model made of a unique alumina ceramic (Figure 1). In addition, since the development of the previous model made of ceramic by Takakura in 1980, the TNK ankle has been a "long-selling" implant which has consistently been used in Japan for more than 30 years [1,2]. One major reason that the TNK ankle has continued to be used despite the large number of selected implants, is apparently that the fact that the TNK ankle has consistently shown stable clinical outcomes.

One of the properties that contributed to the stable outcome might be the material by which it is made. Although the alumina ceramic used in the TNK Ankle is bio-inert, it is a material with biological stability. The tibial component of the sliding surface is made of polyethylene attached to the ceramic; and the talar component is formed from ceramic; this combination is considered unlikely to cause a polyethylene wear. Due to the stability of the sliding surface, alumina ceramic has been used as femoral head, even in past models of artificial hip joints.

The second property is the prosthesis design. Primarily, because the ankle has a strong bone tether, artificial joints with a highly restrictive design would have a limited range of motion, and would be unusable. This is also the reason for the existence of a large number of mobile-bearing-type prostheses; however, the TNK ankle is a two-component type composed of the tibial component and the talar component, and has no mobile meniscal insert. For that reason, it is a semi-constrained type with an established difference in curvature radius between both components. This is the reason why the sliding surface has a slight degree of freedom of motion in the antero-posterior direction. As we will describe later, recent imaging analysis studies have elucidated that a certain motion other than plantar flexion and dorsiflexion existed between the components during gait and during ankle motions.

Since the partial improvement of the TNK ankle in 1991, processed micro beads made of alumina ceramic have been placed at the surface in contact with the bone; and as a result, small irregularities at the surface promote bone formation at the boundary region. In addition, in order to stabilize the initial fixation, an AO mini size screw can be inserted from the anterior side through a polyethylene washer. The flange of the fixed polyethylene insert in the tibia is attached only on the medial side, and controls the lateral movements of the talar component, along with those of the lateral malleolus. In other words, based on the design, the tibial component can be installed without immobilizing the tibiofibular joint.

The third property is the fact that the TNK ankle has a total talus device which can be used for revisions (Figure 2). As known, the outcomes of ankle prostheses have been poor than the hip and knee joints; and revision has been needed in a number of cases because of implant loosening. Because ankle arthrodesis is selected as a general revision, the articular function will be lost, the amount of bone defect will be large, and in most cases, there will be a difference between the lengths of the legs. Originally, the total talus device was created by Takakura et al for patients with necrosis of the talus, for the purpose of replacing the removed talus with prosthesis of the same shape and made of alumina ceramic [3]. The use of the same prosthesis in cases of revision due to a sinking of the talar component after total ankle arthroplasty (TAA) has been reported to result in a stable outcome [4].

We will review the surgical procedures, clinical outcomes and biomechanical research studies pertaining to TNK ankles with the properties listed above; in addition, we will evaluate their components, and will have a look at their future.

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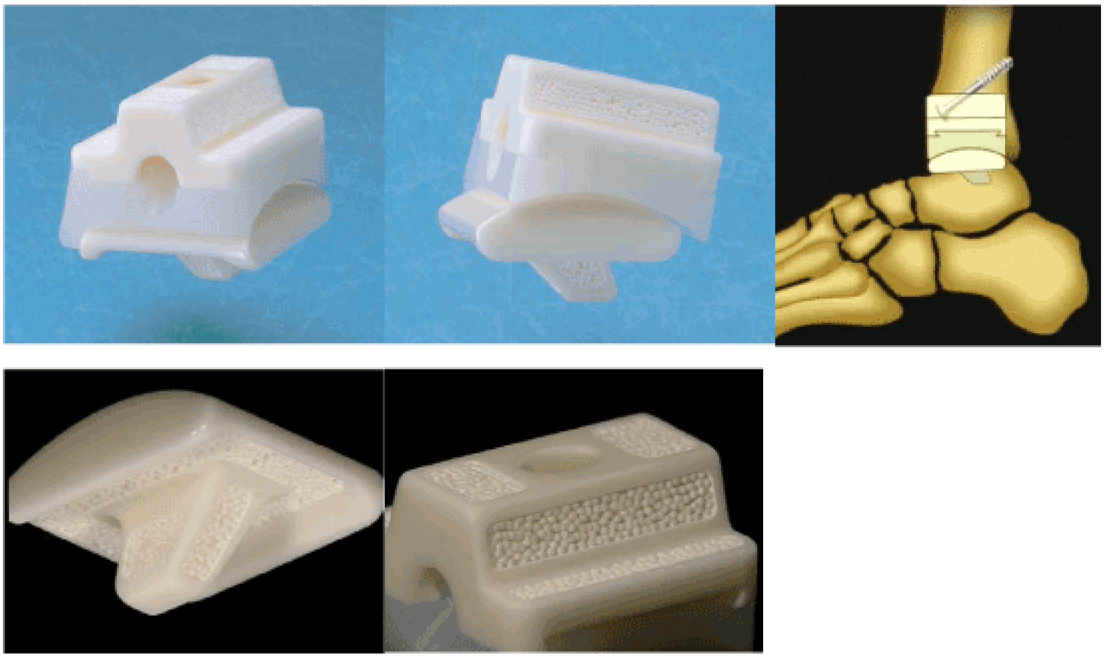

Figure 1: TNK Ankle: Alumina ceramic, 2-component and semi-constrained type.

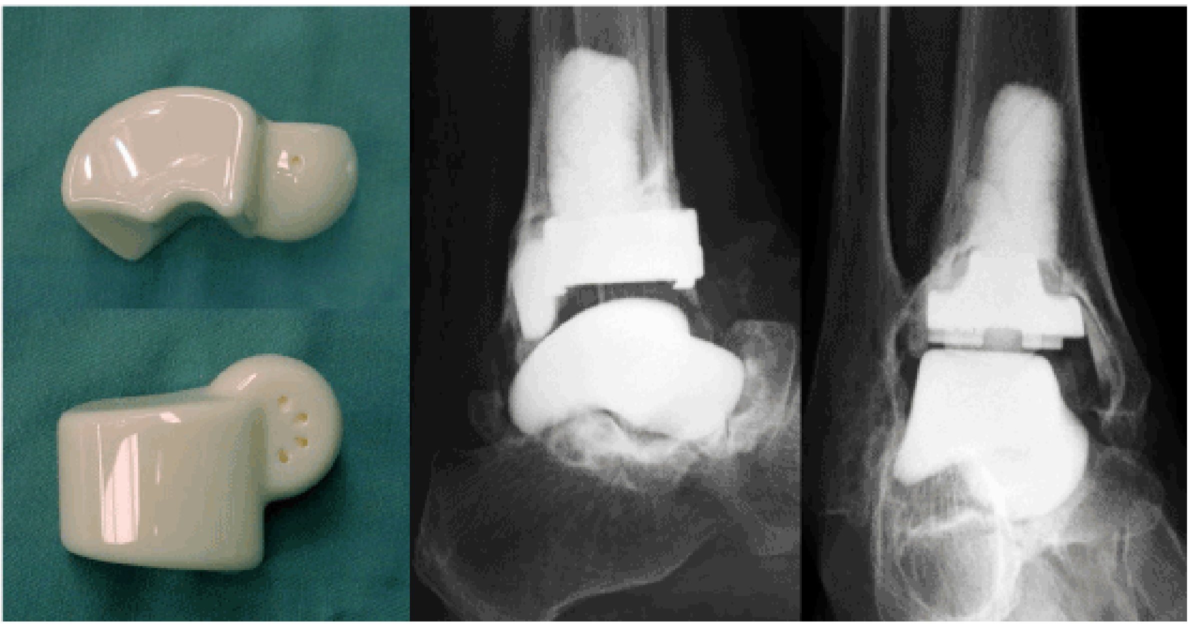

Figure 2: Total talus device for TNK Ankle revision.

Surgical Procedure

The operation is performed using an anterior approach to ankle; and after the synovial membrane of the joint has been resected as much as possible, and an osteotomy of tibial plafond and medial malleolus is first performed perpendicularly to the anatomical axis of the tibia. When doing so, the posterior cortex is left (Figure 3). Later, an osteotomy of the trochlea of the talus is performed in a direction parallel to the plantar surface. Next, the range of motion is checked and confirmed by using a trial insert; and an osteotomy of the convex portion of the tibial component on the proximal side is performed. One can choose to use or not to use cement in each of the components; but the most stable combination would consist of ensuring that the tibial componet be cementless, and that the talar component be fixed with cement. When performing an insertion of tibial component from the front in cementless, calcium phosphate paste is applied onto bone interface of the component (Figure 4) and an AO mini screw is inserted from a screw hole on front face of it towards the direction of the posterior cortex because of its initial fixation. After the movements of both components have been checked and confirmed, the retinaculum and the skin are sutured carefully. For the stability of the wound after a procedure by the anterior approach, short cast fixation is conducted for 3 weeks, and weight bearing is allowed after 2 weeks.

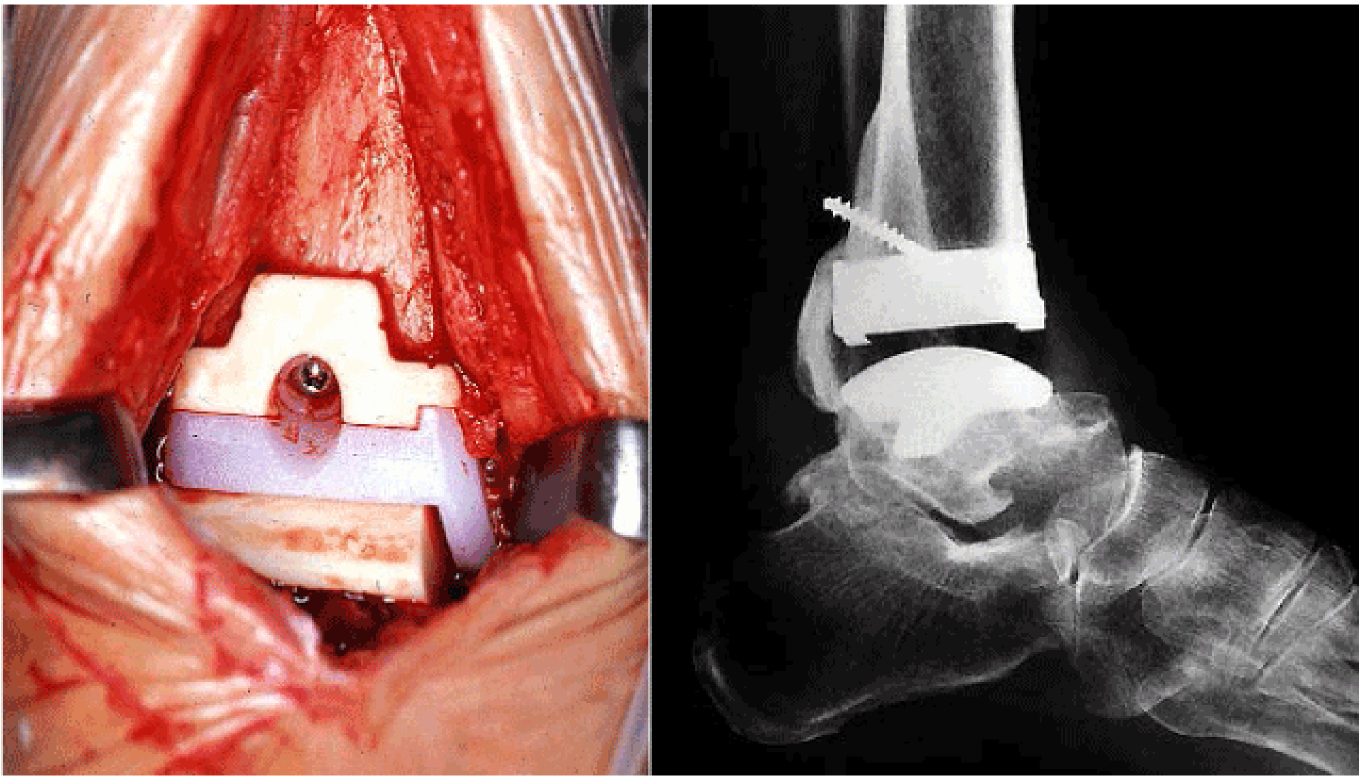

Figure 3: Total ankle arthroplasty using TNK Ankle.

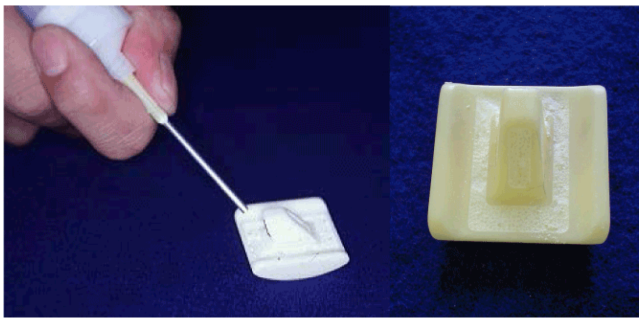

Figure 4: Calcium phosphate cement coating.

Clinical Outcomes

In 2008, in a paper written in Japanese [5], Takakura et al. reported having performed TAAs from 1991 to 2007, using TNK ankles on 126 ankles of 119 patients with OA (106 ankles of 100 female patients, 20 ankles of 19 male patients). The outcome was rated as "excellent" (90 to 100), "good" (80 to 89), "fair" (70 to 79), or "poor" (69), on the basis of the ankle/hindfoot scale according to the American Orthopaedic Foot and Ankle Society (AOFAS). The duration of the post-operative follow-up ranged from 3 months to 15 years and 8 months (mean duration: 5 years and 9 months) after surgery. With the exception of 9 ankles of patients who died and 4 ankles of patients whose fate was unknown, "excellent" outcomes accounted for 54 ankles, "good" outcomes accounted for 40 ankles, "fair" outcomes accounted for 10ankles, and "poor" outcomes accounted for 9 ankles. When the patients with "excellent" and "good" outcomes were classified as "satisfied", the latter accounted for as much as 85.8%. Revision was performed in eight of the 9 ankles with "poor" outcomes. One ankle was treated by arthrodesis, the other 7 ankles were treated by revision using TNK ankles, and the talar component which showed sinking was replaced with ceramic talar body prosthesis. Therefore the survival rate at 5.8 years after surgery was 0.89 (Figure 5), and the longest survival follow-up lasted 16 years. Loosening or sinking of the tibial component occurred in 13 ankles, 6 of which required revision. Loosening or sinking of the talar component was found in 17 ankles, 8 of which were later subjected to a revision. Other complications consisted of intraoperative medial malleolar fractures found in 3 ankles; but in all three cases, union was achieved through treatment by external fixation alone. In addition, in 2007, Takakura et al. reported having used TNK Ankle for the treatment in patients with RA [6], namely 51 ankles of 43 patients (48 ankles of 40 female patients, and 3 ankles of 3 male patients), with an age range of 41 to 79 years, and a mean age of 60.7 years. The duration of the post-operative follow-up ranged from 3 months to 14 years and 3 months (mean duration: 4 years 5 months). The postoperative outcome was excellent in 14 ankles, good in 21 ankles, fair in 6 ankles, and poor in 6 ankles. Excellent or good postoperative outcomes accounted for 74% of the cases. For 9 joints, screw fixation of the subtalar joint was carried out at the same time. For the 5 ankles with poor postoperative outcomes, arthrodesis was performed in 2 cases, and revision using ceramic talar body prosthesis was performed in 3 cases. The survival rate at 4 years after surgery was 0.87; and the longest survival follow-up lasted 14 years. This is why there was no major difference between OA and RA in terms of outcomes. A loosening or sinking of the tibial component occurred in 9 ankles, four of which needed revision. A loosening or sinking of the talar component was found in 17 ankles, and revision was performed in 5 of them.

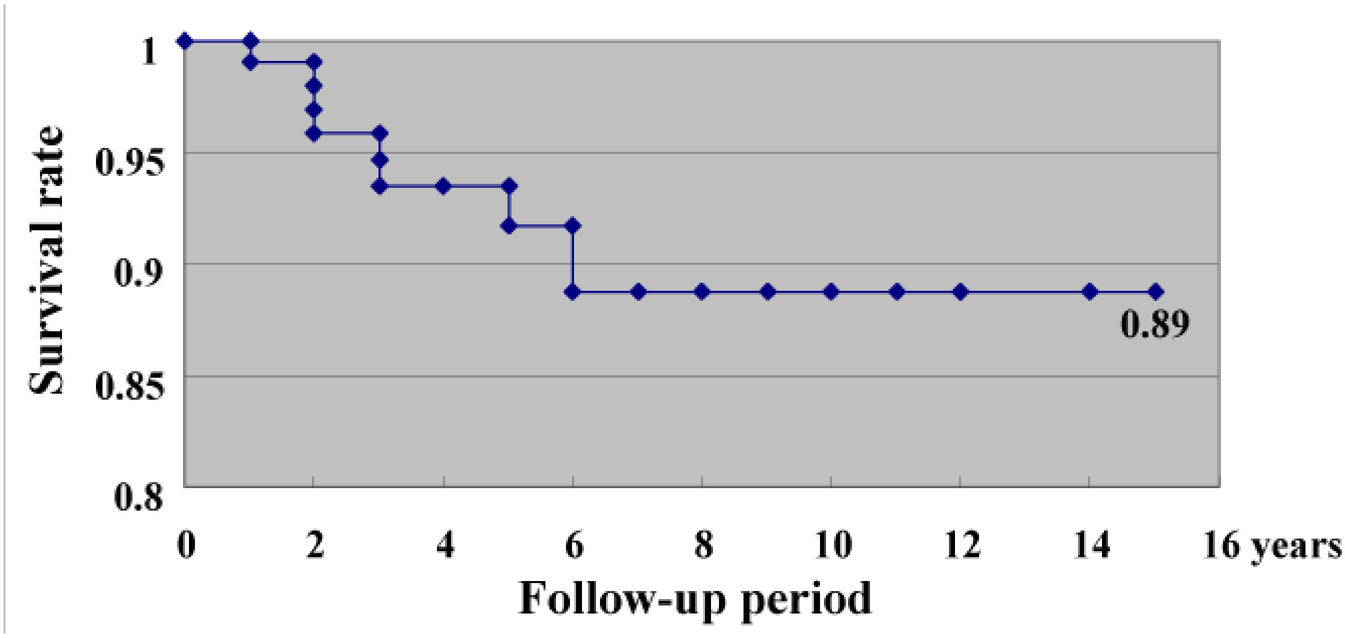

Figure 5: The Survival rate of TAA using TNK Ankle for osteoarthritis. This figure modified from Takakura Y: Total ankle arthroplasty using TNK ankle for osteoarthritis.

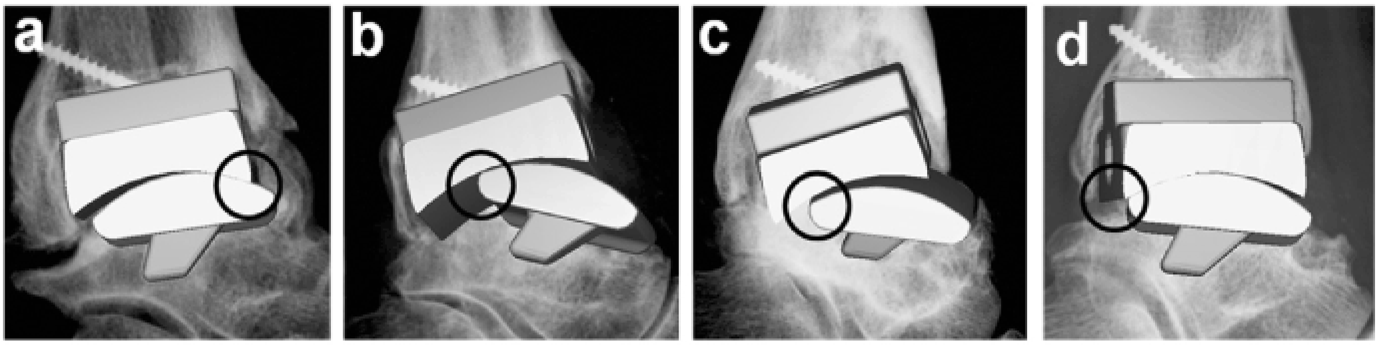

Figure 6: The kinematic analysis using 2D-3D Registration technique (a) anterior hinging, (b) posterior hinging, (c) lift off, and (d) excessive internal/external rotation These figures reprinted from Yamaguchi S et al.: In vivo kinematics of two-component total ankle arthroplasty during non-weight bearing and weight bearing dorsiflexion/plantarflexion.

Furthermore, in 2008, in a study related to TAA for 33 ankles with RA, Tanaka et al. described about a comparison between cases treated by using cement and those subjected to cementless treatment, and reported that while there was no difference in association with the tibial component, loosening was less frequent in cases using cement in the talus component [7].

The indications consist of a severely impaired ankle joint (OA classified as stage 3 or higher), a valgus or varus deformity of 15 degrees or less, and "over 60 years in OA, bilateral OA, without aseptic talar necrosis" [6].

Biomechanical Researches

Some Studies on the TNK ankle, which have started in recent years, have been focused on biomechanical approach, in addition to the clinical outcomes. Yamaguchi et al investigated the three-dimensional motions of ankles which had been replaced with TNK ankle, during ankle motion and gait, by using a 2D-3D registration technique which had been mainly performed in total knee arthroplasty (TKA). The 2D-3D registration technique is a method which was developed in the 1990s by Banks et al. [8] and Komistek et al., and is able to estimate three-dimensional positional relationships by means of shape-matching between the prosthesis silhouette on radiographic images and the prosthesis images obtained from the model data.

First, in 2011, Yamaguchi et al examined 47 ankles at an average of 50 months after surgery, in patients with a mean age of 71 years, by using the 2D-3D registration technique from a lateral view in weight-bearing plain X-ray radiography in a neutral/plantarflexion/dorsiflexion position, and reported that the average range of motion was 17.8 degrees [9]. The movements consisted of a 0.4 degree rotation in the coronal plane (inversion/eversion) at the same time as a 1.8 degree rotation in the axial (plantar) plane; in addition, both components were hinged at only the anterior or posterior edge; an anterior or posterior hinging was found when the opposite side opened, and lift off was found when the latter was in contact with the medial or lateral edge (Figure 6). Particularly, anterior hinging was found in 9 ankles in a maximum dorsiflexion position and in 2 ankles in a neutral position; and posterior hinging was found in 5 ankles in a maximum plantar flexion position.

Next, in a study of the 18 ankles of patients with a mean age of 75 years at an average of 44 months after surgery, Yamaguchi et al captured images of the gait motions of postoperative patients from a lateral side by using X-ray fluoroscopy, analyzed them by using the 2D-3D registration technique, and examined the three-dimensional motions thereof [10]. The findings showed a movement pattern in which the common point was that in gait, a slight plantar flexion occurred immediately after the heel touched the ground, and a dorsiflexion was found until toe off. In addition, the following were found in 8 of 15 ankles: anterior hinging (1 ankle), medial (2 ankles) or lateral (2 ankles) lift off, internal rotation of 5 degrees or higher (4 ankles), and external rotation (1 ankle). Thus the findings clarified that the components showed unexpected motions. However, there is yet no clear definition of hinging, lift off, or excessive rotation; and it remains unclear what kinds of negative effects they have. Clarifications regarding the relationship between the biomechanical phenomena and the clinical outcome are being awaited.

Prospects

In this review, we mentioned that the properties of the TNK ankle are that it is made of ceramic, and that it is a 2-component prosthesis with an original shape. Ceramic is believed to cause less polyethylene wear, and is a substance with actual achievements as a material for sliding surfaces. On the other hand, there was no established standard method for the fixation of the bone interface; however, based on clinical outcomes, cement fixation was used on the talar side and cement fixation or cementless fixation was used on tibial side; and we propose a method which consists of applying bone marrow fluid collected from the iliac bone onto the bone interface, in addition to calcium phosphate paste. In the future, prostheses made of composite with other materials or new materials may potentially be created through future research and development. In such cases, the clinical outcome of the TNK ankle as a unique ceramic prosthesis is certainly helpful.

Next, we will describe the prospects of 2-component prostheses. The currently mainstream 3-component, mobile type prosthesis maintains the fitting between the components through movements of the mobile insert, and at the same time, compensates for the mismatch during the fixed position of the component and the axis of rotation of the ankle. This may allow for attenuation of the stress applied to the bone interface, and may decrease the incidence of the loosening and sinking of components. However, because two sliding surfaces are non-physiologically present, and because the unconstrained insert can move freely, the risk of de-rotation is inevitable. Compared to mobile prostheses, 2-component prostheses are more physiological and pose no risk of de-rotation of the insert; and a better clinical outcome will likely be achieved by optimizing the fixed position and the design of the components through biomechanical research. In order to improve the accuracy of the fixed position, new operation devices, for example with a navigation function might need to be developed.

Next, we will describe the indications of TAA. Unlike the hip and the knee, the ankle has a smaller articular surface as compared to the external force, and is often subjected to traumas such as sprains; therefore, from the perspective of the survival rate and stability of the prosthesis, there is no change to the fact that it is under severe conditions. Therefore, it is also essential that the surgical indications of TAA be established, while distinguishing it from the indication of arthrodesis and that the clinical outcomes of TAA are improved. In fact, Takakura et al. have also suggested conditions such as type 3 or higher in the classification of the stages of OA, a valgus or varus deformity of 15 degrees or less, and "over 60 years in OA" [6], and clinical reports have shown gradual improvements.

As mentioned earlier, the TNK ankle has had a stable outcome over a long period of time, and has continuously influenced the TAA treatment with the clinical outcomes it has provided not only in Japan but all over the world. However, with the advent of 3D printers, the frequent morphological changes and even the customization of prostheses may not be impossible in the future. For that reason, there is need to have an accurate and precise understanding of the movements of prostheses after replacement, and to evaluate the correlation with the clinical outcome, and to provide feedback in relation to plans regarding their site of attachment, as well as additional changes in their shape. To do so, it might be necessary to speed up the improvement of products and their clinical outcomes by presenting convincing theories and justifications to regulatory agencies and by receiving approval for the process itself of improvement of the products.

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