EARLY RESULTS AFTER FOUR YEARS EXPERIENCE WITH THE S.T.A.R. UNCEMENTED TOTAL ANKLE PROSTHESIS

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The first ankle prostheses appeared in 1973 as an alternative to ankle arthrodesis, which was until then the only valid solution for a painful degenerative, rheumatoid or posttraumatic ankle. Several designs followed, all with disappointing results.

Low-constraint prostheses are now being used,with literature studies of 5 years follow-up.

In this study, the authors have evaluated the results of 26 uncemented, hydroxyapatite-coated STAR prostheses, all implanted between January 1996 and December 1999, with an average follow-up of 15.8 months (range: 1.5 to 48 months).

For evaluation, all patients filled out a questionnaire at three different moments in time, and all of them were clinically reviewed by one single observer. The Kofoed ankle score was used for clinical evaluation. All ankle prostheses were also radiographically reviewed, using a radiographic scoring system developed by the authors.

Evaluation with the Kofoed ankle score showed 74% favourable results. When patients were asked to rate their satisfaction on a scale between 0 and 100, an average improvement of 50/100 was reached.

Pain was the most important indication to surgery and is the only parameter that can be predictibly influenced. The effects on motion and walking distance are less predictible.

No major complications occurred and there were no revision operations.

Should prosthetic failure occur, an arthrodesis can still be performed, as bone resection in the primary procedure has been minimal.

INTRODUCTION

Until the second half of the twentieth century, ankle arthrodesis was the only valid solution for a degenerative, inflammatory or post-traumatic painful ankle. Several techniques of arthrodesis exist, with or without loss of height and using several types of fixation device.

Watson Jones praised arthrodesis saying: *"We can see the patient walk without hesitation, run, jump, being able to pursue his occupations and pratice sports with an insignificant disability"* (8). Invalidating pain could thus be solved by fusion if performed in the right position.

Charnley, on the other hand, did not consider this gold standard procedure as an absolute success and reported a complication rate of 60% with as many as 20% nonunions (27).

Since then arthrodesis of the tibiotalar joint proved to have some harmful consequences to neighbouring joints. This procedure should therefore be avoided in patients with degenerative knee-, subtalar- or midfoot joints (17, 40).

In 1973 the first total ankle prosthesis was introduced, offering a solution for the invalidating pain (the most important indication) as well as for restoring motion and stability (34). As in other joints, the ideal prosthesis had to meet certain standards in order to achieve a pain-free ankle joint with a range of motion of $\pm$ 35° (10° dorsiflexion and 25° plantar flexion) which is necessary for normal ambulation and for climbing stairs (2, 8, 34). A construction

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has to be biocompatible, cause minimal wear, respect ligamentous structures, be flexible enough to correct all kinds of deformities and, not least, cause minimal bone loss so that arthrodesis can still be performed in case of failure (2, 3, 4, 9, 13, 14, 16, 17, 22, 28, 29, 36, 38).

Several designs were tested, from a ball-in-socket concept to constrained or unconstrained designs of the present concept, all with their own rationale, results and failures. Most of these types were cemented (1, 5, 10, 11-13, 19-21, 30, 31, 33, 35, 37, 40, 41). In 1998 Kofoed showed that constrained designs lead to significantly worse results than designs allowing cylindrical movement (15, 18). He also underlined that uncemented prostheses perform better than cemented ones (39). In 1994 Kitaoka demonstrated that the results of ankle prostheses in younger patients with previous ankle surgery are clearly worse than in older patients without previous surgery (15, 26).

According to the literature, a total ankle prosthesis should not be used in cases with active or prior infection, avascular necrosis of the talus (which causes more subsidence of the talar component), ligamentous instability, after prior tibiotalar arthrodesis (which causes more heterotopic ossification) and for younger patients with a very high level of physical activity or previous surgery to the ankle joint (3, 9, 12, 15, 25, 28). In cases of prosthetic failure an arthrodesis can be performed since the modern designs resect a minimal quantity of bone.

The S.T.A.R. uncemented total ankle prosthesis has been used in our institution since 1996. We report here the early results of 26 prostheses that were implanted between January 1996 and December 1999.

The department of foot and ankle surgery at the Pellenberg University hospital is involved in further development of the prosthesic design hoping for standardisation of this technically demanding procedure, whih would give rise to long-term improvements of the results.

At this moment there is no specific radiological information to determine the “ideal” position of the components. A radiographic scoring system is needed to evaluate the results technically and to correlate these technical data with the clinical findings. We tried to develop such a scoring system. Tilting, subsidence and radiolucent lines can easily be evaluated on sequential radiographs in the same incidence, but the question is whether or not they depend on the position of the components (40). It is a known fact that there is no correlation between radiographic findings and clinical symptoms (28, 40).

MATERIAL AND METHODS

Between January 1996 and December 1999, 25 patients received 27 ankle prostheses in the orthopaedic department of the University Hospitals of Pellenberg. All patients were operated upon by the senior author (G. D.). Twenty-six of these prostheses are in follow-up. One could not be included in the study because the patient was admitted to the intensive care unit in a coma after surgery unrelated to the index pathology, with fatal outcome.The average age of the patients was 53.9 years (ranging from 32 to 78 years). Fourteen men and 11 women were operated upon. Two men had bilateral prostheses (at different interventions). The operation was on the right side in 10 cases, on the left in 17.

The mean follow-up is 15.8 months (ranging from 1.5 to 48 months). The follow-up was done by means of a questionnaire asking the patient to score his level of pain, functional level, general activity and general satisfaction. This questionnaire was filled out at three separate times (pre-operatively, two months post-operatively and at the latest follow-up visit).

All patients were reviewed clinically by a single independent observer at which time function and pain were again assessed and the results evaluated using the Kofoed ankle score (table I).

The first and last X-ray of comparable incidence of each patient were evaluated using our own X-ray scoring system (table II) as an attempt to evaluate the intervention. The angle of the tibial component to the long axis of the tibia was measured on radiographs (frontal and lateral view). Deviations exceeding 2° from normal (90°) were considered as improper placement. The same was done for the talar component with respect to the talar body and tibial component, again on frontal and lateral view. More than 5 mm distance between the centre of the talar component and the centre of the talar body or the centre of the tibial component were considered as improper placement. The polyethylene insert was evaluated for position and possible fracture. Each of these parameters was rated from 10 points (for perfect

Table I. — The Kofoed ankle score

	Score
PAIN	
No pain	50
Starting pain	40
Pain using stairs	35
Occasional pain	25
Pain on loading the ankle	15
Rest pain	0
FUNCTION	
Toe walking	3
Heel walking	3
One leg standing	6
No external support	6
No stabilising shoes	6
Normal pace stair walking	6
MOTION (max. 20)	
Flexion (in degrees)	
> 30	5
15 to 29	3
< 15	1
Extension (in degrees)	
> 10	5
5 to 9	3
< 5	1
Supination (in degrees)	
> 30	3
15 to 29	2
> 15	1
Pronation (in degrees)	
> 20	3
10 to 19	2
< 10	1
Valgus during load (in degrees)	
< 5	2
5 to 10	1
> 10	0
Varus during load (in degrees)	
< 4	2
4 to 7	1
> 7	0
EVALUATION	
Excellent	85 to 100
Good	75 to 84
Moderate	70 to 74
Unacceptable	< 70

positioning) to 0 points (if any fault was present). Radiolucent lines, subsidence, tilting, fracture or saw cuts and medial or lateral radiographical impingement scored 0 (if present) or 10 points (if absent). The maximum total score in this evaluation is 100 points.

Table II. — X-ray evaluation system

Position: tibial component (AP and lateral)	10/10 (more than 2° deviation from 90° to the tibia axis is fault)
Position: talar component (AP and lateral)	10/10 (more than 5 mm deviation from tibia or talar centre is fault)
Position: polyethylene	10
Absence of radiolucencies	10
Absence of tilting	10
Absence of subsidence	10
Absence of impingement	10
Absence of fracture or saw cut	10
	Max. 100 points

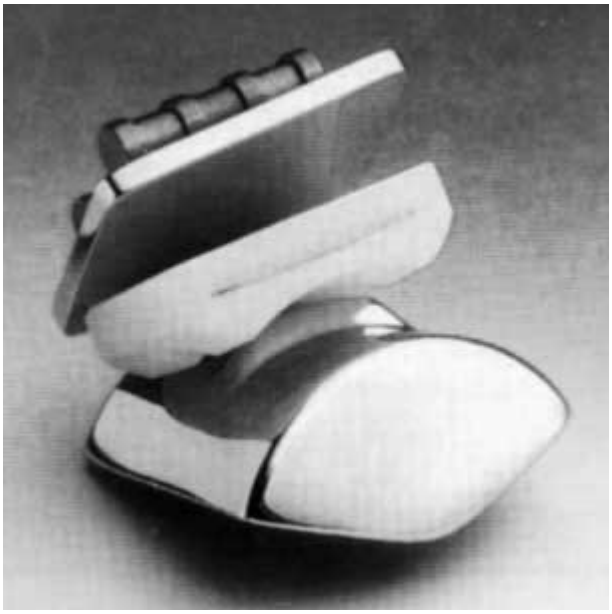

Fig. 1. — The STAR uncemented total ankle prosthesis : talar and tibial components and polyethylene insert.

EN COULEUR ?

The uncemented hydroxyapatite-coated S.T.A.R. total ankle prosthesis (Waldemar Link, Germany) (fig 1) was implanted using an anterior approach. The tibial cut was perpendicular to the long axis of the tibia and was performed with the utmost care in order to avoid fracturing the medial or the lateral malleolus. The talar cuts were then made with the ankle in 90° of flexion and in neutral varus-valgus position. There are three sizes for the tibial component (small, medium, large) and three sizes for the talar component (small, medium, large) with a difference between right and left. The polyethylene insert comes in five different thicknesses from 6 to

Table III. — Indication according to patient

Pain	77%
Walking distance	77%
Motion	18%
Insecurity	18%
Functional limitation	4%

Table IV. — Pain location

	Pre-op	Latest follow-up
Ankle	100%	60%
Lower leg	26%	8%
Heel	26%	13%
Mid/forefoot	4%	13%
Toes	4%	4%
Knee	4%	13%

Table V. — Pain on VAS

	Pre-op.	2 m. postop.	At latest follow-up
Activity	8.4 (4-10)	4.5 (0-10)	2.8 (0-9)
Rest	5.0 (0-10)	3.2 (0-10)	2.0 (0-8)
Night	4.5 (0-10)	2.7 (0-10)	1.5 (0-7)

Table VI. — Professional status

	Pre-op.	2 m. postop.	At latest follow-up
Normal/retired	58%	45%	53%
None because of ankle	33%	45%	26%
None because of other	9%	10%	21%

10 mm. An average of 4 mm of bone was resected on the tibial side and 2 to 3 mm on the talar side.

Full weight bearing in a lower leg cast was already encouraged at one week postoperatively. Cast immobilisation was continued for a period of 4 weeks. A short readmission (average 2.5 days) at the time of cast removal was performed for intensive revalidation, to instruct correct gait rehabilitation and walking pattern.

The indications for operation were posttraumatic osteoarthritis in 7 cases, haemophilia in 6, rheumatoid arthritis in 4, primary osteoarthritis in 4, haemochromatosis in 4, psoriasis and Charcot-Marie-Tooth in one case each. There is a remarkably low percentage of primary osteoarthritis. Apparently the ankle joint resists degeneration better than other large joints, despite a load of 4 times body weight during normal activities (5, 29, 36).

The large percentage of haemophilia patients in this study is also unusual and is related to our connection with a specialised center.

RESULTS

The reasons mentioned by the patient as important in his decision to undergo surgery are listed in table III. In 77% of the cases, invalidating pain was the most important indication for the patient. Decrease in walking distance is mentioned as being important in a similar proportion of cases.

The pain had been present for an average duration of three years and nine months (ranging from 1 to 10 years) before deciding upon an operation. Pain location was mainly around the ankle, lower leg and heel. If postoperative pain was present, it was mostly located at the same place (table IV).

By investigation with the visual analogue scale (VAS) a clear reduction in pain during activity was achieved from an average of 8.4 (4-10) to 2.8 (0-9). This decrease in pain was almost always immediately postoperative (table V).

Pre-operatively, more than 70% of the patients felt continuous severe pain, mainly during walking and climbing stairs as well as during walking on uneven surfaces. Postoperatively only 8% of the patients suffered serious pain. Thirty-nine percent were pain-free, 13% had pain when walking on uneven ground and 34% felt occasional pain. The pain level of 92% of the patients was clearly reduced.

Regarding occupational activities, there were no important changes (table VI).

A clear improvement was also noted for activities of daily life. Seventy-seven percent were very limited or were unable to do most housekeeping activities pre-operatively. A vast majority of the patients had a clear improvement in the activities of daily life. No single patient was totally dependent after the procedure (table VII).

Pre-operatively 96% of patients were unable or almost unable to perform any recreational activity. Postoperatively 43% were able to do almost any activity (table VIII).

Ninety-one percent of the patients needed significant amounts of medication, consisting mainly of anti-inflammatory and analgetic drugs.

Table VII. — Activities of daily living

	Pre-op.	2 m. postop.	At latest follow-up
All housekeeping	9%	9%	28%
No spring cleaning	14%	24%	27%
Very limited	57%	45%	45%
No housekeeping	10%	9%	0%
Dependent	10%	13%	0%

Table VIII. — Recreational activities

	Pre-op.	2 m. postop.	At latest follow-up
Everything possible	0%	4%	8%
Most things possible	4%	32%	35%
Very limited	65%	32%	43%
None	31%	32%	14%

Table IX. — Walking distance

	Pre-op.	2 m. postop.	At latest follow-up
Unlimited	0%	0%	4%
> 1 km	4%	5%	18%
500m - 1 km	18%	22%	28%
< 500 m	21%	17%	23%
In-house	53%	35%	27%
None	4%	21%	0%

Table X. — Ability to use stairs

	Pre-op.	2 m. postop.	At latest follow-up
Normal	4%	5%	13%
Up or down with banister	8%	48%	61%
Up and down with banister	61%	14%	22%
Not possible	27%	33%	4%

Table XI. — External support

	Pre-op.	2 m. postop.	At latest follow-up
Two crutches	32%	45%	23%
One crutch	14%	18%	9%
Cane	13%	9%	4%
None	41%	28%	64%

Table XII. — Gait pattern

	Pre-op.	2 m. postop.	At latest follow-up
No limp	9%	11%	24%
Moderate limp	27%	61%	52%
Serious limp	64%	28%	24%

This improved to 56% of the patients who occasionally needed one of these medications postoperatively.

Fifty-seven percent of patients were limited to in-house activities pre-operatively ; postoperatively, 50% were able to walk 500 m or more (table IX).

Eighty-eight percent could not, or could hardly climb or descend stairs pre-operatively. Postoperatively 74% were able to use the stairs normally (table X).

Some kind of external support was used pre-operatively by 59% of the patients. Postoperatively 64% walked without a crutch or walking aid (table XI).

Shoe fitting did not change dramatically: 64% had no, or only moderate limitations pre-operatively (28% and 38 % respectively) compared to 78% postoperatively (30% and 48% respectively).

Thirty-nine percent could walk barefoot pre-operatively compared to 66% postoperatively.

The assessment of gait pattern revealed that 64% limped seriously pre-operatively. Postoperatively 76% of the patients showed moderate or no limping (table XII).

A subjective total overview showed a clear improvement of 50 points on average (table XIII).

One single independent observer clinically reviewed all patients in January 2000. At that time the Kofoed ankle score was determined and was compared to the pre-operative score (table XIV). According to this score, there was an average improvement of 39.4 points. Reduction of pain made the biggest improvement with an average of 29.6 points. Motion (fig 2) improved by 11.8 points. An improvement in function of 10.2 points was also noted.

Seventy-four percent of all patients scored excellent (48%), good (13%) or moderate (13%).

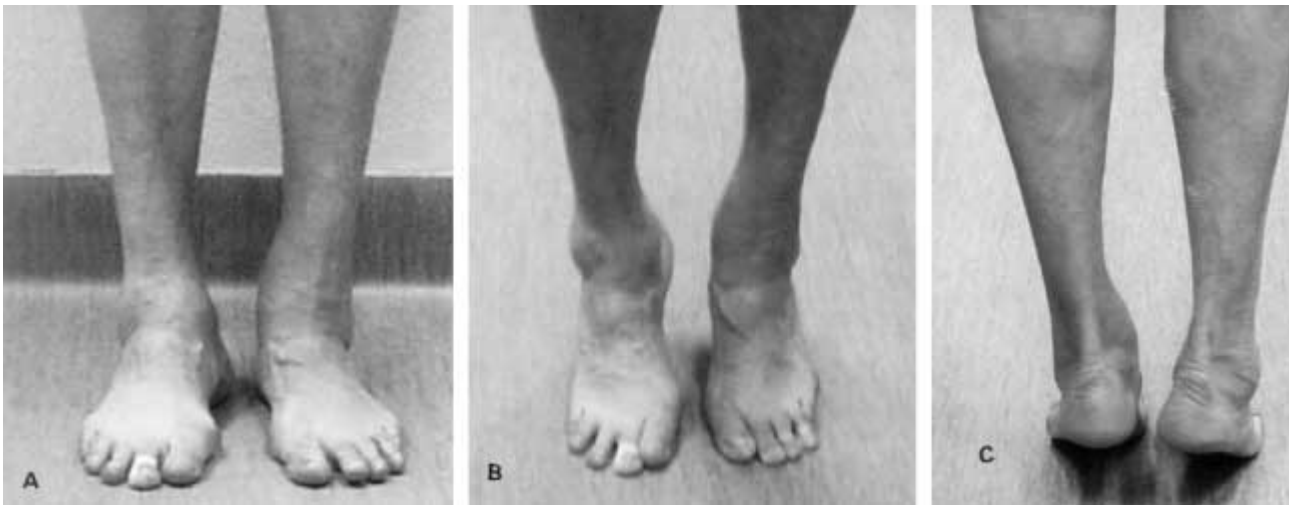

Fig. 2. — Clinical aspect three months after arthroplasty of the left ankle joint with a STAR prosthesis : (a) neutral position ; (b) plantar flexion, anterior view ; (c) plantar flexion, posterior view.

Table XIII. — General satisfaction on 100 points at subjective evaluation

	Pre-op.	2 m. postop.	At latest follow-up
	25.7 (0-70)	59.4 (10-100)	76.5 (35-100)

Table XIV. — Kofoed ankle score (total and separate constituents)

	Pre-op.	At latest follow-up
Kofoed (100p)	35.4 (15-58)	74.8 (24-96)
Pain (50p)	7.8 (0-15)	37.4 (0-50)
Function (30p)	12.5 (0-27)	22.7 (9-30)
ROM (20p)	13.6 (6-16)	25.4 (8-20)

Table XV: Technical X-ray evaluation score (max. 100p)

Constituent	Number	Deviation in detail		
Position tibia (AP)	5	(> 2° deviation) 3	(too lateral) 2	(too big) 1
Position tibia (lateral)	5	(> 2° deviation) 4	(too anterior) 8	
Position talus (AP)	4		(too medial) 1	(too big) 4
Position talus (lateral)	6		(> 6 mm ant.) 6	
Position UHMWP	3		(too anterior) 3	
Fracture UHMWP	3			
Impingement	11	(medial) 9	(lateral) 3	(aggravated) 1
Malleolar fracture	3			
Saw cut / stress fracture	9			
Collapse	0			
Tilting	1	talar component		
Radiolucent lines (< 2 mm)	9	Mainly tibial 1 increased		

TOTAL SCORE (out of 100 p)	Postoperative X-ray	Last X-ray
	75.6 (50-100)	80 (40-100)

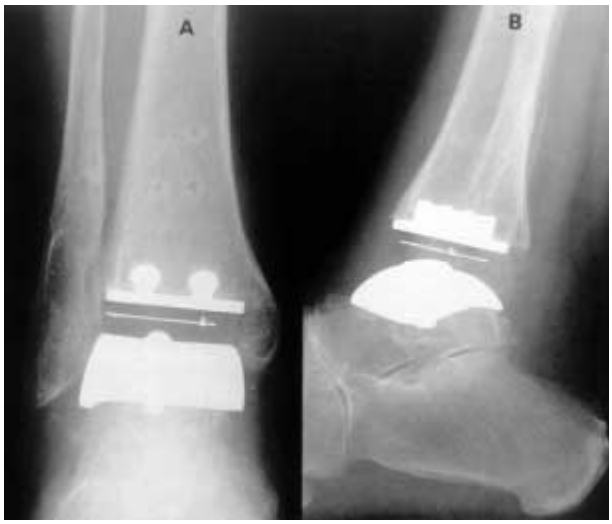

Fig. 3. — Radiographs of the right ankle of a male patient, 12 months after arthroplasty for post-traumatic degenerative changes: anterior view (a) and lateral view (b) showing optimal position of the STAR prosthesis.

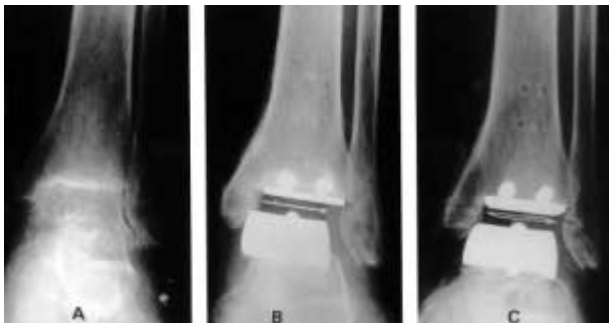

Fig. 4. — Radiographs showing improper placement of a STAR prosthesis and a peroperative complication : (a) preoperative film ; (b) postoperative film showing a medially shifted talar component: (c) oblique view showing intra-operative cut into the fibula.

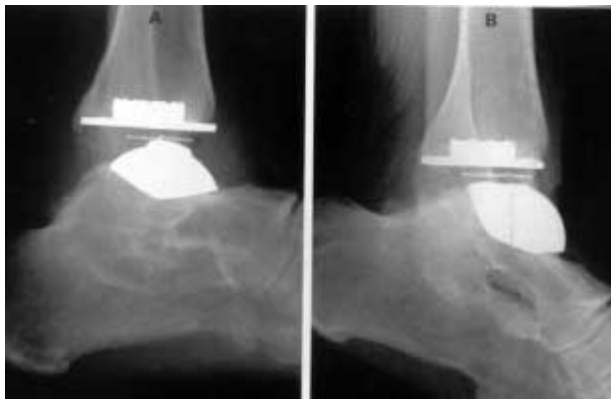

Fig. 5. — Total ankle prosthesis after triple arthrodesis in a male haemophiliac patient: the talar component is positioned too anterior: (a) neutral position : (b) plantar flexion.

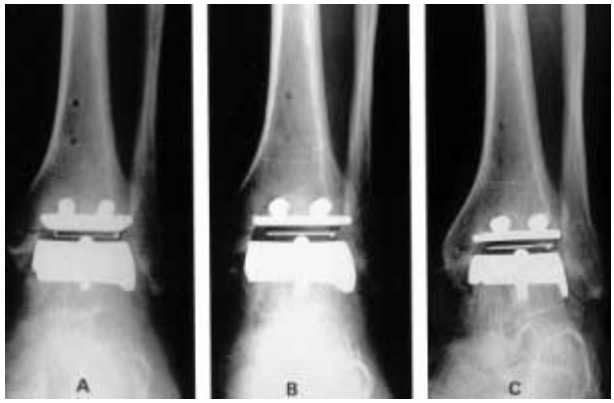

Fig. 6. — Follow-up of a right ankle in a female patient with rheumatoid arthritis: (a) postoperative view ; (b) at three months follow-up ; (c) after 2.5 years with uneventful healing of a saw cut into the fibula.

Finally, a radiographic evaluation of the first and last postoperative X-ray of comparable incidence (table XV) was performed in an attempt to evaluate the operation using our own radiographic scoring system. The angle of the tibial component to the long axis of the tibia was measured on radiographs (frontal and lateral view). Deviations exceeding 2° from normal (90°) were considered as improper placement. The same was done for the talar component with respect to the talar body and tibial component, again on frontal and lateral views. More than 5 mm distance between the centre of the talar component and the centre of the talar body or the centre of the tibial component were considered as improper placement (fig 3, 4, 5).

Intra-operatively made saw cuts to the medial or the lateral malleolus were checked as well. It needs to be emphasised that the lateral malleolus extends medially for a long way on its posterior part and can therefore be easily damaged. All saw cuts and

stress fractures (9 in total) apparently healed without problems and without causing any negative effect on component position or fixation (fig. 6).

A complete fracture occurred in three cases, one of them intra-operatively. It healed uneventfully after screw fixation. The other two were treated conservatively by cast immobilisation of up to 6 weeks and also healed.

On X-rays taken during follow-up, special attention was paid to collapse (none), tilting (1 talar component) and to the appearance of radiolucent lines (9, all of them less than 2 mm, mostly located on the tibial side) and to their evolution (only one has progressed slightly). No collapse of the components occurred.

No correlation could be found between the X-ray evaluation and the clinical findings.

No single major complication occurred following these 27 operations on 25 patients. There was 0% mortality. There were no deep infections and only one superficial infection, which was successfully controlled by antibiotics and local therapy.

Wound healing was very satisfactory in 24 out of 27 ankles. Delayed healing occurred on two occasions, with only one showing signs of superficial infection. One patient presented with some moderate wound necrosis, which healed uneventfully by means of local therapy.

In 7 ankles a stress fracture or complete fracture of the medial or lateral malleolus occurred. They all healed uneventfully. Five of these patients scored "excellent" or "good".

One male patient still complains of residual Achilles tendinitis. He had undergone open Achilles tendon lengthening during the index intervention. Five other patients with percutanously performed Achilles tendon lengthening during the index intervention have presented no problems at all.

Eleven patients present radiographic impingement. Nine of them scored "excellent" or "good". No signs of loosening occurred. Nine ankles show radiolucent lines less than 2 mm (mainly located on the tibial side). Only one of these deteriorated. Six of these 9 scored "excellent" or "good". There were no heterotopic ossifications causing clinical problems. No talar collapse was observed.

DISCUSSION

Reports on total ankle prostheses have appeared in the literature since 1973 (34). The first generations were swiftly abandoned and most authors returned to the gold standard, i.e. tibiotalar arthrodesis.

Starting with the second generation of prostheses, short-term results seemed promising, mainly in patients with rheumatoid arthritis (1, 5, 10, 11, 12, 13, 19, 20, 21, 30, 31, 33, 35, 37, 40, 41). At longer term, a clear deterioration of the results was noticed, in both the rheumatoid and arthritic patients. Cemented prostheses performed worse than uncemented ones (18, 39).

A study of 204 Mayo prostheses with a mean follow-up of 9 years showed an explant rate of 36% (15, 18). Loosening of the talar component seemed to be a particular problem. The same study showed a positive correlation between the survival of the prosthesis and the higher age of the patient at the time of implantation and a negative correlation between survival of the prosthesis and prior surgery to the ankle joint. Young patients with prior surgery have a mean 5-year survival of 75% and a mean 10-year survival of 59%. For the older patient without prior surgery the survival reaches 85% and 74% respectively.

In 1998 Schill *et al* presented a study of 19 S.T.A.R. prostheses with a follow-up of 1 to 12 years (32). They described a spectacular improvement of 86.2 points in the Kofoed score. Seventy-five percent of these patients scored "excellent" or "good".

In our study with a shorter follow-up of 15.8 months (ranging from 1.5 to 48 months) 61% of the patients scored "excellent" or "good" (excellent 48%, good 13%). After overall subjective evaluation, patients find themselves 50 points better than pre-operatively. The Kofoed score also improved by an average of 40 points.

There were no major complications and no revision operation had to be performed. Of course we are aware of the short period of follow-up.

The operation was clearly successful in reducing pain. Although walking distance and ability to climb stairs improved markedly, the evolution of

the range of motion remains unpredictable. Range of motion in this study improved by an average of 11.8 points, reaching a average range of 35°, between 10° dorsi- and 25° plantar flexion (table XIV). Even though this improvement is substantial, it is clinically unclear whether or not motion in all directions occurs only in the tibiotalar joint, or also in the subtalar and midfoot joints (28). To study this in more depth, a cinematographic X-ray study is indicated. This was not done in this study.

The same remarks can be made about the location of postoperative pain (table IV). If pain is still present, 60% locate it around the ankle joint. The contribution of the subtalar and talonavicular joint in this pain pattern should not be omitted. Most of these patients show degenerative X-ray findings of the subtalar joint. A subtalar steroid injection could resolve or improve the pain complaints. The high percentage of haemophilia patients in this study is remarkable and is not mentioned elsewhere in the literature. A large number of patients with persisting pain is made up of these haemophiliacs. This is not surprising since all the midfoot joints and not only the tibiotalar joint are affected in haemophilia.

The most important indication is invalidating pain. If this is not made clear to the patient pre-operatively, disappointments may occur.

The fact that occupational activities did not undergo an significant change may be explained by the fact that 74% of the patients suffered from an invalidating systemic disease (rheumatoid arthritis, haemophilia, Charcot-Marie-Tooth).

Studying a frontal and lateral X-ray, we tried to determine a correct position of the prosthetic components. We have not found any correlation between X-ray findings and clinical symptoms so far. For example, 9 out of 11 patients with radiographic impingement of the components score themselves as “excellent”. Some patients with ideal X-ray findings complain of residual pain, while others score themselves subjectively and clinically as “excellent” with imperfect X-ray findings. Further evaluation is needed to determine if there are certain variations from an as yet to be determined “ideal situation”, that can predict prosthetic failure.

If prosthetic failure should occur, arthrodesis of the tibiotalar joint can still be performed, due to the minimal resection of bone (10, 14, 31, 34, 38). This minimal resection of the subchondral bone may also explain the fact that we encountered no collapse of the components and only once a minimal tilting of the talar component (2). Therefore the operation can be considered safe from all points of view.

This technically demanding procedure offers considerable latitude with regard to instrumentation. The large variation in the X-ray evaluations confirms this as well. Improvement in instrumentation will certainly lead to a better positioning of the components. It is to be hoped that in the future the study of X-ray images will contribute to a better operating technique so that in the end, the total ankle prosthesis could perform as well as the total knee- or hip prosthesis.

Although this study has a short follow-up, early results seem promising. We believe that for the right indication the total ankle prosthesis is a valuable alternative to arthrodesis. Our unit cooperates in every respect to further develop better and more reliable material. Further studies and more data remain necessary to come to further conclusions.

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