

REVIEW ARTICLE

CORE

Total ankle arthroplasty in France st

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KEYWORD	Summary
Total ankle arthroplasty	<i>Objectives</i> : After more than 10 years' experience in France, the French Foot Surgery Association (<i>Association française de chirurgie du pied</i> [AFCP]) presents an update on mobile-bearing ankle prostheses, based on a multicenter study.
	<i>Meta-analysis</i> – <i>Biomechanics</i> – <i>Assessment and indications</i> : A preliminary comparative meta- analysis of the literature studies on ankle and prosthesis biomechanics, reviews validated indications and contra-indications, and details clinical and radiological outcomes assessment protocols.
	Professional survey: Sixty-three surgeons (95% AFCP members) answered a professional online survey, by email or regular post: 70% performed total ankle replacement (TAR), 39% of them at least two per year and 16% more than 10 per year, resulting in 317 TARs per year or 50% of the French activity and 312 arthrodeses per year or 17% of the French activity — which gave the survey considerable power. In 2004–2005, 46% of the TARs implanted were AES [®] , 38% Salto [®] and 9% Hintegra [®] .
	<i>Gait analysis following TAR:</i> This study included two series of patients (15 in Brussels and six in Paris) with laboratory gait analysis preoperatively and at 6 months' and 1 year's FU. Following TAR, speed, cadence and strides increased and mean total work approximated normal values. These two independent studies quantified the advantages of TAR over arthrodesis.

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Multicenter study: This retrospective study had a minimum follow-up of 1 year. Results were not distinguished between the four types of prosthesis (approved by the French Healthcare Agency [HAS]) involved. Inclusion criteria for operators were: AFCP membership, and experience of more than 20 prostheses of a given type. Twelve out of 15 centers responded and undertook to include continuous series. Data were centralized on a dedicated anonymous online site. Five hundred and ninety-two TARs (388 Salto[®], 173 AES[®], 22 Hintegra[®], nine Star[®]) in 555 patients (mean age, 56.4 years; range 17–84 yrs) were included. Indications were posttraumatic arthritis (48%), arthritis associated with laxity (15%), inflammatory arthropathy (20%), primitive arthritis (9%), prosthetic revision (2%), and miscellaneous (5%). Sixty-one percent of operations included associated procedures: 208 Achilles lengthenings, 45 subtalar arthrodeses, nine calcaneal osteotomies and 45 lateral ligament reconstructions. Complications comprised 53 malleolar fractures, and 39 cutaneous and seven infections (9%). At a mean 37 months' FU, 87.5% of patients were satisfied or very satisfied; mean functional score was 82.1/100; radiographic mobility, 23.2°; and total SF 36 score (on the Short Form Health Survey), 66. X-ray found stable anchorage in 98% of cases, cysts in 15%, and calcification in 4%.

Revision for failure: Overall cumulated survivorship was 88% at 71 months: 22 patients underwent arthrodesis (61% satisfied), and 10 implant replacement (50% satisfied).

Conclusion: This multioperator, multi-implant series of 592 patients confirmed literature data. Prospective follow-up of the cohorts managed in these expert centers is essential, in order to make available long-term data.

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Introduction

Since their advent in 1989, third generation (mobile bearing) implants have met with a real enthusiasm in France. The pioneers of ankle implant surgery started off with the models available on the market, then refined certain elements, leading to new implants, and developed ancillary instrumentation to improve implantation quality.

After more than 10 years' experience, the French Foot Surgery Association (Association française de chirurgie du pied [AFCP]) undertook a study of results from a large number of French centers, to shed light on failure and to determine the limitations of this new technology so as to clarify indications and essential associated procedures.

History and meta-analysis

History

The first ankle implantation was performed by Buchholz in Hamburg in 1970, with a spherical device, resembling an inverted hip prosthesis. This first generation, however, did not live up to expectations. Despite many alterations to the design and to the number of components, second-generation results remained disappointing [1]. Not until the 1980s did third-generation models appear, comprising of three components with a mobile bearing [2]. These designs conserved bone capital, rotation axis and foot-tibial alignment, and their biological fixation provided good results, encouraging further development [3–5].

Exhaustive literature review (more than 130 references) proved disappointingly repetitive, with small series and short follow-up. Even so, a horizontal reading can retrieve and define the underlying concepts and a vertical reading spotlights certain articles of special interest.

Horizontal analysis

- Indications and contra-indications: The ideal patient can be defined, in terms of age, normal weight and some minor physical requirements. There should be good bone capital, normal vascular and cutaneous status, and little, if any, medical comorbidity. The ankle should be stable or at least stabilized, with hindfoot axis defect either absent or corrected [6].
- The most frequent complications are peroperative fracture, mechanical impingement, and radiologic abnormality on medium-term follow-up [7,8].
- Results were usually reported as survivorship curves [9], which need precise study, in terms of confidence intervals, and in relation to radiologic evolution [10], functional score [11] and mobility (where results should be measured on weight-bearing views).

The future lies in biomechanical studies (baropodometry, gait analysis) correlated to functional results.

Vertical analysis

- Associated procedures are essential, and the prime difficulty of this kind of surgery lies in their indications and prioritization [12].
- Analysis of results by etiology reveals higher rates of postoperative pain and stiffness associated with post-traumatic indications [10].
- Correlation of surgeon experience with results [13] surprisingly found little benefit of experience: i.e., implantation techniques are now reliable [14]. Other reports recommend solutions to limit peroperative complications [15].

- There was no significant difference in polyethylene weardebris in the ankle as compared to knee implants [16].
- For resumption of sport, once here again, there was no significant difference in comparison with other forms of arthroplasty. There was marked improvement in sports capability, but only for sports such as hiking, cycling, swimming and golf [17].

Ankle arthrodesis is no longer the gold standard in ankle surgery [18]: at medium term, 80% of patients are satisfied, but thereafter progressive arthritis and reduced hindfoot mobility begin to impair function and quality of life.

Seventy to ninety percent 10-year implant survivorship, depending on the series and on the design [19], avoidance of many complications and the option of conversion to arthrodesis in case of failure [20] now argue for the development and implementation of ankle implants.

Professional survey: who does what in France?

According to French (*Projet de médicalisation des systemes d'information* [PMSI]) data, 382 TARs vs. 1,785 ankle arthrodeses were performed in 1999, and 499 TARs (including 150 revisions) vs. 1,885 arthrodeses in 2002. The present survey made an update on professional practice in France.

Methodology

A 6-part questionnaire (general data; TAR experience; TAR indications and revision practice; radiologic assessment and follow-up; number of ankle arthrodeses and TARs in 2004 and 2005) was sent out as part of the three AFCP newsletters in 2006 (contact list of 490 surgeons, 400 of whom in France), with five systematic email reminders (to 150 email addresses) and five individual email or postal reminders (to 50 surgeons). Data were entered on an Excel[®] spreadsheet and processed using StatView software.

Results

General data

Sixty-three surgeons answered the survey, 95% of whom were AFCP members, 57% in private practice, and 24% in public teaching hospitals. They were strongly specialized in foot surgery ($56.3 \pm 4.4\%$ of overall activity).

TAR experience

Eighty-one percent had TAR experience (first TAR: 1985–2006; 1–5 models). Thirty percent were currently implanting AESTM, 28% SaltoTM, 25% HintegraTM, 8% RamsesTM, 4% StarTM, 3% AkileTM, and 2% MobilityTM.

Indications

Indications were well-aligned arthritis (absolute indication [AI], 87%; relative indication [RI], 13%); rheumatoid arthritis (AI, 76%; RI, 24%); and post-traumatic arthritis (AI, 70%; RI, 30%). Absolute contra-indications (CI) were: neurologic foot, 100%; cutaneous problems, 100%; infectious arthritis, 97%; arteriopathy, 90%; talar necrosis, 89%; severe malalignment, 85%. Opinion was divided as to: arthritis with associated lax-

ity (RI, 73%; CI, 23%); moderate malalignment (RI, 80%; CI, 20%); severe ankylosis (RI, 67%; CI, 33%); and young patients (AI, 15%; RI, 23%; CI, 62%).

For revision of TAR, they recommended: arthrodesis, 52%; arthrodesis or implant exchange, 38%; implant exchange, 10%.

Radiographic assessment and follow-up

One hundred percent of the surgeons took preoperative weight-bearing X-ray views (AP ankle Méary view + AP foot view); 66% performed full-length AP view of both lower limbs, standing; 43%, dynamic X-ray (dorsiflexion [DF]; plantar flexion [PF]); 67%, CT-scan; 6%, MRI. At 1 year, 83% performed weight-bearing X-ray, 10% full-length AP view of both lower limbs, standing, 37% dynamic X-ray, and 4% CT; at last follow-up, 51% performed weight-bearing X-ray, and 22% dynamic X-ray.

Forty-four percent used no functional score, 31% the AOFAS (Kitaoka) score, 18% the AFCP score, and 7% both.

Cumulated activity 2004-2005

- 92% of those surveyed had performed arthrodesis: 623 arthrodeses (mean age, 54.6 years; range, 14–91 yrs), or 312 arthrodeses/year (17% of PMSI activity) and 5.3 arthrodeses/surgeon/year (range, 1–40). Indications were: post-traumatic, 56%; arthritis with associated laxity, 17%; TAR revision, 9%; rheumatoid polyarthritis, 8%; infectious arthritis, 3%; and talar necrosis, 2%.
- 60% had performed mobilization surgery: 173 isolated arthrolyses, 67 supramalleolar osteotomies (0.9/surgeon/year), and 55 ankle malunion osteotomies (0.8/surgeon/year).
- 70% had performed TAR: 634 TARs (mean age, 57.7 years; range, 15–88 yrs), or 317 TAR/year (50% of PMSI activity) and 7.2 TARs/surgeon/year (range, 1–40). Indications were: post-traumatic, 50%; rheumatoid arthritis, 25%; arthritis with associated laxity, 11%; primitive, 6%; TAR revision, 9%. Associated procedures comprised: 21% Achilles lengthening, 8% subtalar arthrodesis, 7% osteotomy (tibia-fibula-calcaneus), 5% ligament plasty, 2% bone graft. Complications comprised: 14% malleolar fracture, 4% severe cicatrization deficit, 0.7% deep infection, 0.4% displaced mobile bearing.

Salient facts

Seventy percent (44/63) of the surgeons performed TAR, but 39% do less than two per year, and 16% (7/63) more than 10 per year. This amounts to 317 TARs per year or 50% of PMSI activity, and 312 arthrodeses per year or 17% of PMSI activity, giving the present survey considerable power.

In 2004–2005, 46% (292) or TARs implanted were AES[®], 38% (244) Salto[®], and 9% (54) Hintegra[®].

Biomechanics

Biomechanics of the ankle vs. the implant

Living cartilage bestows on the ankle joint properties of adaptive congruence varying with load. TAR fails to restore

this, apart from a play of mechanical tolerance, to adapt to very high stress (four to five times body-weight during walking).

- The ankle is essential to locomotion as well as to balance: it needs to be able to cushion, absorb, distribute and transfer forces and movements. The ankle is the second pivot in walking (10° DF is sufficient), with a preferentially sagittal mobility arc. There are also smaller coronal and anteroposterior movements, especially in rotation [21]. There is coupling with the subtalar joint and Chopart's midtarsal joints The anterior tibiocalcaneal and fibulocalcaneal ligament fibers govern and guide movement [22].
- In the hindfoot joint complex, the ankle supplies a degree of freedom (not just a single axis of movement). Joint mechanics becomes more complex under loading (variable instantaneous axes), losing mobility and becoming more stable, with the fibulotalar joint coming into play. TAR should enable transfer of movement and stability, dissipating rotational movement.
- TAR provides hardly any correction of deformity, and can only function in a well-balanced environment. The surgeon needs to be able to align, center, mobilize and stabilize, and perform the requisite associated corrective procedures (preoperative planning, ancillary precision), to avoid excessive stress with consequent risk of complications (stiffening or instability, and wear inducing inflammatory granuloma and subsequent osteolysis and implant migration).
- TAR: anatomically perfect or an ''anatomic'' mechanical approach —, to adapt to intersubject anatomic variation?

Evolution of TARs

After 37 years' evolution [6], 3-component third-generation TARs put the accent on stability under sagittal movement, but also enable rotation to be transmitted with minimal wear, although at the cost of greater drawer movement and of possible bearing instability. While frontal dome-type geometry would not seem to be recommended, the verdict on cylindrical or conical profiles is still open. Solutions based on elastic tightening of the tibiofibular mortise remain to be found.

Most TAR implants use a polyethylene/cobalt-chromium friction couple; under more than 10 MPa/cm² on the polyethylene, there is a risk of creep and wear [23]. Bone anchorage surface shape and cover (hydroxyapatite) is important for osseointegration; cementing is no longer recommended. The implant should be monoblock; a superstructure on the tibial side seems to be needed to ensure long-term anchorage.

Charge-book issues

TAR implants have to be tolerant of the restored movements, to minimize stress [24], because:

- loads are enormous for such a small area, and increase with increasing activity;
- bone capital is small, and unequally distributed;

- soft-tissue coverage is thin and fragile (concept of angiosomes);
- talar vascularization is fragile, with intersubject variation in geometry;

TAR should now be seen as a good biomechanic compromise, partially restoring function and normalizing gait parameters. New designs and materials will doubtless emerge.

Why? When? How?

Assessment

Indications and complementary procedures are intrinsically determined by clinical and, above all, radiological assessment. The ankle is a suspended joint, part of the articular chain of the lower limb and therefore governed above by the mechanical axis of the latter and below by the helicoid torsion of the foot. It acts like a hinge joint transmitting homokinetic rotation. This determines the morphology and orientation of the talus and bimalleolar mortise.

Radiologic assessment

It is essential:

- to determine the physiologic or pathologic mechanical axis of the lower limb (varus, valgus, torsion) by static study of both lower limbs under loading;
- to assess not only the morphologic or pathologic axis of the hindfoot or change in forefoot ground-contact but also malleolar malunion, on complementary AP ankle Méary views, AP and lateral foot views and sometimes dynamic X-ray.

AP ankle Méary view: interpretation and information

Technique. Feet loaded, one after the other. Metal landmarks on either side of heel: either two coins or metal wire ring. Heel raised 1.5 cm. AP view, with ray in second space axis.

First information: assessment of differential malleolar height. From the tips of the two malleoli, a line is drawn down perpendicular to the ground, and distances from the ground are measured on the healthy and pathologic sides.

If the difference between the medial and lateral malleoli is identical on both sides, there is no malleolar or diaphyseal malunion (high fibular fracture not to be overlooked).

If the difference between sides exceeds 3 mm, explore for medial or lateral malleolar or diaphyseal malunion, to determine millimetric correction to perform.

Second information: assessment of hindfoot axis. Trace a parallelogram between the medial and lateral metal landmarks and the medial and lateral summits of the talus. Mark the midpoints of the superior and inferior bases, and draw a line between the two. The axis from the midpoint of the heel ground-contact base, perpendicular to the ground, through the midpoint of talar dome joint surface, defines hindfoot varus or valgus; physiological valgus being $4^{\circ}-8^{\circ}$.

These two lines describe the angle " α " of the hindfoot axis, the normal value of which is between 4° and 8° (varus < 4° < α < 8° < valgus). When the perpendicular of the

Table 1 Contra-indications	for TARC.
Contra-indications for TAR	
Absolute	Relative
Active infection	Previous treated infection
Poor skin status (multiple scars, varicose ulcers, etc.)	Skin graft or flap
Severe bone defect	Multi-operated ankle
Severe unreconstructed ligament laxity	Stiff ankle
	Obesity
	Heavy work
	Unrealistic patient expectations

angle is not medial but lateral, there is severe varus; 4° should then be added to the measured angle to determine the true varus.

Etiology and Indications

Indications

In the overall Symposium series (n = 592), the main indications for TAR were post-traumatic arthritis (48%), inflammatory rheumatoid arthritis (21%), arthritis with associated laxity (15%) and primitive arthritis (9%), with functional results according to AOFAS score of respectively 81.6 ± 14 , 79.5 ± 12 , 85 ± 10 and 86 ± 8 .

Nine TARs were implanted for sequelae of osteochondritis dissecans or localized talar necrosis (mean postoperative score, 71.5; two failures), two for hemochromatosis, one for hemophilic arthritis and one in neurologic foot.

Contra-indications

Contra-indications for TAR may be absolute or relative (Table 1), and are associated with high risk of infection (history of ankle osteoarthritis or exposed open fracture), cutaneous risk factors (multiple scarring, thin or poorquality skin graft), or severe bone defect or ligament laxity.

Post-traumatic arthritis

Post-traumatic arthritis raises specific problems due to associated periarticular lesions. The preoperative check-up is essential, to assess difficulties and risks: CT analysis of deformity, bone capital and neighboring joints; biological analysis, bone-scan and possibly bone biopsy, to assess infectious risk; and arteriography or angio-MRI, to assess arterial status. Where cutaneous status is poor, the opinion of a plastic surgeon may be sought. Several difficulties requiring specific surgery are to be considered (Table 2).

Rheumatoid arthritis

In rheumatoid arthritis, tibiotarsal arthritis is seldom isolated and management is global. Certain points are to be highlighted: frequent associated subtalar or talonavicular arthritis, frequent involvement of other lower-limb joints, skin and bone fragility, and elevated infection risk due to multiple treatment. The terrain should also be taken into

Table 2 Difficulties of TAR in	n post-traumatic arthritis.		
Causes of difficulties of TAR Technical consequences			
Stiffness or equinus	Posterior arthrolysis, Achilles lengthening		
Tibial malunion	Supramalleolar osteotomy		
Hindfoot deformity	Subtalar \pm midtarsal arthrodesis or calcaneal osteotomy		
Varus ankle	Medial collateral ligament release		
Lateral malleolar malunion or non-union	Malleolar osteotomy. Plate osteosynthesis		
Syndesmosis injury	Syndesmosis fixation/arthrodesis		
Laxity	Ligament balancing, reinsertion or plasty		

account in planning treatment, as prolonged periods of nonweight-bearing or cast or splint immobilization are badly tolerated.

Can everything be repaired?

TAR does not correct malunion, malalignment or ligament instability...

Depending on the degree of physiological or pathological deformity, various techniques may be deployed:

- Tibia (guided by study of both lower limbs under loading):
 - Superior tibial metaphyseal osteotomy (lateral closure, medial opening).
 - Diaphyseal osteotomy to correct axis and rotation.
 Supramalleolar valgization or varization osteotomy.
- Bimalleolar mortise (assessed on AP ankle Méary view):
 - Tibial or peroneal lengthening/shortening or malleolar repositioning osteotomy.
- Hindfoot (guided by Méary view):
 - Subtalar arthrodesis, respecting valgus.
 - Kostouglianis or Myerson calcaneal osteotomy.
 - Chronic ankle instability: usually overall instability secondary to overall anterior plus posterior lateral capsuloligamentary lesions (posterior fibulocalcaneal ligament progressively inducing subtalar laxity). The Castaing technique is completely insufficient here: Emslie-Vidal ligament plasty provides much greater stability.
- **Composite problems** (calcaneal varus + chronic ankle instability, tibial + calcaneal varus, etc.):
 - different techniques must be associated to position the implant stably and with a good mechanical axis.

TAR and gait analysis

The study concerned two series of patients in whom gait was analyzed in the lab (Brussels: Gait Laboratory of the Rehabilitation Unit of the Catholic University of Leuven, Pr. C. Detrembleur; Gait Laboratory, Raymond Poincaré Hospital, Paris medical faculty, Saint Quentin en Yvelines). Twenty-one patients were analyzed on objective criteria.

Patients and methods

Patients walked at spontaneous speed on a standard treadmill, fitted with stress gauges to measure the horizontal, lateral and vertical reaction forces of the foot on the ground. Six infrared cameras (ELITE) detected markers positioned at anatomic landmarks, following Davis et al. [25], at an acquisition frequency of 100 Hz.

Gait analysis was performed before and 6 months and 1 year after surgery. The variables assessed in the respective studies were: gait parameters, kinematics, dynamic variables, energy cost and mechanical work.

Results

- **Speed:** After TAR, mean walking speed distinctly improved, approximating normal values.
- **Step length:** Mean step length increased postoperatively, approximating but not reaching normal values. The increase was, however, significant (p < 0.001) when the patient's individual walking speed was factored in: i.e., when normalized according to speed.
- Cadence (step/min): Mean pre- and postoperative cadence differed significantly (p = 0.020).
- Stance phase duration: Taking each patient individually, 80% (vs. 40% preoperatively) were in the normal range, and 20% slightly below. The comparative study of arthritis patients performed at Garches found the arthrodesis group to show a longer pace than preoperatively, at the cost of gait symmetry, while the implant group showed improved symmetry and reduced limping, without improved pace length or walking speed.
- Kinematics (functional ROM in sagittal plan): Postoperative ankle joint amplitude was between 9° and 12°. The knee joint showed no postoperative change in mean amplitude, which remained near-normal (Leuwen data). TAR distinctly improved mean total work, which was significantly reduced postoperatively, approximating normal values.

Conclusion

As reported by Doets et al. [26], these two independent studies quantified and identified the interest of TAR as compared to arthrodesis, encouraging us to persist in an attitude that is still often criticized.

Multicenter study

Methodology in the overall series

Analysis of the present literature by no means answers all of the questions raised by the current third-generation concept of TAR. A round-table provided the opportunity to draw up the methodology for the analysis of a multicenter series regardless of implant type.

Inclusion criteria (implant types and centers)

Time allowed only a retrospective series, with a minimum 1-year FU.

The inclusion questions to be addressed were: Which implant? Which surgeons? What database?

 Implants: the four implants approved by Agence française de sécurité sanitaire des produits de santé (AFSSAPS) were included: AESTM (Biomet), HintegraTM (Newdeal), SaltoTM (Tornier) and STARTM (Link).

It was decided not to individualize respective results on each of the four types of implant.

- Surgeons
 - French or European AFCP member.
 - Proven expertise: more than 20 implantations of a given type by 31st December 2004 (information given by TAR manufacturers).
 - Twelve of the 15 centers selected agreed to include continuous series representing all or part of their activity (Saint-Luc University Clinic, Brussels; Garches University Hospital; Lyon-Sud University Hospital; Lille University Hospital; Amiens University Hospital; Nîmes University Hospital; St Anne Private Hospital, Lyon; Les Franciscaines Private Hospital, Nîmes; Union Private Hospital, Toulouse; Cours Dillon Private Hospital, Toulouse; Tondu Private Hospital, Toulouse; Jouvenet Private Hospital, Paris).

Database

- <u>Data form</u> (54 parameters, 155 possible response items, 14 free comment or numeric entry zones).
 - The form comprised five rubrics:
 - Patient information.
 - Diagnosis and talocrural score, regional and general anatomic context.
 - Description of surgery and postoperative course.
 - Complications, failures and revisions.
 - Status at last FU.
- Data were centralized on an html website under PHP at a MySql base. The site could be accessed by all participants, with anonymity in accordance with French data protection law (*Commission nationale de l'informatique et des libertés* [CNIL]).
 - 1. Excel[®] spreadsheet data were analyzed statistically using StatView[®] and SPSS[®] software.
 - 2. Implant revisions by arthrodesis were centralized in the same way.

Limitations

- Surgeon selection precluded assimilation to a nationwide study of TAR.
- The dedicated retrospective study form was efficient, but with room for improvement (inevitably incomplete, but with some ambiguous items).
- The distribution of the various implant types was unequal and represented sales volumes rather than actual use in implantation.
- Records could not be reviewed by an independent observer.

Table 3 General data.

Number of ankles Patients Mean age at surgery Type of implant	592 555 inc. 37 bilateral 56.4 yrs [17–84] SALTO TM (<i>n</i> = 388) 655% AES TM <i>n</i> = 173 292% HINTEGRA TM (<i>n</i> = 22) 37% STAR TM (<i>n</i> = 9) 15%
Sex ratio	327 [55%] female 265 [45%] male
Side	277 [46%] left 315 [54%] right
Diagnosis at implantation	 48% post-traumatic 15% arthritis with laxity 20% inflammatory arthropathy (RA) 9% primitive arthritis 2% implant revision 5% misc.: 9 partial talar necrosis or osteochondritis 6 sequelae of infectious arthritis or osteomyelitis 2 club foot varus equina 2 neurologic foot 2 hemochromatosis 1 multiple epiphyseal dysplasia 1 hemophilic arthropathy 1 submalleolar impingement 2 TAR after arthrodesis

Conclusion

The procedure proved efficient, with 592 usable files collected in less than 6 months. It could be adapted to a prospective study comparing arthrodesis vs. TAR.

Results

Series

The round-table series (Table 3) comprised 592 TARs (277 left, 315 right) in 555 patients (37 bilateral; 307 female, 248 male; mean age, 56.4 yrs [17–84 yrs]).

The four types of implant used in the 12 centers were: 388 SaltoTM (65.5%); 173 AESTM (29.2%), 22 HintegraTM (3.7%) and nine StarTM (1.5%).

Indications were: 48% post-traumatic arthritis, 15% arthritis with associated laxity, 20% inflammatory arthropathy (rheumatoid arthritis), 9% primitive arthritis, 2% implant revision, 5% miscellaneous (26 ankles, including nine partial talar necroses, and six sequelae of infectious arthritis). The cases of talar necrosis and osteochondritis were not severe and were operated on at the arthritis stage; extensive talar necrosis counted as a contra-indication.

On preoperative assessment, mean functional score (AOFAS and/or AFCP-SFMCP) was 32.5/100 [4–72]. DF was 1.6° [$-30^{\circ}-20^{\circ}$] and PF 21.6° [$0^{\circ}-50^{\circ}$]. Mean tibiotalar radiologic amplitude was 19.6° [$0^{\circ}-40^{\circ}$].

2	9	7

 Table 4
 Clinical results and radiologic mobility.

	Pre-operative	FU (37 months)
Functional score (/100)	32.5 [4–72]	82.1 [43–98]
Clinical dorsiflexion	1.6° [−30° à 20°]	9.1° [-5° à 30°]
Clinical plantar flexion	21.6° [0° à 50°]	23.6° [0° à 50°]
Number of equinuses	n=107 [−5° à −30°]	n=4 [-5°]
Radiologic mobility arc	19.6° [0°-40°]	23.2° [0°—40°]

Surgical data

Surgical technique. The approach, although not specifically reported, but was generally anterior. Implantation details were not reported, being specific to the type of implant and to the center.

Implantation precision. Postoperative X-ray found 90% (n = 535) satisfactory positioning. Thirty-one of the 57 defective implantations concerned imprecise positioning (16 cases of frontal and 10 of sagittal malalignment, and five of poor talar positioning). Bearing stability issues concerned 14 ankles (four cases of frontal instability, 10 of sagittal centering). Nine implants showed immediate tibial radiolucency and three talar components were oversized.

Peroperative complications. Peroperative complications affected 12% (n = 71) of operations.

There was malleolar fracture in 53 cases (35 medial, 18 lateral), secondary either to component oversizing or to a faulty surgical movement, requiring longer immobilization but without impact on the final result: FU score 80.6/100 vs. 32.7/100 preoperatively, radiographic mobility 21.46° at FU vs. 18.0° preoperatively, with no significant difference in comparison to the series as a whole (Table 4). In the 128 rheumatoid arthritis patients, there were not significantly more malleolar fractures (n=8), although involvement was medial in seven of the eight cases.

There were six cracked pilons due to tibial component impaction, one talar neck fracture, five cases of peroperative bearing instability, three defective implant fixations (two talar, one tibial) and two cases of tendon sectioning. There were no vascular lesions.

Postoperative management. Postoperative management (immobilization time, type of contention, weight-bearing) in the various centers was not studied.

Early complications

Ninety-one percent of implants showed no early complications.

Seventy-three percent (n = 38/52) of complications were skin healing problems, of all degrees of severity (from simple inflammation to severe necrosis requiring a flap). Three patients underwent revision for skin problems. There was no significant correlation between cutaneous complication and vascular status. Vascular problems induced not more frequent but more severe necrosis (p < 0.001): five of the six patients with vascular disorder associated with cutaneous complications underwent arthrodesis. The remaining complications comprised seven early infections, with four deep infections requiring revision, and six sensorineural complications (hypoesthesia or neuroma) in the approach (superficial peroneal nerve).

Associated procedures

Associated procedures depended on the context (stiffening, osseous or articular malalignment, neighboring articular pathology), and concerned 61% (n = 364/592) of implantations.

Major stiffness. Fifty-one percent of patients showed ankle stiffness (Table 4): 23% showed equinus, and 29% DF = 0°. Implantation (automatic posterior capsulectomy as part of the tibial section) corrected some of this. In 208 cases, Achilles lengthening was performed (193 percutaneous, four open, 11 gastrocnemius lengthenings). The procedure proved very effective peroperatively, but sometimes induced prolonged pain or loss of force.

Frontal malalignment. Malalignment is a major point in the diagnostic check-up, and must be corrected either before or during TAR. Thirty-six percent of ankles showed subarticular bone malalignment, 19% torsion-couple malalignment and 29% intra-articular malalignment.

- Above the tibiotalar joint line
 - Leg malalignment

The leg was misaligned in 22% of cases (18% in varus, 4% in valgus). In the vast majority, malalignment was not more than 5° and was not corrected, although preoperative realignment remote from the TAR (superior or diaphyseal tibial osteotomy) was not recorded for study purposes, and no such realignment was ever performed during implantation. There were, however, four proximal tibial realignments during follow-up.

- Tibial pilon malalignment

Talocrural bone malalignment affected 14% of ankles (6% bone valgus, 8% bone varus). Only 20% exceeded 10°. Severe cases were treated by supramalleolar osteotomy. Some cases (data not available) had undergone realignment prior to the TAR program. In three cases, osteotomy was performed during arthroplasty; one of these three implants subsequently underwent revision for displacement or subsidence and one was replaced by arthrodesis.

— Malleoli

Malleolar malunion affected 12% of ankles (n = 68; 45 lateral, 23 medial). Correction osteotomy was performed on 28 lateral and seven medial malleoli. There were five cases of nonunion (four lateral, one medial).

• Below the tibiotalar joint line

Subtalar stiffness affected 67% of cases and midfoot stiffness 51%. Foot morphotype was normal in 62% of cases, flat in 13% and cavus in 25%.

Subtalar bone malalignment affected 13% of patients. The degree of malalignment was not calculated.

 Forty-five subtalar or mid-tarsal arthrodeses were performed, either for local malalignment or for painful hindfoot arthropathy: 31 at 6 weeks preimplantation and 14 during implantation. There was no increase in morbidity perioperatively or at follow-up whatever the program, but functional scores at FU were better following 2-step programs (84/100 vs. 75/100; p < 0.003). There were four secondary arthrodeses for pain.

- Nine calcaneal osteotomies were performed. They were sui generis, halfway between malalignment and instability correction: while secondary to malalignment, all were performed for varizing arthritis. Immediate postoperative course featured four skin complications. Three late osteotomies were subsequently performed for recurrence of instability.
- Intra-articular malalignment

Chronic instability sequelae and varizing arthritis were grouped together as being clinically and anatomically identical. 29.5% of ankles showed ligamentary imbalance. When the ligamentary framework was unsatisfactory, some centers performed medial release, others lateral ligament plasty.

- 45 lateral ligament reconstructions were performed. Postoperative course featured five fractures, eight skin complications and two early infections. There were six late recurrences of instability, four managed by ligament plasty revision.
- Extensive isolated ligament release was performed in 102 cases. Postoperative course featured 11 fractures, four cases of mobile-bearing instability, and seven skin complications. There were five late recurrences of instability, two of which required ligamentoplasty.

Other procedures. Twenty-five other procedures were performed according to local status, not specifically linked to TAR: 12 arthritic cyst bone grafts, two synovial cyst ablations, nine tendon procedures, four forefoot procedures, one tibiofibular arthrodesis and one isolated midtarsal arthrodesis.

Overall results

Of the 592 ankles of the series, at a mean 3 years 1 month's FU (1 yr to 11 yrs 5 months), 6.6% (n = 39) were lost to FU (after 1 year). Nine patients died, but with enough follow-up for their data to be included. Revision, with or without TAR ablation, was sometimes performed during follow-up. *Revision without implant ablation*. Eleven percent (n = 66) of implants underwent revision without ablation, at a mean 22 months.

Forty-seven percent of such indications were implantlinked: 19 cases of isolated pain underwent arthrolysis with synovectomy, and 12 evolutive cysts were grafted. The mobile-bearing component was systematically replaced. Thirty-eight percent of revisions were for complications secondary to context of TAR indication: eight for stability correction and 17 for re-alignment. Fifteen percent of revisions were for other reasons: six posterior tibial nerve neurolyses and four intercurrent complications (one open wound, one tibial fracture, one non-lengthened Achilles rupture, and one lateral peroneal dislocation).

Revision with implant ablation. Six percent (n=32) of implants were removed, at a mean 27 months.

Twenty-two arthrodeses and 10 implant replacements were performed, at a mean patient-age of 52 years. Two significant risk factors emerged: infection (p < 0.001) and skin disorder (p < 0.01).

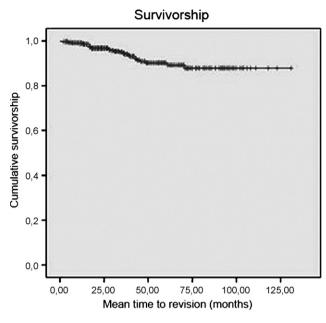


Figure 1 Overall survivorship (implant in place) at 71 months.

• Ablation with arthrodesis

In the 22 cases of arthrodesis, 50% of indications for implant ablation were for pain (n = 11), 14% for infection (n = 3), 18% for implant loosening (n = 4), 9% for instability (n = 2) and 9% for intercurrent complications (n = 2).

Ablation with replacement

For the 10 uni- or bipolar replacement, the indication was implant loosening in eight cases.

Overall survivorship. At follow-up, 521 of the 553 implants (94%) were in place.

Overall, cumulative survivorship, with implant ablation as failure criterion, was 88% at 71 months [95% CI: 39-100] (Fig. 1). Cumulative survivorship, with revision as such (with or without ablation) as failure criterion was 70% at 65 months [95% CI: 63-76].

Clinical results

Subjectively, 40% of patients very satisfied, 47.5% satisfied, 7.5% indifferent and 5% dissatisfied.

Clinical results showed significant improvement (p < 0.001) on all parameters (Table 4): mean functional score, 82/100 [43–98]; dorsiflexion, 9.1°; plantar flexion, 23.6°; equinus, n = 4 (down from 107).

In the particular case of rheumatoid polyarthritis patients, there were not significantly more perioperative complications or revisions, and clinical improvement was significant (functional score, 28.1/100 preoperatively vs. 78.8/100 at FU; p < 0.001).

Radiologic results

Implant anchorage

Anchorage was stable in 98% of cases. There were eight cases of tibial and nine of talar loosening. No predictive factors (such as defective positioning: ns) emerged. Partial radiolucency was much more frequently tibial (n = 98) than talar (n = 22); the talar interface was, how-

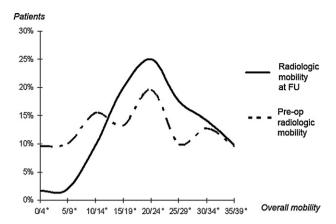


Figure 2 Distribution of radiologic talocrural mobility.

ever, difficult to interpret, due to the shape of the implant, inducing underestimation. Although frequent, radiolucency did not affect results (functional score at FU = 80/100).

• Bone structure

Bone structure abnormalities were in the form of cysts and affected 15% of implants (n = 76), mainly on the tibial side. No predictive factors emerged.

Calcifications

Severe calcification affected 4% of implants, reducing mobility in comparison to the series as a whole (p < 0.001), with a radiologic arc of 16.5° and clinical arc of 24.4°.

• Wear

There was no obvious wear; but follow-up was only medium-term, and radiologic criteria were imprecise.

Kinematics

Radiologic mobility amplitude rose from 19.6° [0-40] to 23.1° [0-40]. Comparing preoperative and FU mobility curves showed a multimodal distribution becoming unimodal around $20^{\circ}-24^{\circ}$ (Fig. 2). There was no significant correlation between preoperative and FU mobility: the former was neither an indication criterion nor a predictor of the latter.

SF 36

Based on the Medical Outcome Study which began in 1986, the SF 36 (MOS 36-item Short Form Health Survey) questionnaire with 36 questions measures population health status and quality of life. The 36 items, grouped into eight scales (physical functioning [PF], role limitations due to physical health (RL], pain [BP], general health [GH], energy/fatigue or vitality [VT], social functioning [SF], role limitations due to emotional problems [RE], and emotional well-being or mental health [MH]), provide two scores (Physical Composite Score [PCS] and Mental Composite Score [MCS] and a total score [TS]). It has been translated and validated in several languages and has been available in France since 1998 [27].

It is widely used in national or regional health surveys, public health research, clinical research (randomized drug trials, chronic disease and, more recently, orthopedic surgery). Between 2001 and 2006, 20 articles in Foot Ankle Int. included assessments using the SF 36.

Methodology

The SF 36 questionnaire was sent to patients of three centers (Lyon, Nîmes, Paris). Responses were entered on an Excel[®] spreadsheet and processed according to the calculation formulae of a user license (Quality Metric Survey).

Results

Three hundred and fifty-six patients (mean age, 57 years; range, 23–77 yrs) sent back usable questionnaires (complete response rate: 72–89%).

Mean total score total was 66 ± 20.3 (23–97), Physical Composite Score 63 ± 20.7 (PF 74 – RP 44 – BP 72 – GH 67), and Mental Composite Score 68 ± 20.4 (VT 58 – SF 82 – RE 67 – MH 65).

Discussion

The SF 36 covers broad fields and there are databases for several countries, including France. There are, however, floor and ceiling effects on certain items. Results depend on age, gender, social class and educational level. Scores correlate directly with general health status but only weakly with AOFAS score. The SF 36 gives a good assessment at 12 months postevent.

The present results were better than those of the Agility TAR study (PCS 49.5 - MCS 56.1) [28] and Blair tibiotalar arthrodesis study (PCS 46 - MCS 61) [29]. They were comparable to those for osteosynthesis for calcaneal fracture (TS 65.3 and 67.1) [30,31].

The SF 36 is an indispensable tool for prospective and/or randomized studies (TAR vs. arthrodesis). Protocols should include preoperative, 1-year and end-of-FU SF 36, with analysis by age group and gender.

Discussion: good points, worries and the future

Good points

This multicenter, multioperator, multi-implant series of 592 patients (the largest presently published) confirmed literature findings: major functional improvement between preand postoperative functional scores, and acceptable ongoing survivorship compared to previous-generation implants.

The difficulties of surgery and especially of strategic decision-making to adapt to the anatomic context are real enough; the procedure is, however, reproducible, teachable and transmissible, with (in expert hands) satisfactory implantation quality.

Unlike with previous-generation and other types of implants, bone anchorage seems to be stable.

Complication and revision rates are tolerable. In case of failure, solutions (implant or arthrodesis) are available. Unlike in literature reports, no amputations were required.

Worries

There are no prediction criteria for outcome, whether in terms of mobility (no correlation between pre- and postoperative values) or of total functional score. In particular, no significant difference in results emerged between the two main indications (post-traumatic vs. inflammatory arthritis).

A certain number of unaccountable complications may arise, leading to failure: isolated pain, periarticular ossification, evolutive abnormality of the bone structure. The follow-up precluded long-term conclusions: is TAR to be seen as a definitive operation or a ''relay'' postponing excess subtalar and midtarsal stress during the implant's lifetime?

Future issues

Concerning the choice between TAR and arthrodesis: only a prospective multicenter study with a clear-shared protocol could provide, not an answer, but details on respective indications.

Concerning survivorship: systematic follow-up of expertcenter cohorts is essential.

Concerning improvements to the implants themselves: detailed clinical, radiological and kinematic analysis could shed light on the improvements provided by third-generation models and determine the main factors — surgical precision, cementless anchorage, minimally invasive attitude or systematization of the mobile bearing.

Solutions in case of failure

Multicenter series - results

Forty-five of the 592 implants (7%) required revision surgery.

These were 33 women and 12 men. There was no difference in laterality: 23 right, 22 left. Mean age was 52 years [20-78 yrs] (vs. 57 years for the total population).

Patients

• Etiology: Etiology was mainly traumatic in 23 cases. Instability was implicated in seven cases, inflammation in eight and primitive arthritis in three. There were also four miscellaneous cases: club foot, dysplasia or impingement.

Twenty-seven percent of patients had preexistent medical comorbidity (diabetes, obesity, polyarthritis), compared to 17% in the total population. In one-third of cases, the associated pathology was not specified (45% in the total population). Twenty-eight patients had history of surgery (61%, compared to 46% in the total population): 12 isolated procedures and 16 with at least two procedures.

- Anatomy: the leg axis was well-aligned in 33 cases, in varus in seven and not specified in five. The talocrural axis was well-aligned in four cases. Wear-related varus was found in 14 cases (eight osseous), and valgus in four (three osseous); data were lacking in four cases. In three cases, there was tibial pilon malunion.
- Associated procedures: 30 patients had associated procedures (65%, vs. 61% in the total population): six malleolar osteotomies (two medial, four lateral); eight ligament reconstructions; two osteotomies and one arthrodesis for hindfoot correction; 14 supramalleolar osteotomies; and 14 Achilles lengthenings (13 percutaneous).
- Seven cases showed peroperative complication (15%, vs. 12% in the total population): six malleolar fractures (four medial, two lateral), and one bearing displacement.

Postoperative course was simple in 30 patients; 15 (33%) showed complications: 10 skin problems, two early infections, one bearing displacement, and one non-specified.

 Clinical reasons for revision were basically pain (n = 15), stiffness (n = 5), instability (n = 4) or infection (n = 4). Radiology found 11 loosenings, 12 evolutive cysts and five bearing displacements.

Revision procedures

Revision was performed within 2 years (mean, 2 years; range, 0-12 years) 10 implant ablations, 22 arthrodeses, and 13 arthrolyses. There were also 10 bone grafts and two ligamentoplasties.

Pain was mainly managed by arthrodesis (9/15), or by arthrolysis in five cases and ankle arthroplasty replacement in one. Instability was managed by arthrodesis in two cases, ankle arthroplasty replacement in one and arthrolysis with ligamentoplasty in one.

For loosening (11 cases), attitudes were either arthrodesis or ankle arthroplasty replacement, with simple arthrolysis in one case. Evolutive cysts were managed by arthrodesis (seven cases) or arthrolysis and graft (five cases).

Mobile-bearing dislocation was managed by arthrodesis in one case and replacement in four. The four cases of infection were managed by arthrodesis in two cases and ankle arthroplasty replacement in the other two.

Results

For revision by arthrodesis, 61% of patients were satisfied and 30% disappointed. For ankle arthroplasty replacement, likewise 50% of patients were satisfied and 50% disappointed. In assessing these results, however, it is to be borne in mind that data were lacking in several cases (Table 5).

Revision with implant conservation

Complications are to be distinguished from failure.

Revision for complications

- Cutaneous, sometimes with anterior tibial tendon protrusion.
- Persistent synovitis.
- Malleolar fracture.

These complications require simple immediate revision, by either progressive induced skin healing, scar revision, reverse malleolar covering flap, joint lavage-drainage or osteosynthesis.

Non-implant-linked failure

Indications may be at fault, due to hasty preoperative analysis, or overlooked or insufficiently studied X-ray assessments.

- Partial varus: tibial or hindfoot, overlooked.
- Global varus: tibial and associated hindfoot, requiring fine analysis to determine correction site (tibial or calcaneal or both).
- Overlooked or non-diagnosed chronic ankle instability, with or without associated hindfoot varus, requires at least ligamentoplasty and calcaneal osteotomy to correct

the varus and, at most, complete surgical revision, with repositioning of the talar implant.

• Isolated or associated malunion should be corrected ahead of TAR.

Subtalar or mid- and/or forefoot pathology must be corrected by arthrodesis or osteotomy, to eliminate malpositioning, which causes pain, implant displacement and failure.

Revision by implant replacement

- The choice of revision technique depends on prior correction of the causes of failure (periarticular abnormality, etc.). The technical aspects of revision by replacement are, however, worth reviewing.
- The choice of approach depends on the preexisting scar, and any associated procedure(s) or preexisting lesions. Bacteriological and anatomopathologic sampling is systematic.
- Implant ablation is often straightforward, but should always maximize conserved bone capital — which may be difficult, for example in case of a tibia with a large cylindrically shaped fin or stem and anchored —, or of a talus with lateral access limited by hemiprosthetic lateral and/or medial wings.
- Joint cleaning should first consist in complete synovectomy, and ablation of any metallosis and periarticular ossification. Closure must even so be conserved, and especially the tendon sliding planes
- **Resection** must be in healthy bone. In the tibia, height is variable and resection may cause problems when hampered or prevented by risk to the malleoli or risk of incomplete bone support or of extensive bone defect. In the talus, resection is possible in case of localized cyst, but may cause serious problems in case of necrosis or when the subtalar joint is very nearby.
- Residual bone capital assessment:
 - If the bone is intact and of good enough quality, with limited defect, partial implant replacement may be performed as in primary implantation, with or without grafting around prosthesis components The implant can be partially conserved if it is correctly positioned, without abnormality, with good bone anchorage and compatible with the new element. Filling uses autologous cancellous or corticocancellous fragments in case of very limited defect or limited subtalar cyst. The recipient bone bed must be healthy and well prepared by complete curettage with microfractures for revascularization perforation. This filling technique may encounter difficulty in peroperative location of cysts or difficulty of access.
 - 2. If the bone is intact and of good enough quality, with limited defect, complete implant replacement may be performed as in primary implantation. If the defect is a bit greater but still moderate, a revision prosthesis may be used (long central tibial stem, thick talus, etc.) The development of revision implants and ancillaries is still very limited, and needs improving.
 - 3. If the bone is of poor quality, with a large defect, some reconstruction may still be reasonable,

Subjective result	Implant replacement (<i>n</i> = 10)		lant replacement (n = 10) Arthrodesis (n = 22)		Arthrolysis (n=13)	
Very satisfied	1	50%	1	61%	2	54%
Satisfied	3		10		5	
Indifferent	2	50%	3	39 %	4	46%
Dissatisfied	2		4		2	
Not specified	2		4		0	

associated to graft. But these are extreme situations. Reconstruction may be difficult, and always requires grafting. The graft should be as limited as possible, with maximal healthy bone support. The tibia is easier than the talus. Filling always uses more or less massive autologous corticocancellous fragments. Bone-bank grafts or massive allografts are not easily available. The bone should be as well compacted as possible, for maximal implant stability.

- In case of infection, the problem is as in any arthroplasty. One- or two-step revision requires firstly implant ablation, then ''carcinologic'' excision of infected substance, and complete cleansing. Only when the infection is judged to have been resolved can the defect and reconstruction options be assessed.
- Finally, reconstruction may be judged difficult or non-desirable, and arthrodesis is preferred.

Ankle arthrodesis secondary to TAR

Tibiotarsal arthrodesis is the last resort before amputation in case of failure of TAR. Causes of failure, especially massive talar necrosis and infection, must be analyzed to determine indications for surgery. Assessment should analyze the bone defect, lower limb axes and terrain, to avoid nonunion and shortening.

Technique

The approach is either anterior nor transmalleolar. Periprosthetic tissue is excised; histology may be useful.

- **Bone graft** is essential for consolidation and to conserve length. There are various options:
 - Corticocancellous autograft from the anterior or posterior iliac wing, into healthy bone.
 - Corticocancellous autograft from the distal extremity of the fibula, bridging the arthrodesis zone, or as an anterior tibial rod sunk into the talus.
 - Fibular fragments.
 - Bank-bone, using the ''cup-and-ball'' technique, which consists in crossing a femoral head allograft freed of cartilage and calibrated by an intramedullary nail
 - Bone substitutes are not recommended.
- The choice of osteosynthesis depends on bone quality and subtalar joint status.
 - A healthy subtalar joint is an indication for isolated tibiotarsal fixation by two crossed screws, sometimes completed by percutaneous fibular fixation by transverse screws or anterior fixation by Blount staple or

anterior plate (the sole means of osteosynthesis for some authors).

 A pathologic subtalar joint requires tibiotalar and subtalar arthrodesis by calcaneotibial screwing or intramedullary nailing, which provides good stability but entails specific complications: hindfoot varus, plantar nerve lesions, or plantar migration of the nail.

External fixators are used in 1-step revision for severe defects and infections, whereas internal osteosynthesis may be used in 2-step revision.

Results

The most feared late complication is nonunion (15% in the present series). Treatment was surgical revision with grafting and repeat osteosynthesis, giving good consolidation in all but one case.

Arthrodesis after TAR gave good results in the present series, but the technique is difficult enough to require a specialized center.

Conclusions

Has this update answered every question?

• Is the surgical technique simple?

With the development of step-by-step guided techniques and procedural standardization, TAR is available to any surgeon. The problem lies rather in indications and associated procedures, which concern 60% of cases and cause many specific complications. Indications and prioritization may be difficult, requiring specialized centers.

• Do we have all the data?

Analysis of the patient provides the elements, but it is still not possible to predict individual results. The question remains open as to whether the best candidate for TAR is a patient with an inflammatory or with a posttraumatic pathology.

Analysis and interpretation of results needs refining and pursuing; we lack data on TAR implants and further randomized prospective clinical studies are needed to supply long-term data.

What is to be done now?

We need to continue the attempts to conserve tibiotarsal mobility. Ideas need to evolve: no, arthrodesis is not the gold standard; yes, even 9 years' survival is a gain for the patient.

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Conflict of interest statement

M Bonnin, JA Colombier, and T Judet are the designing surgeons of Salto TAR. J Asencio is the designing surgeon of AES TAR.

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