

Short-term Results of the Agility Total Ankle Arthroplasty

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Agility 인공 삽입물을 이용한 족관절 전치환술의 단기 추시 결과

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Purpose: Recently, there has been increasing interest in total ankle arthroplasty as an alternative to ankle arthrodesis. This study examined the short-term results of total ankle arthroplasty using an Agility prosthesis.

Materials and Methods: This study reviewed the results of 11 patients who underwent total ankle arthroplasty using the Agility prosthesis between May, 2003 and May, 2004. With a postoperative follow-up period of 2 years, 10 patients (10 ankles) were available for review at the time of the follow-up. The clinical evaluation included the ankle range of motion, the personal type of preferred shoe, walking pain (VAS score) and the American Orthopaedic Foot and Ankle Society (AOFAS) ankle score. In addition, the patients were asked whether they were satisfied with the outcome and if they would choose to undergo the same procedure again. The radiologic evaluation included the loosening of the prosthesis, osteolysis and syndesmosis union. The anterior surgical approach was used. The syndesmosis area was fixed using 2 cannulated screws inserted percutaneously in 9 cases and a plate in 1 case.

Results: The patients consisted of two men and eight women. The average age was 51.8 years (range 41 to 67) with an average follow-up of 30.3 (range 24 to 36) months. The mean preoperative and postoperative AOFAS ankle scores were 38.2 and 73.8, respectively, demonstrating significant improvement. The mean preoperative and final follow-up walking pain was 8.9 and 2.8, respectively. The ankle range of motion was decreased slightly at the final follow-up. Five patients required a cane to walk. Radiographic analysis showed no prosthesis failure, even though osteolysis occurred around the prosthesis in all cases. Only one case showed further progression. Union in the syndesmosis area occurred within 6 months in 5 cases and delayed union was observed in 3 cases, and nonunion was observed in 2 cases. Sensory loss in the area innervated by the deep peroneal nerve and a fracture in the lateral malleolus was encountered in one case, but this recovered with conservative treatment. Subtalar joint arthritis was noted in one case.

Conclusion: Agility total ankle arthroplasty results in a favorable outcome at the short-term follow-up. However, total ankle arthroplasty is associated with radiographic complications including syndesmosis nonunion and osteolysis. Only syndesmosis nonunion was associated with the clinical results. Therefore, long-term follow-up is considered to be necessary to demonstrate osteolysis and loosening with their clinical association.

Key Words: Ankle osteoarthritis, Agility total ankle prosthesis, Total ankle arthroplasty

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INTRODUCTION

Many studies have shown that the development of ankle arthritis is the result of a variety of conditions, including primary osteoarthritis, post-traumatic osteoarthritis following the fracture or sprain, gouty osteoarthritis and rheumatic osteoarthritis^{14,16}. Although non-surgical treatment may be successful in early arthritis, progressed arthritis requires surgical treatments such as a corrective osteotomy, ankle arthrodesis, or distraction arthroplasty using an external fixator or ankle joint arthroplasty.

Currently, the standard surgical treatment option is ankle arthrodesis⁵. However, total ankle arthroplasty has been considered because the long-term follow up has revealed potential shortcomings of ankle arthrodesis. Despite the increasing failure rates, the interest in total ankle arthroplasty has been renewed because ankle arthrodesis causes degenerative arthritis in the adjacent articulations and a limited range of motion in the latter stage. Although many surgeons believed in early days that the results of total ankle arthroplasty would be encouraging, several shortcomings have been reported including limited tolerance, low patient satisfaction and high complication rates. Many second-generation implants have been introduced as a result of the disadvantages of first-generation implants, among which Agility (Depuy, Warsaw, Indiana) is a prototypical design. There are few reports on the results of total ankle replacement using the Agility total ankle prosthesis in Korea whereas many are available in other countries. Therefore, we report the short-term results of total ankle arthroplasty using the Agility prosthesis in patients with ankle osteoarthritis who did not respond to conservative management.

MATERIALS AND METHODS

1. Materials

This study reviewed the results of total ankle arthroplasty using the Agility prosthesis, which were performed between May, 2003 and May, 2004, in 10 patients (10 ankles, two males and eight females) suffering from ankle osteoarthritis despite medication, physical therapy, orthosis application and strengthening exercises over a 6 month period. All patients had a minimum postoperative follow up period of 2 years. The average age was 51.8 (range 41 to 67) years and the average follow up was 30.3 (range 24 to 36) months. The preoperative diagnoses were rheumatoid arthritis (3 ankles), primary osteoarthritis (3 ankles) and posttraumatic arthritis following an ankle fracture (4 ankles). All the procedures were performed by a single surgeon. Both the clinical and radiological results were reviewed at the postoperative 6 weeks, 3 months, 6 months, one year, then annually until the most recent follow up.

2. Methods

The clinical evaluation included the ankle range of motion, walking pain (VAS score) and the American Orthopaedic Foot and Ankle Society (AOFAS) ankle score⁶ at the most recent follow up. The overall range of motion was obtained using the method proposed by Coetzee et al³, who measured the angle formed between a line drawn from the superior horizontal plane of the tibial component to the inferior horizontal plane of the talar component and then the tibio-talar and the midfoot range of motion separately using a line extending from the axis of the first metatarsal. In addition, the patients were asked whether they were satisfied (excellent, good, fair, poor) with the outcome and if they would choose to undergo the procedure again. They were also asked if they used the orthosis. Weight bearing radiographs, consisting of antero-

posterior, lateral, and mortice views as well as the lateral views of the ankle at maximal flexion and extension were reviewed at each follow up. In addition, the evidence of syndesmosis union, loosening and migration of the prosthesis, osteolysis, and posttraumatic hindfoot arthritis were also examined. The syndesmosis was examined for any evidence of union defined as bony trabeculation across the union site, and was defined as either union (in less than 6 months), delayed union (in more than 6 months), or nonunion (lack of union at the time of most recent follow up)¹¹. Subsidence was measured using the relationship between the position of the component in a parallel plane and the sclerotic line near the osteotomy site⁸. The MML (medial malleolar line: the distance between the position of talar component in parallel plane and the tip of medial malleolus) was also measured¹¹. Angular migration of a component was defined as evidence of a minimum of 5° shifts in the anteroposterior and lateral views, according to the protocol outlined by Saltzman et al¹¹.

Lucency was defined as a radiolucent line of 2 mm or less in width and lysis was defined as a radiolucency of >2 mm. The distal tibia was divided into six zones on the anteroposterior view,

and into three zones on the lateral view^{11,8}.

3. Surgical Techniques

The preoperative evaluations including the size of implant and the extent of the osteotomy, were determined using plain radiographs. After spinal anesthesia, a sandbag was placed on the operating table under the hip involved in order to help maintain the ankle in the neutral position with the patient in the supine position. Initially, the external fixator was positioned over the tibia, the neck of the talus, and calcaneus, followed by traction of approximately 5 mm to 7 mm. The alignment of the ankle joint was then checked to determine if it was acceptable. The anterior surgical approach, using the interval between the anterior tibial tendon and the extensor hallucis longus tendon, was used to expose the ankle joint and place the Zig at the appropriate site so that the distal tibia and talar dome were resected approximately 4 to 5 mm and 5 to 6 mm, respectively. The implant was inserted and the soft tissues around the syndesmosis were debrided. A bone graft was performed with the remaining cancellous bones, and the syndesmosis was then fixed using two screws inserted percutaneously (Fig. 1). After skin closure, a short leg cast

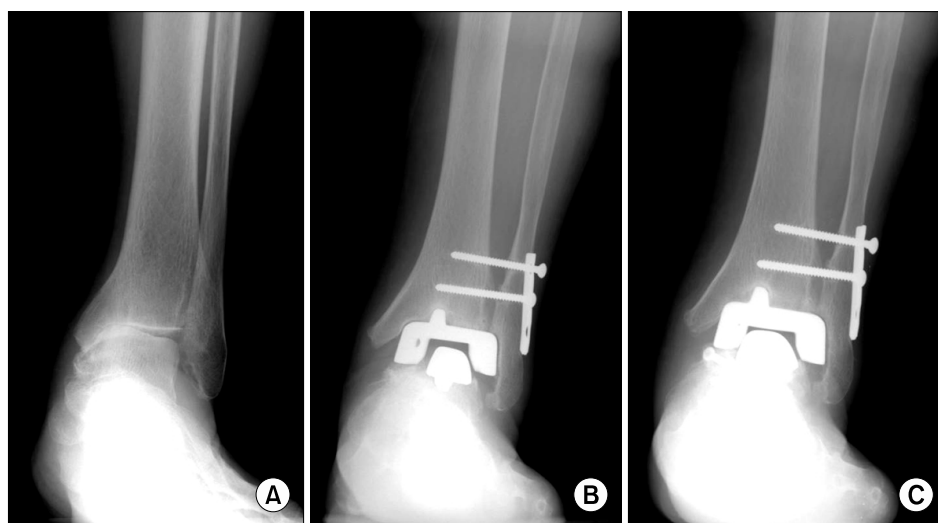


Fig. 1. (A) Preoperative standing AP radiograph of a 67 years female patient showing a collapsed medial joint space and varus tilting of the talus. The syndesmosis area was fixed using a plate and screws. (B) At 12 months after surgery, the standing AP radiograph shows proximal screw loosening, circumferential lucency and syndesmosis nonunion. (C) At 24 months after surgery, the standing AP radiograph shows persistent proximal screw loosening and syndesmosis nonunion. However, lucency from zones 1 to zone 5 had disappeared.

was applied. Wound care and swelling were managed for several days. This was followed by an additional 6 weeks of protected weight bearing in a short leg cast. Range of motion exercises and rehabilitation were initiated once the short leg cast had been removed.

RESULTS

1. Clinical Results

The mean preoperative and postoperative AOFAS ankle scores were 38.2 (range 14 to 52) and 73.8 (range 61 to 85), respectively, demonstrating significant improvement. The waking pain at the final follow up improved to an average of 2.8 (range 1 to 5), compared with 8.9 (range 8 to 10) before surgery. The mean ankle range of motion decreased slightly by 10° (range 0° to 25°) and 23% (range 0 to 50%) at the final follow up (Table 1). Five patients required a cane to walk. Among a total of ten patients, eight, one and one reported satisfaction, good and dissatisfaction with the clinical outcomes of their surgery, respectively. Interestingly, the improvement in the level of ankle pain resulted in satisfactory outcome on three out of eight patients even though they required a cane to walk. Five patients stated that they would undergo total ankle arthroplasty again

under similar circumstances.

2. Radiographic Results

According to the final radiographic analysis, none of the ankles showed evidence of component migration in the transverse plane or evidence of sclerotic line changes. There was no subsidence of the components, as demonstrated by the lack of change in the MML. None of the components failed. Radiographic analysis showed a lucent line in all cases, which were, according to Pyevich and Saltzman et al^{11,13)}, three in Zone 6, one in Zone 1 to 6 and one in Zones 1, 5 and 6 on the anteroposterior radiographs. Lysis, involvement of only Zone 6, was noted in three ankles. One ankle with lysis showed progression, whereas the remaining subjects showed sclerosis at the last follow up radiographs (Fig. 2). Syndesmotic fusion was observed within 6 months in 5 ankles. Three ankles showed delayed union, taking longer than 6 months, but less than 10 months to unite. Two ankles were associated with nonunion on the syndesmosis. One patient was dissatisfied while the other was satisfied or good. They all required a cane to walk and would not undergo a similar procedure under similar circumstances. Although there was a loss of sensation in the area innervated

Table 1. Patient's Clinical Results

CASE	SEX	AGE	f/u (ms)	AOFAS score		Pain score (VAS)		ROM		Satisfaction
				Preop.	Last f/u	Preop.	Last f/u	Decrement	Percentage	
1	F	41	24	34	83	9	2	0	0	Fair
2	F	61	26	36	61	8	4	10	22.2	Good
3	F	67	30	14	65	10	4	15	30	Poor
4	F	43	25	41	75	8	4	0	0	Good
5	F	44	31	38	65	9	5	5	25	Good
6	M	45	31	49	70	8	2	15	50	Good
7	M	60	34	36	82	10	1	25	41.6	Good
8	F	51	36	45	85	9	1	20	33.3	Good
9	F	61	30	37	67	10	4	5	16.6	Good
10	F	45	36	52	85	8	1	5	12.5	Good
Mean		51.8	30.3	38.2	73.8	8.9	2.8	10°	23.1%	

AOFAS, American Orthopaedic Foot and Ankle Society; VAS, visual analog scale; ROM, range of motion.

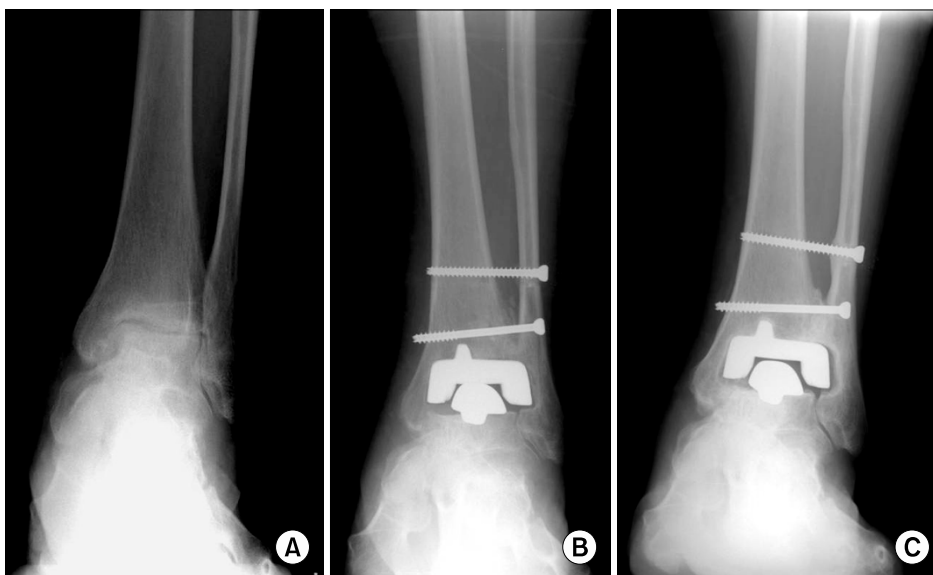


Fig. 2. A 44 years old female patient underwent total ankle arthroplasty using an Agility implant. (A) Preoperative standing anteroposterior radiograph showing advanced osteoarthritis. (B) Postoperative AP radiograph taken 6 months after surgery showing mild osteolysis around the lateral side of tibial component. Syndesmosis fusion is not complete. (C) At 31 month after surgery, the standing AP radiograph shows further progression of lysis at zone 6 and lucency at zone 1.

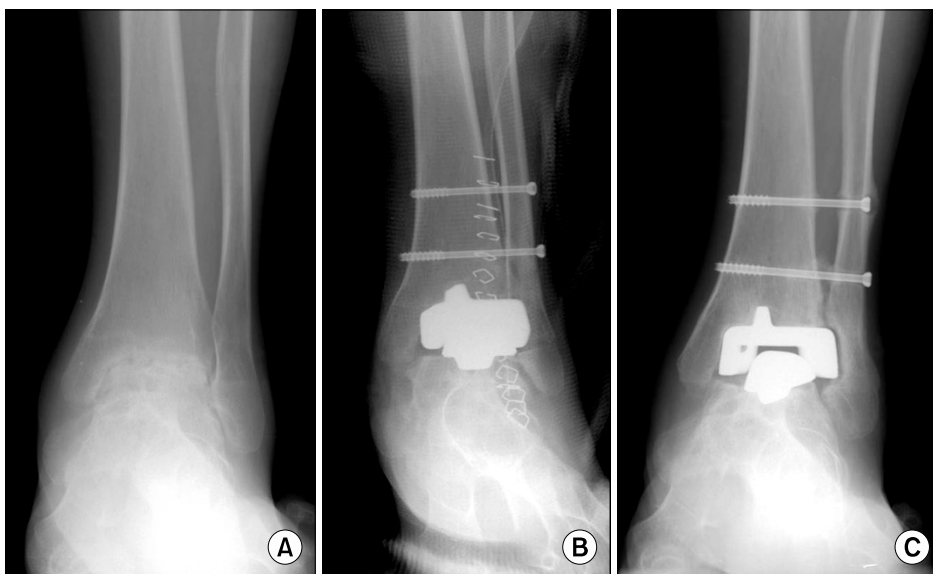


Fig. 3. (A) Preoperative standing AP radiograph of a 41 year old female patient showing a collapsed joint space, sclerotic margin and osteophytes. (B) Postoperative AP radiograph shows a transverse fracture of the lateral malleolus immediately below the tibial component. (C) At 24 months after surgery, the standing AP radiograph shows complete healing of the lateral malleolar fracture. However, syndesmosis nonunion and lucency at zone 6 can be seen.

by the deep peroneal nerve in one patient, it returned normal at 6 months after surgery. One case was complicated by a lateral malleolar fracture, which was treated with cast immobilization and bony union was achieved (Fig. 3). Subtalar arthritis was observed in one ankle at 31 months after surgery (Table 2).

DISCUSSION

The Agility (Depuy, Warsaw, Indiana) and Scan-

dinavian Total Ankle Replacement or STAR (Link Inc., Hamburg, Germany) are examples of prototypical second generation implants. The Agility ankle is especially popular in the USA and a two-component design that allows medial-lateral shift as well as axial rotation is commonly used because the polyethylene liner is firmly fixed to the tibial component. The syndesmotic fusion must be achieved for the Agility ankle, making it disadvantageous because nonunion of the syndesmosis is

Tabel 2. Patient's Radiographic Results and Complications

Case	Syndesmosis fusion	Stem subsidence	Lucency	Lysis	Complication
1	Nonunion	No	Zone 6	No	LM Fx.
2	Delayed	No	No	Zone 6	DPN injury
3	Nonunion	No	No	No	Plate fixation
4	6 months	No	Zone 6	No	No
5	Delayed	No	No	Zone 6	No
6	Delayed	No	No	No	Subtalar arthritis
7	6 months	No	Zone 6	No	No
8	6 months	No	Zone 1, 5, 6	No	No
9	6 months	No	Zone 1-5	Zone 6	No
10	6 months	No	No	No	No

LM, lateral malleolus; DPN, deep peroneal nerve.

associated with the stability of the tibial component¹¹. There are no standard parameters for measuring the ankle range of motion during the follow up after a total ankle replacement. Indeed, most studies have reported a mixture between the ankle and the midfoot range of motion^{2,7,17}. The ankle range of motion reported by Pyevich et al¹¹, was greater than in other reports, because they measured a mixture of the ankle and the midfoot range of motion. The method reported by Kitaoka and Patzer et al⁷, did not exclude the midfoot range of motion because the axis of the leg and foot using a goniometer on the lateral side was measured relatively. Therefore, Coetzee et al³, recommended a more objective and reliable method to measure the angle using the horizontal plane of a prosthesis. This led to a lower measured value than that measured in the above two studies. This shows that even a small change in the range of motion was exaggerated in most studies. At the final follow up, the average range of motion of ankle was 28° showing a mean 10° (range 0° to 25°) and 23% (range 0 to 50%) change compared with that measured before surgery. Another study reported a mean 36° change in the average range of motion after a mean follow up of 4.8 years¹¹. The mean AOFAS score in this study at the last follow up was the average of 73.8 whereas Deland et al⁴, and Pyevich et al¹¹, reported the average of 83.3 and

85, respectively. The difference in the AOFAS score was attributed to a higher union rate of syndesmosis.

According to Pyevich and Saltzman et al^{11,13}, delayed union or nonunion of the distal syndesmosis is closely associated with the migration and stability of the tibial component and might result in an unsatisfactory clinical outcome. On the other hand, union of syndesmosis prevents subsidence of the tibial component from its further progression. They reported a nonunion rate of syndesmosis, and delayed union rate of 9% and 29%, respectively, after an average follow up of 4.8 years. In the other study, a 12% of nonunion rate was reported¹⁴. A literature review reported by Pomeroy and Barrow et al, showed a delayed union rate and nonunion rate of 29–38% and 9–18%, respectively¹. The results from the present study, although a small group was involved, are considered to be similar to that of Pyevich and Saltzman et al, reported that two patients with nonunion showed fair and dissatisfaction. These patients required a cane to walk and said that they would not undergo the procedure again. Several studies including the injection of an autologous platelet concentrate¹ and syndesmosis fixation using plate and multiple screws¹¹ were carried out to promote a syndesmotomic union. Using an autologous platelet concentrate, Barrow and Pomeroy et al¹ reported union

in all cases within 6 months. Pyevich and Saltzman et al^{11,13} reported that plate fixation of syndesmosis is a good method in that it not only it promotes union, but also it prevents and treats a fibular fracture. Therefore, it is currently favorable to use a plate and multiple screws for distal syndesmotomic fixation. However in this study, distal syndesmotomic fixation using a plate, with the aim of promoting union, resulted in nonunion because of screw loosening (Fig. 1). It is believed that this nonunion and loosening were attributed to the incomplete penetration of the screw into the medial tibial cortex and the syndesmotomic instability by the tibial component upon weight bearing. Therefore, complete penetration of the screw into the medial tibia cortex will prevent the screws from loosening and promote union.

Pyevich et al. stated that periprosthetic radiographic lucency was always present in less than 2 years after surgery and ceased progression after several years. This was believed to result from the insufficient fixation of the component in the early stage. Osteolysis occurred frequently in the lateral side of the tibial component and occurred even more frequently when complicated by delayed union of the syndesmosis or nonunion. This was described as a result of bone absorption as a result of the shearing force produced between the remnant fibula and the lateral tibial component. In addition, of the end of progressive bone absorption could be indicated once sclerosis around the fibular margin was detected¹¹.

Osteolysis in Zone 6 on the anteroposterior plain radiographs were reported to be closely related to the score of walking pain, whereas that in Zones 1 to 5 were associated with the subsidence of the tibial component^{11,13}. Subsidence of the tibial component occurs less frequently than that of the talar component and the incidence of subsidence of talar components increases with time because there is no

further progression of tibial subsidence is observed once syndesmotomic fusion is completed¹¹. Deland et al⁴, and Pyevich et al¹¹, reported migration or a subsidence rate of the stem in 45% or 25.3%, respectively. However, the short-term follow up results of this study showed no subsidence or failure of the talar component. Degenerative changes to the adjacent joints are among the many complication encountered after ankle arthrodesis. Many studies reported that hindfoot arthritis occurs in more than 50% and 100% after a follow up of 8 years and 20 years after ankle arthrodesis, respectively^{9,10,12}. A total ankle replacement is associated with a much lower incidence of hindfoot arthritis than ankle arthrodesis.

However, Pyevich et al¹¹, reported that the occurrence of hindfoot arthritis is not as rare as demonstrated by its less than 25% occurrence after a 7 year follow up. Deland et al⁴, and Saltzman et al¹³, reported that the occurrence of hindfoot arthritis was 0% and 34%, respectively, at after a midterm follow up. In this study, one patient showed subtalar arthritis at the most recent follow up of 31 months and is currently under follow up.

The lower patient satisfaction rate in this study is believed to be associated with a lower rate of syndesmosis union. Three techniques may improve the union rate of syndesmosis. The first is a thorough debridement near the syndesmosis and a sufficient autogenous bone graft. The second is the engagement of the far cortex in syndesmotomic fixation using a plate. The third is an injection of an autologous platelet concentrate. Precise procedures and good planning will help achieve the better results.

CONCLUSION

The overall results of total ankle arthroplasty using the Agility prosthesis were favorable even though radiographic complications including nonu-

nion of syndesmosis and periprosthetic osteolysis are often encountered. Despite of the small number of patients involved, syndesmotic nonunion was associated with the clinical results. However, long-term follow up will be needed to demonstrate osteolysis, loosening and subsidence of the talar component along with their clinical association.

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= 국문초록 =

목 적: 최근 족관절 전치환술이 관절 고정술의 대안으로 많이 연구되고 있으며 빠르게 발전하고 있다. 본 연구에서는 Agility 인공 삽입물을 이용한 족관절 전치환술의 단기 추시 결과를 알아보고자 하였다.

대상 및 방법: 2003년 5월부터 2004년 5월까지 Agility 인공 삽입물을 이용한 족관절 전치환술을 시행받은 11명 중 2년 이상 추시가 가능하였던 10명(10족)을 대상으로 하였다. 임상적으로 관절 운동 범위, 보행시의 통증(VAS 점수), AOFAS 점수를 측정하였고 환자의 만족도, 수술 권유 의사, 신발의 선택도 등을 조사하였다. 방사선적으로 삽입물의 해리, 골용해 유무, 경비 인대 부위의 골 유합 등을 조사하였다. 수술 술기는 족관절의 전방 도달법을 이용하였으며 2개의 유관 나사못을 이용하여 경피적 술기로 경비 인대 부위를 고정하였고 1예에선 금속판을 이용하였다.

결 과: 남자가 2명, 여자가 8명이었으며 평균 나이는 51.8세(41-67세), 평균 추시 기간은 30.3개월(24-36개월)이었다. 수술전 진단은 류마티스 골관절염이 3예, 만성 족관절 불안정성에 의한 경우가 3예, 족관절 주위 골절에 의한 후외상성 골관절염이 4예였다. AOFAS 점수는 수술 전 평균 38.2에서 최종 추시 평균 73.8로 향상되었고 보행시 통증은 수술전 평균 8.9에서 최종 추시 2.8로 개선되었다. 관절 운동 범위는 최종 추시에서 약 23% 감소하였으며 보행시 5예에서 지팡이를 사용하였다. 방사선적으로 삽입물의 해리나 실패를 보인 경우는 없었고 전례에서 삽입물 주위에 골용해가 관찰되었으나 1예에서만 진행되었다. 5예에서 6개월 이내에 원위 경비 인대 골유합이 관찰되었고 3예에선 지연 유합, 2예에선 불유합이 관찰되었다. 심부 비골 신경 지배 영역의 감각 소실, 외과 부위의 골절이 각각 1예에서 관찰되었으나 보존적 치료로 모두 회복되었고 1예에서 거골하 관절에 관절염이 발생되었다.

결 론: Agility 인공 삽입물을 이용한 인공 관절 전치환술의 단기 추시는 비교적 만족스러운 결과를 보였으나 경비 인대 결합 부위의 불유합, 삽입물 주위의 골용해 등의 방사선적 문제를 상당수에서 볼 수 있었다. 원위 경비 인대 불유합만이 임상 결과와 연관이 있었으며 골용해, 해리 등의 연관성은 장기 추시가 필요할 것으로 사료된다.

색인 단어: 족관절 골관절염, Agility 인공 삽입물, 인공 관절 전치환술