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CLINICAL RESULTS AFTER TOTAL TALAR REPLACEMENT WITH ALUMINA CERAMIC PROSTHESIS EVALUATED USING SAFE-Q FOR OSTEONECROSIS OF THE TALUS

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Abstract

Background: The purpose of this retrospective review was to evaluate the clinical outcomes of patients who underwent total talar replacement for talar necrosis using the SAFE-Q score, which was hypothesized to improve postoperatively.

Methods: The study included 24 ankles of 22 patients who underwent total talar replacement from 2012 to 2018 and were evaluated using SAFE-Q preoperatively and postoperatively. Statistical analysis was performed using the mean values of the SAFE-Q and JSSF scale scores, and the range of ankle motion was compared before and 3 years after the surgery using the Wilcoxon signed-rank test.

Results: The SAFE-Q scores improved postoperatively in all the subcategories. "Pain and Pain-Related" changed from a mean value of 42.2 ± 23.9 points preoperatively to a mean value of 84.6 ± 12.6 points postoperatively ($p<.01$); "Physical Functioning and Daily Living" changed from 36.3 ± 25.2 points to 73.4 ± 20.5 points ($p<.01$); "Social Functioning" changed from 34.1 ± 34.8 points to 81.0 ± 25.3 points ($p<.01$); "Shoe-Related" changed from 41.3 ± 28.9 points to 75.4 ± 22.3 points ($p<.01$); and "General Health and Well-Being" changed from 36.7 ± 32.1 to 76.9 ± 29.3 points ($p<.01$).

Conclusion: Twenty-four osteonecrotic tali of 22 patients treated with alumina ceramic total talar replacement achieved good clinical results, as evaluated using the JSSF ankle/hindfoot score and SAFE-Q. Alumina ceramic total talar replacement is the mainstream treatment for talar osteonecrosis.

Level of Evidence: Level Ⅳ, retrospective comparative study.

Key words: SAFE-Q, total talar replacement, talar osteonecrosis

Background

Approximately 60% of the talus' surface is covered with articular cartilage, and there are no soft tissue attachments such as muscles or tendons, except for ligaments [1, 2]. Therefore, blood flow to this bone is relatively poor compared to that to other bones because of the limited area covered with the periosteum. Pathologies such as trauma, steroid use, or heavy alcohol intake

cause impaired blood flow, which can lead to osteonecrosis [3-5].

Surgical treatment for osteonecrosis of the talus has been performed using tibiotalar arthrodesis with a sliding tibial bone graft, as reported by Blair [6]. However, a higher rate of unstable hindfoot and pseudoarthrosis has been reported. To avoid these complications, Reckling reported tibiocalcaneal arthrodesis after resection of the affected talus [7], and Russotti et al. reported tibiotalocalcaneal arthrodesis [8]; however, inconveniences such as leg length discrepancy and a limited range of hindfoot motions remain.

To address these disadvantages, we developed an alumina ceramic talar prosthesis in 1999 and adapted it for avascular necrosis of the talus [9]. The first-generation model of artificial talar body prosthesis was initially designed with a bone peg for cement fixation to the neck of the talus. The peg was removed from the second-generation implants, and cement fixation was not performed in this model, expecting it to serve a bearing role only. However, in some cases, loosening and sinking of the residual talar head and neck occurred; therefore, we developed a third-generation model of alumina ceramic total talar prosthesis [10]. Total talar replacement using customized alumina ceramic implants is effective for the treatment of extensive osteonecrosis of the talus, and favorable postoperative clinical results have been reported using subjective and objective evaluation tools [11, 12].

The American Orthopaedic Foot and Ankle Society (AOFAS) scale and the Japanese Society for Surgery of the Foot Standard Rating System (JSSF) scale have been used to evaluate postoperative results. Previously, objective evaluation by medical staff was emphasized as an outcome measure for clinical results; however, recently, patient-based evaluation methods that lead directly to patient satisfaction have been frequently adopted. However, patient-based evaluation scales have not been developed specifically for foot and ankle disorders. The Self-Administered Foot Evaluation Questionnaire (SAFE-Q) was developed in 2012 to respond to these demands as a subjective evaluation scale dedicated to foot and ankle conditions [13]. This evaluation tool has five subcategories: “Pain and Pain-Related,” “Physical Functioning and Daily Living,” “Social Functioning,” “Shoe-Related” and “General Health and Well-Being,” and an additional category “Sports-Related,” which are answered in a five-choice format or recorded as a visual analog scale (VAS) score. Each question is assigned to any of these subcategories, and the total scores of each subcategory are converted to the maximum 100 points. Questions in the “Pain and Pain-Related” subcategory are associated with the pain experienced during various activities of daily living, questions in the "Physical Function and Daily Living” subcategory are about capability to perform activities of daily living such as going up and down the stairs and walking on uneven ground, questions in the "Social Functioning" subcategory are about capability to perform social life activities such as job, school life, and recreational activities, questions in the "Shoe-Related" subcategory are associated with inconveniences in shoe selection and their use, and questions in the “General Health and Well-Being” subcategory are associated with mental health conditions such as depressive state of mind and irritability due to foot problems.

To our knowledge, there have been no reports on evaluation of a certain number of cases after total talar replacement using the SAFE-Q. Herein, the clinical results 3 years after total talar replacement were investigated using the SAFE-Q.

This study aimed to evaluate the clinical outcomes of patients who underwent total talar re-

placement for talar necrosis using the SAFE-Q; the SAFE-Q score, which was hypothesized to improve postoperatively.

Materials & Methods

This retrospective case series study was approved by the institutional review board of the relevant hospital, and written informed consent was obtained from all study participants.

Cases were retrospectively selected from 24 ankles of 22 patients who underwent total talar replacement at the authors' institute from 2012 to 2018 and were evaluated using SAFE-Q preoperatively and postoperatively. There were 19 women and three men with 12 right and 12 left ankles. The average age at the time of surgery was 57.5 ± 14.2 years. Patients who underwent replacement on the distal tibial articular surface with the tibial component of the total ankle implant were excluded. The mean body mass index of the patients was 24.6 ± 5.0 kg/m^2. The causes of talar necrosis were trauma in one patient, steroid use in six patients with seven tali, diabetes mellitus in three patients with three tali, excessive alcohol intake in one patient with two tali, metastatic bone tumor in one talus of one patient, paralysis due to poliomyelitis in one talus of one patient, and idiopathic pathology in nine patients with nine tali. A patient with a habit of smoking was included in this case series. All patients were evaluated preoperatively and 3 years postoperatively by SAFE-Q, JSSF ankle/hindfoot scale, and ankle range of motion.

The artificial talus was produced by KYOCERA Medical, Inc. and was made of alumina ceramic. A computed tomography (CT) scan of the contralateral talus was used to create the prosthesis, but in cases where both sides were affected, the less deformed talus was used as a reference. The model of the customized implant was created from CT data using CAD, and the alumina ceramic was sintered, so manufacture took approximately 6 weeks from order to completion.

The patient was positioned supine with the ankle joint facing forward. During the procedure, a bloodless field was achieved using a tourniquet.

An anterior ankle approach was used in this procedure. The extensor retinaculum was exposed carefully to avoid damage to the branches of the superficial peroneal nerve. A longitudinal incision was made on the extensor retinaculum to protect the neurovascular bundle of the anterior tibial artery and the deep peroneal nerve. A joint capsule of the tibiotalar and talonavicular joints was made so that the entire anterior aspect of the talus could be exposed.

The talar neck was cut with a surgical bone saw first, and then the talar body was osteotomized and resected approximately 1 cm thick sequentially in the coronal plane. The posterior part of the talar body was cut in the sagittal plane and excised to avoid damage to the flexor hallucis longus tendon.

An artificial talus was inserted into the cavity where the talus was removed. The articular capsule was sutured to the maximum possible extent. The extensor retinaculum was repaired to prevent wound disruption.

Cast immobilization was applied for 3 weeks, and partial weight-bearing was gradually allowed from a week after the surgery.

Statistical analysis was performed using the mean values of the SAFE-Q and JSSF scale scores, and the range of ankle motion was compared before and 3 years after the surgery using

the Wilcoxon signed-rank test. A p-value <.05 was estimated to be statistically significant. Statcel 4 (version 4; OMS, Tokyo, Japan) was used for statistical analysis.

Results

The mean JSSF ankle/hindfoot scale score improved from a mean value of 42.3 ± 17.9 points preoperatively to 89.2 ± 9.4 points postoperatively (p<.01). The range of motion improved from a mean value of 40.7 ± 12.9° preoperatively to 48.7 ± 11.4° postoperatively (p<.01) (Table 1).

Table 1. Patient Characteristics and JSSF ankle/hindfoot scale and Range of motion

					JSSF ankle/hindfoot scale		Range of motion	
Patient	Age(yrs)	Gender	Cause	Side	Pre-operative	Final follow-up	Pre-operative	Final follow-up
1	52	F	Steroid	L	20	85	48	53
2	63	F	Idiopathic	L	57	85	50	48
3	44	M	Over drink	L	71	100	50	43
4	34	F	Steroid	L	18	98	47	58
5	42	F	Steroid	L	29	84	50	65
6	66	F	Tumor	R	22	100	33	47
7	34	F	Steroid	R	42	87	40	52
8	63	F	Steroid	R	32	72	50	40
9	66	F	Idiopathic	R	34	87	42	42
10	60	F	Idiopathic	R	57	100	61	70
11	67	F	Idiopathic	L	36	73	44	45
12	69	F	Diabetes	L	45	90	30	65
13	46	M	Over drink	R	49	95	58	53
14	37	F	Steroid	L	68	87	39	52
15	45	F	Paralysis	R	23	90	29	38
16	67	F	Steroid	R	56	80	66	57
17	54	M	Idiopathic	R	74	100	35	46
18	43	M	Diabetes	R	63	98	31	44
19	83	F	Idiopathic	L	40	82	52	40
20	68	F	Diabetes	L	42	98	25	48
21	57	F	Idiopathic	L	62	71	20	15
22	68	F	Fracture	R	39	84	20	58
23	81	F	Idiopathic	R	16	100	26	54
24	72	F	Idiopathic	L	22	97	30	36

Patients 3 and 13, 4 and 7 are the same patient.

The SAFE-Q scores improved postoperatively in the subcategories as follows: "Pain and Pain-Related" changed from a mean value of 42.2 ± 23.9 points preoperatively to a mean value of 84.6 ± 12.6 points postoperatively (p<.01); "Physical Functioning and Daily Living" changed from 36.3 ± 25.2 points to 73.4 ± 20.5 points (p<.01); "Social Functioning" changed from 34.1 ± 34.8 points to 81.0 ± 25.3 points (p<.01); "Shoe-Related" changed from 41.3 ± 28.9 points to 75.4 ± 22.3 points (p<.01); and "General Health and Well-Being" changed from 36.7 ± 32.1 to 76.9 ± 29.3 points (p<.01) (Table 2).

In this study, scores in all subcategories improved significantly, especially in the "Pain and Pain-Related" and "Social Functioning" subcategories. Severe pain and deteriorated alignment caused by idiopathic necrosis and collapse in the talus was improved by total talar replacement, resulting in the restoration of social functioning.

No serious postoperative complications requiring revision surgery, such as implant failure or

Table 2. Changes in each SAFE-Q item

Patient	Pain and Pain-Related		Physical Functioning and Daily Living		Social Functioning		Shoe-Related		General Health and Well-Being	
	Pre-operative	Final follow-up	Pre-operative	Final follow-up	Pre-operative	Final follow-up	Pre-operative	Final follow-up	Pre-operative	Final follow-up
1	45.6	86.7	43.2	88.6	62.5	95.8	41.7	66.7	60	95
2	38.3	75.6	36.4	36.4	29.2	45.8	50	41.7	30	40
3	61.7	87.8	43.2	70.5	41.7	87.5	58.3	91.7	40	95
4	38.9	66.7	29.5	56.8	0	95.8	8.3	66.7	25	80
5	25	77.8	25	59.1	45.8	66.7	8.3	50	40	90
6	36.7	100	20.5	88.6	4.2	91.7	8.3	91.7	0	95
7	44.4	66.7	50	56.8	75	95.8	33.3	66.7	55	80
8	60	66.7	52.3	38.6	29.2	41.7	41.7	41.7	10	45
9	80	88.9	88.6	79.5	100	100	75	75	95	85
10	71.7	100	90.9	95.5	100	100	83.3	100	85	100
11	38.9	79.4	18.2	40.9	29.2	8.3	41.7	58.3	15	55
12	19.4	88.9	43.2	93.2	16.7	100	33.3	100	10	95
13	27.8	94.4	36.4	63.6	4.2	75	66.7	83.3	15	100
14	80	86.1	13.6	93.2	4.2	100	66.7	100	30	100
15	0	70.6	0	43.2	0	83.3	0	58.3	0	20
16	18.9	66.7	18.2	81.8	0	62.5	41.7	50	0	0
17	64.4	100	52.3	97.7	70.8	100	100	100	75	95
18	78.3	95.6	77.3	86.4	95.8	100	83.3	83.3	100	100
19	20	86.1	43.2	65.9	79.2	54.2	25	66.7	35	70
20	49.4	93.3	43.2	93.2	29.2	95.8	41.7	100	50	95
21	45	69.4	38.6	52.3	41.7	50	41.7	33.3	35	35
22	41.7	83.9	18.2	63.6	20.8	79.2	50	58.3	45	75
23	5	95.6	4.5	97.7	0	100	16.7	100	5	100
24	41.7	100	31.8	93.2	20.8	100	25	100	75	100

subsidence, were observed during the postoperative follow-up period.

Discussion

As described by Blair, ankle arthrodesis has been performed using a sliding tibial graft as a surgical treatment for osteonecrosis of the talus [6]. However, this technique results in an unstable hindfoot, which sometimes leads to pseudoarthrosis at the fusion site. Therefore, some modified techniques have been developed to overcome these disadvantages, including stabilization via the insertion of a Styman pin from the calcaneus to the tibia, as reported by Morris [14]. Lionberger reported compression screw insertion from the posterior tibia to the talar neck for compressed fixation [15].

To obtain hindfoot stability, Reckling reported tibiocalcaneal arthrodesis with partial excision resection of the affected talus and calcaneus [7]. A leg length discrepancy of approximately 3 cm occurred in this technique, and the range of hindfoot motion was highly restricted. Russotti reported tibiotalocalcaneal arthrodesis with autograft [8]; however, the problem of loss of hindfoot motion remained.

An artificial talus was designed and developed to prevent disabling complications. In 1997, Harnroongroj reported the successful clinical application of a stainless-steel artificial talar body prosthesis [16]. According to experimental studies concerning the affinity to the articular cartilage, alumina ceramic has been proven to be better than stainless steel as the material facing the articular cartilage [17, 18]. Therefore, we developed an artificial talar implant made of alumina ceramic in 1999, which has been improved through some modifications since then [9].

With the development of 3D printing technology, there have been reports of total talar replacement using 3D printed metal implants; Kadakia reported a titanium nitride-coated chrome

implant and Tracey reported a nickel-plated cobalt implant [19, 20]. One of the advantages of this technique is shortening the time required for the creation of the implant, which leads to rapid surgical intervention compared with the past [19]. The durability of the metals used in these investigations is favorable [21] however, their effect on articular cartilage has not been sufficiently evaluated until now.

Customized alumina ceramic artificial talar prostheses have been reported to be effective for irrecoverable talar necrosis. Taniguchi reported results for talar body prostheses [10]. The clinical results of eight patients who underwent replacement with the first-generation talar body prosthesis that mounts a peg for cement fixation to the talar neck were excellent in three patients, good in one, fair in three, and poor in one. The clinical results of 14 patients who underwent replacement with the second-generation talar body prosthesis without peg and fixation to the talar neck were excellent in three patients, good in five, fair in four, and poor in two. Two patients in each group required revision with a total talar prosthesis. Although the first- and second-generation implants showed favorable clinical results, loosening of the fixation site and bursting of the talar head occurred in some cases. Currently, third-generation prostheses that replace the entire talus are being adopted. The postoperative results of total talar prostheses have been reported in recent years. Taniguchi reported that the JSSF ankle/hindfoot scale score improved from 43.1 ± 17.0 preoperatively to 89.4 ± 8.4 postoperatively, and the "pain at its worst" item on the Ankle Osteoarthritis Scale (AOS) scale improved from 6.1 ± 3.3 preoperatively to 2.0 ± 1.7 postoperatively [11]. Katsui et al. performed total talar replacement in six ankles of six patients with post-traumatic osteonecrosis of the talus and reported significant improvement in the JSSF scale score from a preoperative mean of 64 points to a postoperative mean of 88.5 points and ankle joint range of motion from a preoperative mean of 29° to a postoperative mean of 35° [12]. In this case series, the JSSF scale score improved from a preoperative mean of 42 points to a postoperative mean of 89 points, and the ankle joint range of motion improved from a preoperative mean of 41° to a postoperative mean of 49° at 3 years postoperatively.

The AOFAS and JSSF scales have been used as objective evaluation tools for foot and ankle disorders from the viewpoint of medical staff. In recent years, evaluation scales have been used not only as a scale for diagnosis and treatment efficacy but also for the evaluation of validity; therefore, scales should be easily understood by ordinary people.

From this perspective, the SAFE-Q was developed as a patient-based questionnaire to evaluate patients' quality of life from multiple perspectives [13]. The former patient-based assessment methods include the Medical Outcome Study Short-Form 36-Item Health Survey (SF-36) and the AOS.

The SF-36 is a self-reported health status questionnaire widely used worldwide [22]. It is designed to assess comprehensive health concepts and consists of 36 items and eight subscales (physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health perceptions). However, this is not a specific tool for foot and ankle disorders. It is widely used for a variety of purposes, including health reports of patients, outcome evaluation for treatment and mental care status, and surveys of health in the general population. As the SF-36 is a comprehensive evaluation scale, it is difficult to use it to evaluate specific foot and ankle diseases with

high sensitivity.

The AOS consists of nine questions on pain and disability in foot diseases, and the questions are answered using a VAS [23]. Although this is an excellent evaluation of foot diseases, questions concerning patient satisfaction are not included.

The SAFE-Q was designed as a patient-based evaluation method specifically for determining the effectiveness of treatments for foot and ankle diseases [13]. The subscale includes six items: "Pain and Pain-related," "Physical Functioning and Daily Living," "Social Functioning," "Shoe-Related," "General Health and Well-Being," and an optional item "Sports-Related." This allows a more detailed assessment of pre- and postoperative symptom changes. Niki et al. reported a study on SAFE-Q and SF-36 responsiveness before and after hallux valgus surgery and stated

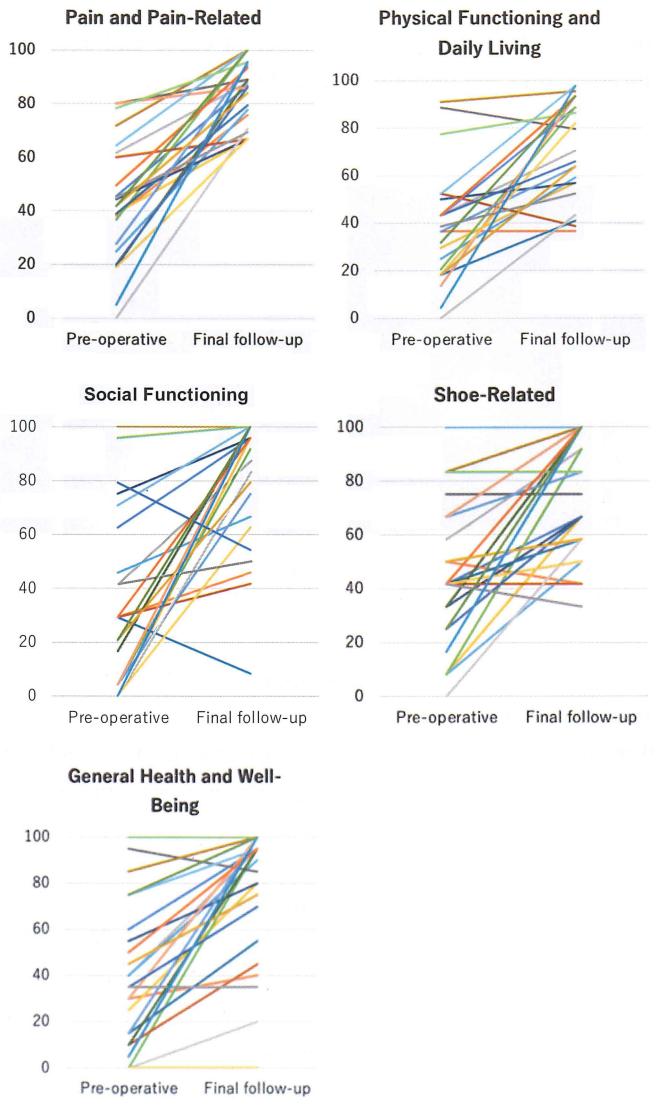

Fig. 1. Changes in SAFE-Q items at preoperative and final follow-up

that the SAFE-Q is sufficient to assess the quality of life of the patient before and after surgery [24].

The SAFE-Q has been increasingly used in recent years to report the treatment outcomes for foot and ankle disorders. Since the first alumina ceramic talar replacement for osteonecrosis of the talus was performed in 1999, the number of cases has been gradually increasing with improvements, and the results of treatment have been reported, but currently, there are no reports of evaluation using the SAFE-Q for this. Morita et al. evaluated the long-term results of alumina ceramic total talar replacement in 19 feet of 18 patients with idiopathic necrosis of the talus using radiological imaging, JSSF scale, and AOS and reported good results [25]. In their report, the AOS was used as a patient-based evaluation method and had fewer evaluation items than the SAFE-Q did. Therefore, it is necessary to use more segmented evaluation tools for an increasing number of patients.

The limitations of this study are the small number of cases and short follow-up period because of the brief duration after the development of the SAFE-Q.

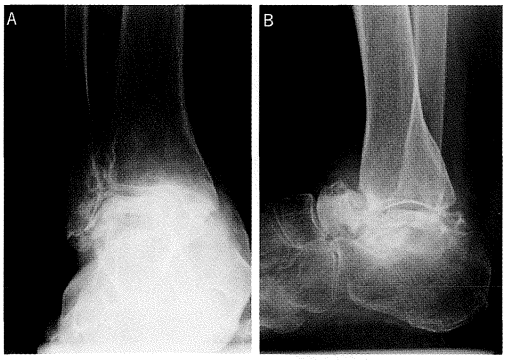

Fig. 2. Radiograph of 66-year-old women with osteonecrosis of the talus. (A) Anteroposterior view. (B) Lateral view.

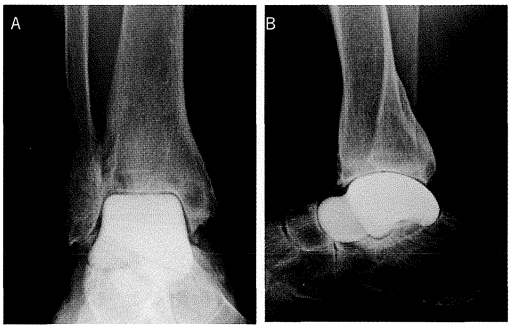

Fig. 3. Postoperative weightbearing radiography. (A) Anteroposterior view. (B) Lateral view.

Conclusion

Twenty-four osteonecrotic tali of 22 patients treated with alumina ceramic total talar replacement achieved good clinical results, as evaluated using the JSSF ankle/hindfoot score and SAFE-Q. Alumina ceramic total talar replacement is the mainstream treatment for talar osteonecrosis.

Conflict of interest

The authors report no conflicts of interest. The authors alone are responsible for the content in and writing of the paper.

References

1) Mulfinger GL, Trueta J: The Blood Supply of the Talus. The Journal of Bone and Joint Surgery British volume 52-B: 160-167, 1970

2) Gelberman RH, Mortensen WW: The arterial anatomy of the talus. Foot Ankle 4: 64-72, 1983
3) Harris RD, Silver RA: Atraumatic aseptic necrosis of the talus. Radiology 106: 81-83, 1973
4) Adleberg JS, Smith GH: Corticosteroid-induced avascular necrosis of the talus. J Foot Surg 30: 66-69, 1991
5) Vallier HA, Nork SE, Barei DP, et al: Talar neck fractures: results and outcomes. J Bone Joint Surg Am 86: 1616-1624, 2004
6) C.BlairM.D. H: Comminuted fractures and fracture dislocations of the body of the astragalus: operative treatment. Am J Surg 59: 37-43, 1943
7) Reckling FW: Early tibiocalcaneal fusion in the treatment of severe injuries of the talus. J Trauma 12: 390-396, 1972
8) Russotti GM, Johnson KA, JR C: Tibiotalocalcaneal arthrodesis for arthritis and deformity of the hind part of the foot. J Bone Joint Surg 70: 1304-1307, 1988
9) Tanaka Y, Takakura Y, Kadono K, et al: Alumina Ceramic Talar Body Prosthesis for Idiopathic Aseptic Necrosis of the Talus. Key Engineering Materials 240-242: 805-808, 2003
10) Taniguchi A, Takakura Y, Sugimoto K, et al: The use of a ceramic talar body prosthesis in patients with aseptic necrosis of the talus. J Bone Joint Surg Br 94: 1529-1533, 2012
11) Taniguchi A, Takakura Y, Tanaka Y, et al: An Alumina Ceramic Total Talar Prosthesis for Osteonecrosis of the Talus. J Bone Joint Surg Am 97: 1348-1353, 2015
12) Katsui R, Takakura Y, Taniguchi A, et al: Ceramic Artificial Talus as the Initial Treatment for Comminuted Talar Fractures. Foot Ankle Int 41: 79-83, 2020
13) Niki H, Tatsunami S, Haraguchi N, et al: Validity and reliability of a self-administered foot evaluation questionnaire (SAFE-Q). J Orthop Sci 18: 298-320, 2013
14) H D Morris WLH, A W Dunn: The Modified Blair Fusion for Fractures of the Talus. J Bone Joint Surg Am 53: 1289-1297, 1971
15) Lionberger DR, Bishop JO, Tullos HS: The modified Blair fusion. Foot Ankle 3: 60-62, 1982
16) Harnroongroj T, Vanadurongwan V: The talar body prosthesis. J Bone Joint Surg Am 79: 1313-1322, 1997
17) Yoshinaga K: Replacement of femoral head using endoprosthesis (alumina ceramics vs metal). An experimental study of canine articular cartilage. Nihon Seikeigeka Gakkai zasshi 61: 521-530, 1987
18) Degreif J, Hammer M, Wenda K, et al: Long-term outcome of managing medial femoral neck fractures with ceramic head endoprostheses. Unfallchirurg 99: 744-749, 1996
19) Tracey J, Arora D, Gross CE, et al: Custom 3D-Printed Total Talar Prostheses Restore Normal Joint Anatomy Throughout the Hindfoot. Foot Ankle Spec 12: 39-48, 2019
20) Kadakia RJ, Akoh CC, Chen J, et al: 3D Printed Total Talus Replacement for Avascular Necrosis of the Talus. Foot Ankle Int 41: 1529-1536, 2020
21) van Hove RP, Sierevelt IN, van Royen BJ, et al: Titanium-Nitride Coating of Orthopaedic Implants: A Review of the Literature. Biomed Res Int 2015: 485975, 2015
22) Ware JE Jr SC: The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 30: 473-483, 1992
23) Robyn T. Domsic CLS: Ankle Osteoarthritis Scale. Foot Ankle Int 19: 466-471, 1998
24) Niki H, Haraguchi N, Aoki T, et al: Responsiveness of the Self-Administered Foot Evaluation Questionnaire (SAFE-Q) in patients with hallux valgus. J Orthop Sci 22: 737-742, 2017
25) Morita S, Taniguchi A, Miyamoto T, et al: The Long-Term Clinical Results of Total Talar Replacement at 10 Years or More After Surgery. J Bone Joint Surg Am, 2022