

Ankle-foot prosthesis with articulated human bone endoskeleton: Force-deflection and fatigue study

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Abstract—The durability and function of three ankle-foot prostheses fabricated using a naturally articulated, fresh cadaveric human bone endoskeleton set in a fiber reinforced rubber shell were studied. Radiographic and force-deflection analyses before and after cyclic dorsiflexion for 5,000, 100,000, and 3 million cycles revealed no structural or functional changes. The endoskeleton foot compared favorably with the Jaipur ankle-foot prosthesis. It is concluded that formalin-fixed fresh foot bones with intact articulations obtained from cadaveric or surgically amputated limbs are suitable for use in ankle-foot prostheses because they withstand prolonged use without functional or structural deterioration.

Key words: *ankle-foot prostheses, endoskeleton, fatigue testing, force-deflection analysis, fresh cadaveric bones, Jaipur foot, lower limb amputees.*

INTRODUCTION

The feasibility of using articulated human bones as an endoskeleton in ankle-foot prostheses was established in an earlier pilot study (6). Formalin-fixed cadaveric bones which retained their capsular and pericapsular ligaments (and thus their articulations) were encased in a tire cord reinforced rubber shell (**Figure 1**). After active use for 4 weeks by an amputee volunteer, radiological examination of the prosthesis showed no bone or joint changes, and the articulations were undisturbed. The prosthesis was favor-

ably received by the amputee. Exhumed, copper wire articulated bones, when similarly incorporated into a prosthesis, showed stress fractures after a similar field trial. Hence, while exhumed bones could not be recommended for use, fresh cadaveric bones with their capsules and peri-articular ligaments appeared promising as endoskeleton material in ankle-foot prostheses. These encouraging results notwithstanding, the long-term durability of cadaveric bone endoskeleton prostheses was uncertain. This paper reports the results of bench-testing of cadaveric bone endoskeleton prostheses for durability and function under simulated conditions. Standard Jaipur ankle-foot prostheses (7) were used for comparison.

MATERIALS AND METHODS

Fabrication of the bony endoskeleton prosthesis

Freshly dissected, formalin-fixed cadaveric limbs were obtained from a medical college. The limbs were sawed transversely through 6 cm above the tip of the medial malleolus, denuded up to the periarticular ligaments and joint capsules, and placed in 10 percent formalin for 48 hours. They were then washed in running tap water for a few hours, boiled in water for 1 hour to remove fat, and allowed to dry at room temperature for a day.

A conventional wooden ankle-block (as used in the Jaipur foot, but shorter) was gouged on its lower surface to fit the upper ends of the tibia and fibula. A steel bolt was passed upward through the ankle-block and its head flanged for stability. The flange was nailed to the block. The upper ends of the tibia and fibula were painted with

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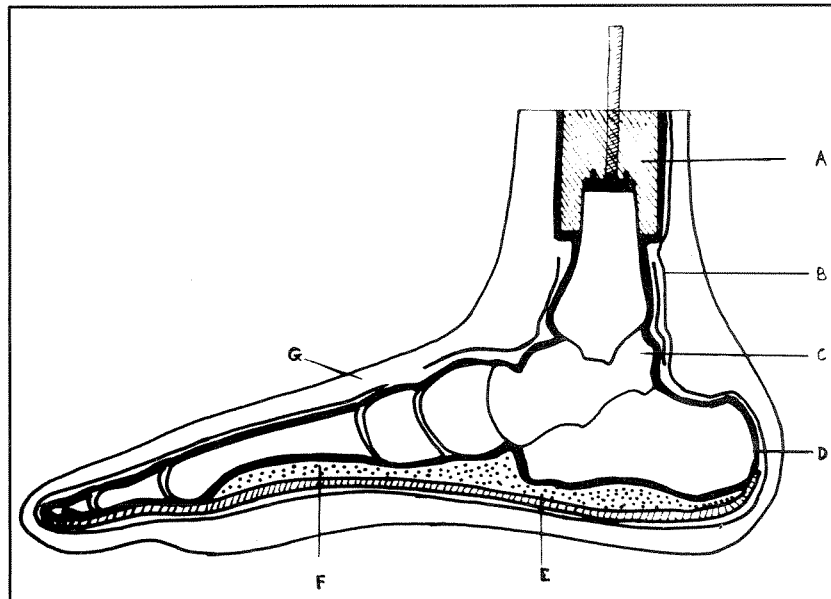


Figure 1.

Human endoskeleton ankle-foot prosthesis (sagittal section).

A: Wooden ankle block incorporating the carriage bolt assembly and gouged to fit the upper ends of the tibia and fibula.

B: Tire cord (specifically the longitudinal plantar cord with parts of the ankle crosses).

C: Articulated bone endoskeleton.

D: Black cushion compound covering.

E: Tread compound sole-plate.

F: Microcellular rubber sole.

G: Red cushion compound external shell.

vulcanizing cement and black cushion compound and then firmly engaged into the ankle-block (**Figure 1**). The feet and block were painted with vulcanizing cement (Diamond Rubber Industries, Jhansi, India) and covered with a layer of black cushion compound (unvulcanized rubber compound: Madras Rubber Factory, MRF—Code 7401203, Madras, India). Thereafter, the process of fabrication closely paralleled that of the Jaipur foot (7). Four pairs of 5-cm-wide strips of tire cord (rubberized rayon/nylon cord: MRF, CRF 70×500; Code 7311400/7321400) were laid vertically around the ankle, each pair crossing at the level of the malleoli (**Figure 2 top**) and **Figure 3**). These crosses were laid anteriorly, posteriorly, and on either side of the ankle. The lower ends of the strips lay across the tarsals.

A microcellular rubber (MCR—Shore A 35) sole (**Figure 2 bottom**) was fashioned to fit the arched concavity of the articulated foot and trimmed to correspond to the contours of the cavity of an aluminium vulcanizing mold. A sole-plate was cut out from a sheet of unvulcanized tread compound (MRF—Code 7403303) corresponding to the outline of the foot-plate of the aluminium mold and then stuck to the plantar aspect of the MCR sole (**Figure 2**

bottom). A 5-cm-wide strip of the tire cord (plantar strap) was applied longitudinally onto the tread compound sole. Just anterior to the heel, this strip divided into five rays corresponding to each metatarsal. Another tire cord strip was applied transversely onto the heel of the tread compound sole-plate. The microcellular rubber-tread compound assembly was then stuck onto the plantar aspect of the endoskeleton. The transverse tire cord ends were carried upward on either side of the heel and ankle up to the wooden ankle-block. The five rays of the longitudinal plantar strap were carried forward to wind around each toe and then onto the dorsum of the foot to end on the tarsals. The posterior extension of the plantar strap was carried behind the heel and the ankle onto the wooden block (**Figure 3**). The entire ankle-foot assembly was covered with two layers of red cushion compound (unvulcanized skin-colored rubber compound: Asia Rubber Mills, Gurgaon, India) and placed inside an aluminium mold. The mold was closed and the ankle-foot assembly vulcanized by placing the mold in a steam sterilizer at 120 degrees C and 175 kN/m² pressure for 2 hours. The prosthesis was then bench-tested.

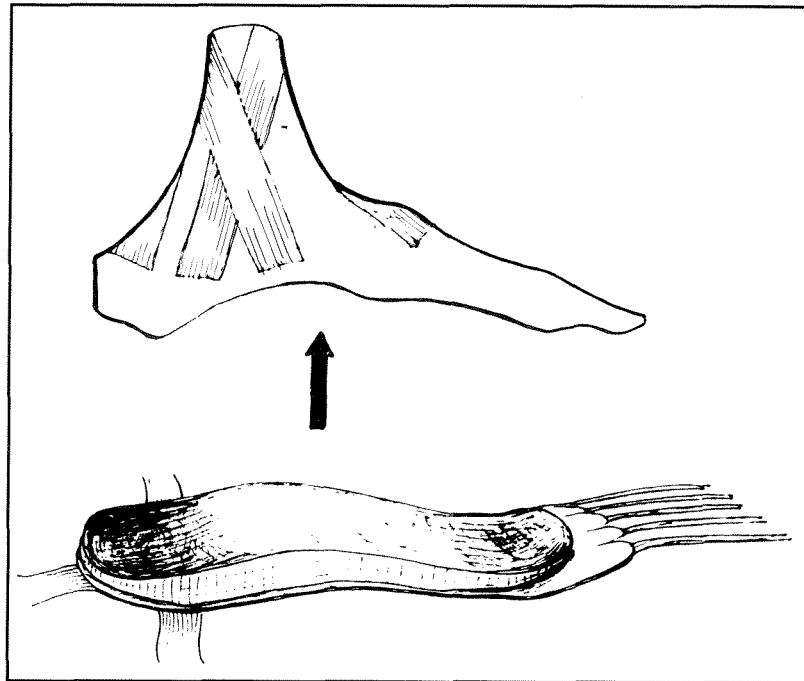


Figure 2.

Top: Lateral view of the bony endoskeleton covered with vulcanizing cement and a layer of cushion compound. The medial pair of cross-laid tire cords is shown. Four such pairs are laid around the ankle. The lower ends of the anterior and posterior pairs are just visible lying across the tarsals.

Bottom: Semi-profile of the sole assembly. The thicker, microcellular rubber (MCR) sole is shaped and trimmed to correspond to the concavity of the endoskeleton. The flat tread compound sole-plate is fixed to its outer surface. Also seen are the five rays of the longitudinal plantar tire cord strap, its free end at the rear, and the two ends of the transverse tire cord. Once the sole assembly is stuck (arrow) onto the endoskeleton, these tire cord straps are carried and fixed onto the foot. The five rays pass around the toes to end on the dorsum, while the other end of the longitudinal strap passes behind the heel and ankle. The two ends of the transverse cord pass onto the sides of the ankle.

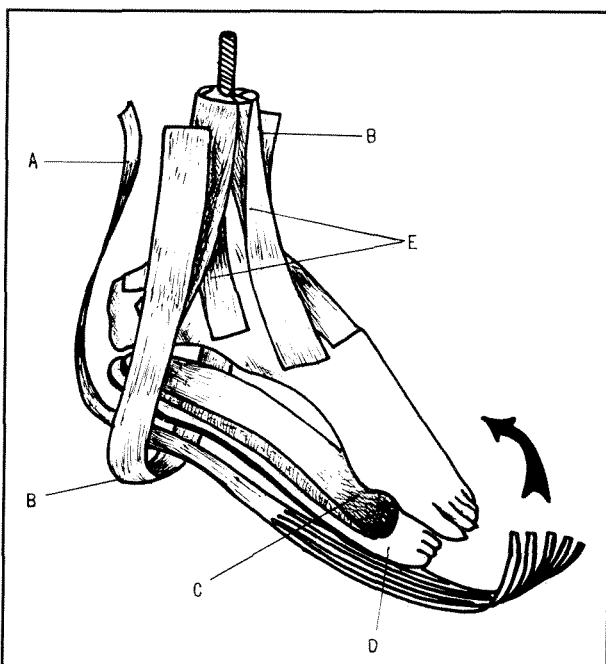


Figure 3.

Exploded view of the endoskeleton foot to show the lie and direction of the plantar tire cords.

A: Longitudinal tire cord plantar strap.

B: Transverse tire cord.

C: Microcellular rubber sole.

D: Tread compound sole-plate.

E: Crossed tire cords around ankle.

The arrow shows how the five rays of the longitudinal plantar strap cross each toe to end on the dorsum of the tarsals. In practice, the plantar tire cords are adhered to the sole assembly and the latter is then incorporated onto the endoskeleton.

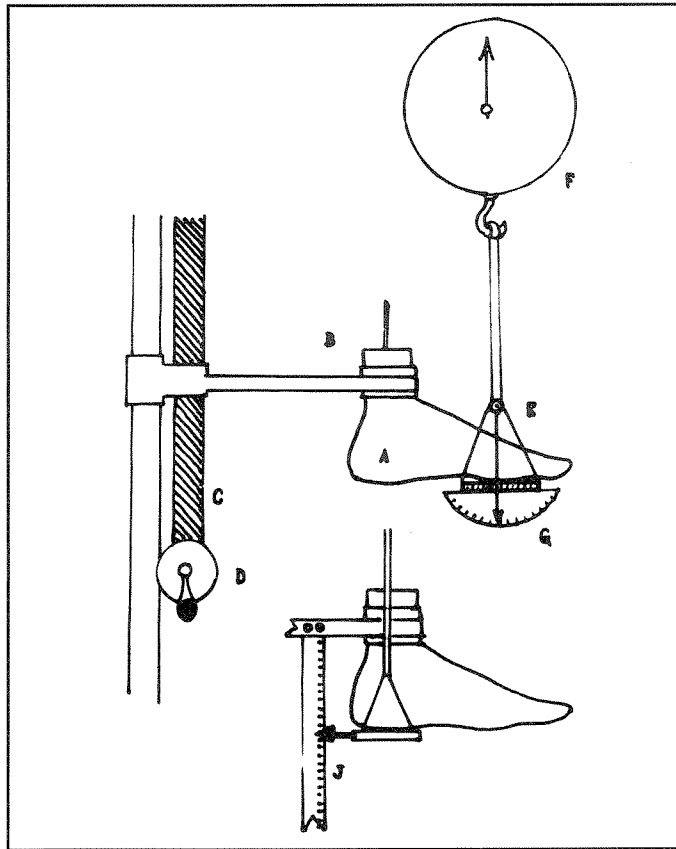


Figure 4.

Principle of the load-deflection analysis device. The foot (A) is clamped and, through a rigid side-arm (B), can be raised or lowered on a thread-shaft (C) by a handle wheel (D). A stirrup (E) slung from a spring balance (F) engages the forefoot and carries a fixed goniometer (G). The degree of dorsiflexion is read off the goniometer by a vertically disposed, freely swiveling pointer. For measurement of heel compression, the stirrup is modified to carry a fixed pointer that reads off the linear excursion of the heel on a vertical scale (J).

Force-deflection analysis and fatigue testing

Indigenously developed equipment was used in force-deflection analysis and fatigue testing. (See page 23.)

Dorsiflexion (Figure 4). The spring balance was suspended directly above the forefoot. The dorsiflexion stirrup was slung from the spring balance and slid over the forefoot. By turning the hand wheel, the foot-plate of the stirrup was engaged with the forefoot and the spring balance was set to zero. The sliding bracket was lowered until the spring balance read 10 kg. The change in angular deflection (in degrees) of the foot-plate at the swivel joint was read from the goniometer. The process was repeated for increments of 10 kg until 70 kg was reached. The increase in deflection of the forefoot versus the net force acting on the forefoot was calculated. Although the true

deflecting force on the heel would be a function of the angle (Θ) of deflection (net force \times Cos Θ by the law of parallelogram of forces), this calculation was ignored because only comparisons were pertinent in the study.

Heel deflection (Figure 4). The spring balance was suspended directly above the heel. The dorsiflexion measuring stirrup was replaced by a heel deflection stirrup which was slung from the spring balance and positioned until its foot-plate rested under the heel. By rotating the hand wheel, the heel of the prosthesis was moved to make contact with the stirrup and the position of the pointer on the scale was read (mm). The sliding bracket was further moved by rotating the hand wheel until the spring balance read 10 kg. Again, the position of the pointer on the scale was read. This procedure was repeated at 10 kg increments until 70 kg was reached. The increase in the scale reading at each step was taken to indicate deflection of the heel versus the net force acting on the heel. As in the dorsiflexion test, the true deflecting force was not calculated separately.

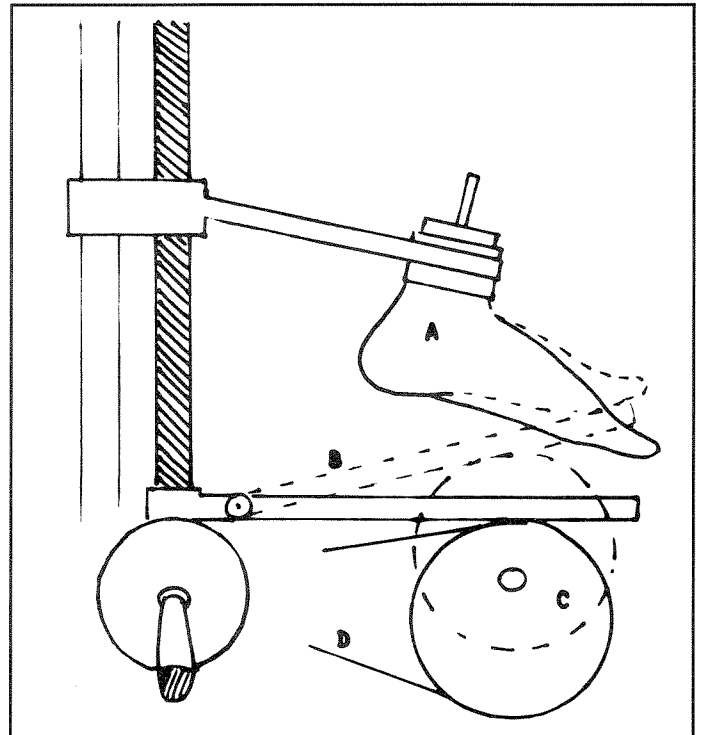


Figure 5.

Principle of the cyclic dorsiflexion device. The foot (A) is fixed by an angled side arm that can be moved on a thread shaft. A hinged flap-plate (B) is rocked up cyclically by an eccentrically mounted cam (C), which in turn is driven through a belt (D) by a motor. As the flap-plate rocks upward, it flexes the forefoot. The magnitude of flexion can be predetermined (to 3 cm in this study) by adjusting the position of the foot via the thread shaft by the handle wheel.

Table 1.
Forced deflection (dorsiflexion).

Force (kg)	Deflection (degrees)												
	Before cyclic dorsiflexion									After (cycles) of cyclic dorsiflexion			
	Jaipur foot			5000						100,000			3M
	7R	7L	E1	E2	E3	E1	E2	E3	E1	E2	E3	E2	
10	5.75 (0.96)	2.75 (0.89)	7	3	2	5	1	1	10	4	5	10	
20	9.75 (0.50)	6.35 (1.15)	15	8	7	12	6	6	15	10	10	15	
30	14.15 (1.75)	10.29 (1.59)	22	13	12	19	10	11	21	14	14	20	
40	21.00 (5.15)	14.90 (2.13)	25	17	16	25	13	16	26	18	17	23	
50	26.75 (6.02)	19.90 (3.21)	29	20	21	30	16	19	31	21	21	27	
60	31.75 (6.02)	24.90 (4.05)	33	23	25	35	18	23	35	25	24	30	
70	36.75 (6.40)	30.00 (4.87)	38	25	29	39	20	26	39	27	26	32	

*Average values \pm SD (in parentheses)

7R: Jaipur foot size 7(right); total 4 feet; average weight 864+30G

7L: Jaipur foot size 7(left); total 11 feet; average weight 895+60G

E1-E3: Fresh cadaveric bone endoskeleton prostheses.

E1: Size 7(right); weight 900G

E2: Size 7(left); weight 920G

E3: Size 7(right); weight 850G

Size 7 = 22 cm (heel-to-toe) and 12.5 cm (mid-heel to toe-break)

3M = 3 million, E2 foot only

Fatigue testing by cyclic loading (Figure 5). The prosthesis was clamped in position at an angle of 10 degrees horizontal. The hand wheel was rotated to allow the fore-foot of the prosthesis to be positioned so that the flap-plate would dorsiflex the foot by 3 cm during a cycle. Force-deflection studies showed that about 60 kg load to the forefoot was required to produce a 3 cm displacement. With the sliding bracket locked in position, the motor was switched on and allowed to run for the desired number of cycles. At the rate of 60 cycles-per-minute, the foot was run continuously for 11 hours (about 30,000 cycles). It then was allowed to rest for about one-half hour between each 11-hour running period. At the rate of approximately 80,000 cycles a day, it took about 40 days to complete 3 million cycles.

Sequence of testing

Three prostheses (E1, E2, and E3) underwent sequen-

tial testing. For purposes of comparison, force-deflection studies were carried out on 11 Jaipur feet of similar size (size 7), which were made using the same aluminium mold as that used for the endoskeleton feet. The test protocol included the following:

1. An initial lateral radiograph verifying the positions of the bones in order to establish a baseline and for further reference;
2. A force-deflection study of dorsiflexion and heel deflection;
3. Cyclic dorsiflexion for 5,000 cycles;
4. Repeat of the force-deflection study;
5. Repeat of the cyclic dorsiflexion up to 100,000 cycles;
6. Repeat of the lateral radiograph; and,
7. Repeat of the force-deflection study.

The E2 prosthesis was further cyclic-loaded to a total of 3 million cycles which was followed by a repeat lateral radiograph and force-deflection study.

RESULTS

Radiographic studies

Radiographs of the three prostheses after 100,000 cycles (Figures 6, 7, and 8) and the E2 prosthesis after 3 million cycles (Figure 9) were compared to the initial radiographs. Results were as follows:

1. The gross morphology of the bones and their trabecular pattern were unchanged after cyclic dorsiflexion. No cortical or trabecular fractures were evident.

2. The joint locations and their relative positions showed no change, deterioration, distortion, or displacement.

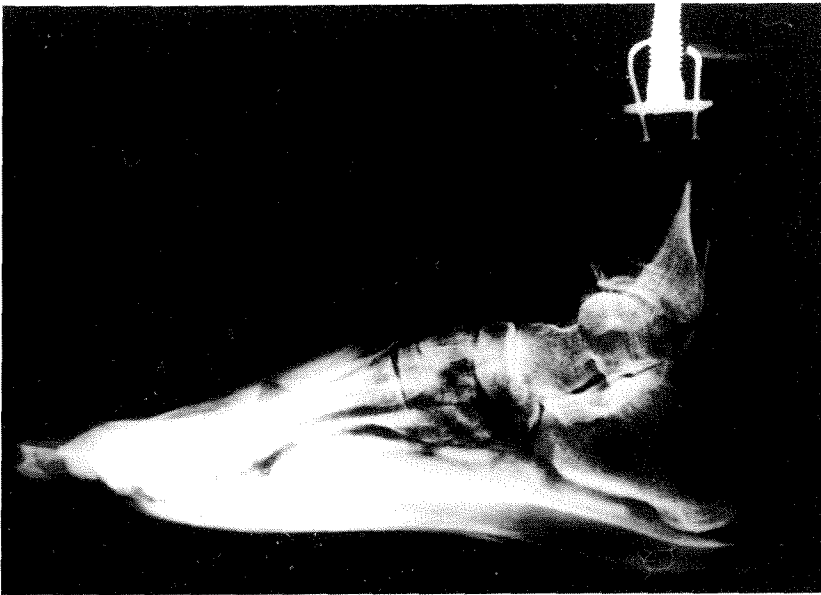


Figure 6.

Radiograph of bony endoskeleton prosthesis EI after 100,000 cycles. The bones are intact with no trabecular or cortical fractures and maintain their relationship to one another. The joint configurations are normal.



Figure 7.

Radiograph of bony endoskeleton prosthesis E2 after 100,000 cycles. The bones are intact with no trabecular or cortical fractures and maintain their relationship to one another. The joint configurations are normal.

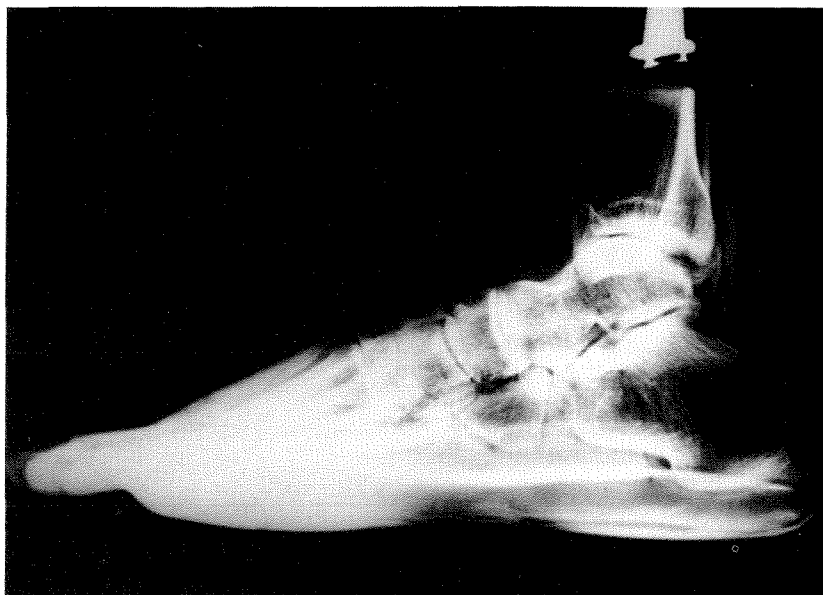


Figure 8. Radiograph of bony endoskeleton prosthesis E3 after 100,000 cycles. The bones are intact with no trabecular or cortical fractures and maintain their relationship to one another. The joint configurations are normal.

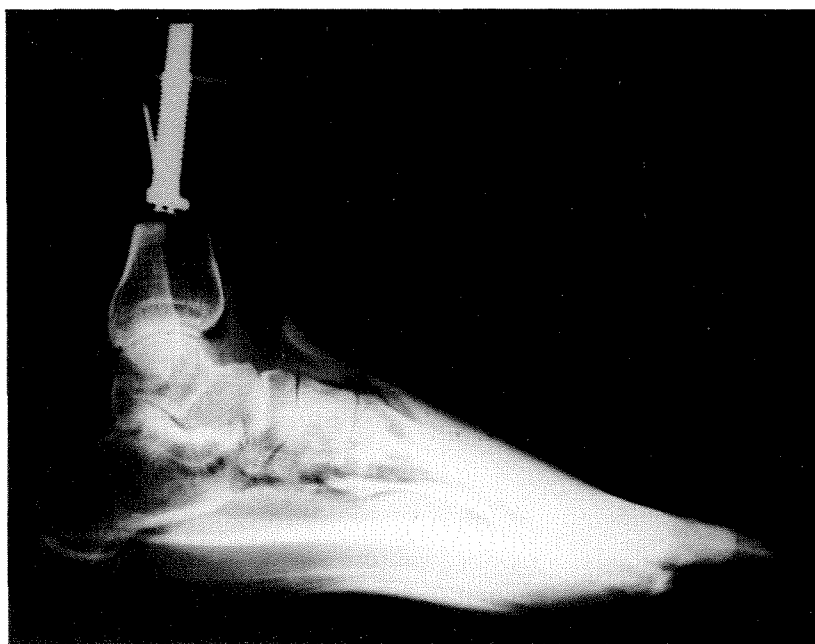


Figure 9. Radiograph of bony endoskeleton prosthesis E2 after 3 million cycles. The bones are intact with no trabecular or cortical fractures and maintain their relationship to one another. The joint configurations are normal.

Force-deflection studies before and after cyclic dorsiflexion

Results of these studies are presented in **Table 1** through **Table 4** and are described below.

1. The raw data (**Table 1**) revealed no gross change in the magnitude of dorsiflexion with incremental loading after cyclic dorsiflexion to 5,000 cycles. After 100,000 and 3 million cycles, dorsiflexion appeared to increase. How-

ever, when the average dorsiflexion was calculated per 10 kg load increase (**Table 3**), it was quite apparent that the increase was limited to the initial 10 kg and that subsequent 10 kg loads made no difference to the readings as compared to the pre-cyclic dorsiflexion figures. (Though not tabulated, the foot pieces individually showed no real increase in dorsiflexion either.)

2. No apparent or real changes in the degree of heel

Table 2.
Forced deflection (heel deflection).

Force (kg)	Deflection (mm)											
	Before cyclic dorsiflexion					After (cycles) of cyclic dorsiflexion						
	Jaipur foot		5000			100,000			3M			
	7R	7L	E1	E2	E3	E1	E2	E3	E1	E2	E3	E2
10	4.25 (2.50)	2.75 (1.42)	2	2	2	2	2	2	3	2	1	2
20	6.25 (3.30)	3.92 (1.50)	4	3	3	3	4	4	5	4	3	4
30	8.75 (3.78)	5.17 (1.69)	5	5	5	5	6	5	7	5	4	5
40	10.75 (3.59)	6.58 (1.78)	7	6	6	7	7	7	9	7	5	7
50	13.00 (4.40)	8.00 (1.91)	8	7	8	9	9	8	11	8	6	8
60	14.75 (4.03)	9.50 (2.19)	10	8	9	10	10	9	14	9	7	9
70	17.00 (4.97)	11.25 (2.01)	12	10	11	12	12	11	17	10	8	10

*Average values \pm SD (in parentheses)

7R: Jaipur foot size 7(right); total 4 feet; average weight 864+30G

7L: Jaipur foot size 7(left); total 11 feet; average weight 895+60G

E1-E3: Fresh cadaveric bone endoskeleton prostheses.

E1: Size 7(right); weight 900G

E2: Size 7(left); weight 920G

E3: Size 7(right); weight 850G

3M = 3 million, E2 foot only

deflection consequent to incremental loading were seen after cyclic dorsiflexion up to 3 million cycles (Table 2 and Table 4).

Force-deflection comparison of the endoskeleton foot and the Jaipur foot

1. The range of dorsiflexion was similar in both types of prostheses (Table 1). The range of heel deflection in the Jaipur foot was marginally greater than in the endoskeleton foot (Table 2).

2. Incremental loads applied to the forefoot caused greater dorsiflexion in the endoskeleton feet as compared to the Jaipur foot in the initial stages (Table 1). As dorsiflexion increased, the degree of dorsiflexion appeared to level off in the endoskeleton foot but not in the Jaipur foot. The only change in the endoskeleton foot was mild thinning of the sole of the rubber shell, which was first noticed after 100,000 cycles on the cyclic dorsiflexion device.

Table 3.
Average dorsiflexion per 10 kg (incremental) load.

Before cyclic dorsiflexion	Deflection (degrees)		
	After 5000 cycles	After 100,000 cycles	After 3M cycles
4.0	2.3	6.3	10.0
6.0	5.7	5.3	5.0
5.6	5.3	4.6	5.0
3.7	4.6	4.0	3.0
4.0	3.7	4.0	4.0
3.7	3.7	3.3	3.0
3.7	3.0	2.7	2.0

Average values of 3 endoskeleton feet

3M = 3 million, E2 foot only

Table 4.
Average heel deflection per 10 kg (incremental) load.

Before cyclic dorsiflexion	Deflection (mm)		
	After 5000 cycles	After 100,000 cycles	After 3M cycles
2.0	2.0	2.0	2.0
1.3	1.7	2.0	2.0
1.7	1.7	1.3	1.0
1.3	1.7	1.7	2.0
1.3	1.7	1.7	1.0
1.4	1.0	1.4	1.0
2.0	2.0	1.6	1.0

Average values of 3 endoskeleton feet
3M = 3 million, E2 foot only

DISCUSSION

Field-testing of the bony endoskeleton prosthesis for 4 weeks by an amputee was considered inadequate as a test of durability (6). Cyclic dorsiflexion of the prosthesis for 3 million cycles (corresponding to 3 years of use by an amputee) was recommended. The present study, carried out in deference to this recommendation, proves that fresh formalin-fixed cadaveric bones retain their integrity after cyclic dorsiflexion up to 3 million cycles. Radiological studies after cyclic dorsiflexion showed preservation of bone and joint morphology.

The rapid fatigue test was conducted in about 40 days whereas if the foot were in use by an amputee for an identical number of cycles, it would take 3 years. This opens the cyclic loading test to the possible criticism that it ignores time-related changes that might occur in the foot over an extended period of actual use. However, prior to fabrication, the foot was formalin-fixed and consisted of a bony ligamentous endoskeleton. It was then enclosed in a totally impervious external rubber shell so that autolysis and/or dehydration were unlikely to occur.

Force-deflection studies showed that the foot did not suffer functionally as a consequence of prolonged cyclic dorsiflexion. After cyclic dorsiflexion, there was an increase in dorsiflexion following an initial 10 kg load, but this was not sustained following progressive loading. The increase was possibly due to the lack of sensitivity of the measuring apparatus for such a small load and should not suggest deterioration of either the endoskeleton or its shell.

Thus, it is amply evident that fresh cadaveric, articulated human bones are suitable for use as an endoskeleton

in ankle-foot prostheses. Macerated, osteoporotic, osteomyelitic, or otherwise brittle or diseased bones are obviously unsuitable. Coating or impregnating normal bones with suitable plastics to augment their durability could be researched, but untreated bones appear satisfactory for most purposes. As our study shows, under simulated conditions they will have a minimum expected lifespan of 3 years.

In contrast to the Jaipur foot, the bony endoskeleton prosthesis exhibited leveling off of dorsiflexion (by fore-foot deflection) once the deforming force reached a critical level. When the distracting forces were removed, both the Jaipur foot and the bony endoskeleton foot regained their resting shape. X-rays of the bony endoskeleton prosthesis showed that the bony articulations were restored to their resting positions. The restraining forces that limit deformation in the bony endoskeleton foot include the configuration of the articulating surfaces under compressive forces (3), articular and periarticular ligaments, and the cord-reinforced rubber shell, while probably only the last is operative in the Jaipur foot. The restoring force in both prostheses is the rubber shell.

The tire cords appear to restrain as well as modulate movement in both the endoskeleton and the Jaipur foot. The strip that passes down behind and under the heel and along the sole and breaks up into five rays which pass onto the dorsum of the toes appears to be particularly important. Posteriorly, it firmly adheres to the top of the wooden ankle-block and the back of the tibia and calcaneum. In the sole, it runs horizontally forward from the calcaneum to the tips of the phalanges while separated from the concavity of the bony arch and the toe-break by the micro-cellular rubber sole. The five rays are continued across the dorsum of the phalanges, metatarsals, and tarsals, to which they are adherent. This strip corresponds to the "plantar fascial strap" of the SAFE foot (1) where it is believed to subserve the "windlass effect" of the natural plantar aponeurosis (5). However, the plantar strap of the bony endoskeleton foot with its five rays (**Figure 2**) more closely corresponds to the plantar aponeurosis (**Figure 10**) than does the "plantar fascial strap" of the SAFE foot. Extension of the toes and dorsal deflection of the forefoot would put the five rays of the plantar strap under tension. Because the nylon or rayon tire cords are nonyielding, tension on the ends of the plantar arch may tend to accentuate and stabilize the arch.

Unlike any other prosthesis currently available, the endoskeleton prosthesis provides all the joints of the ankle and foot and, because these are naturally located joints, they allow for natural movement. As in the living foot, these joints and their ligaments limit excessive movement, coor-

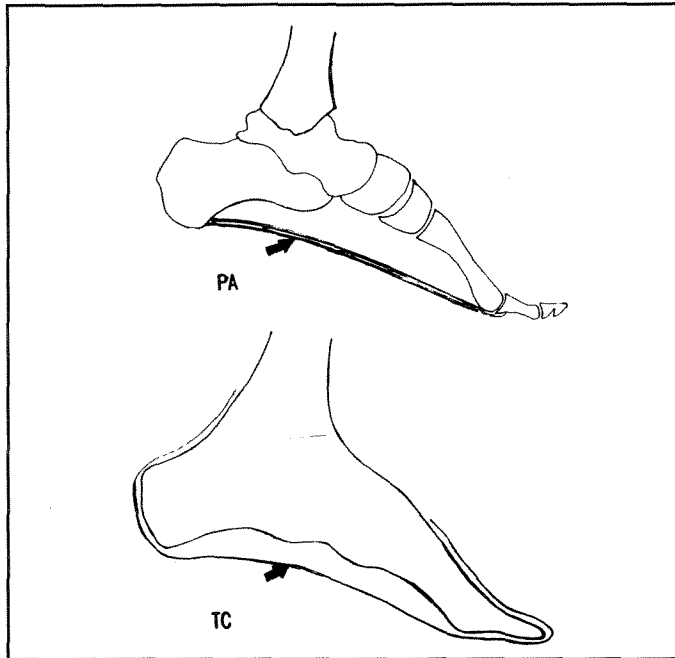


Figure 10.

The rubberized tire cord (TC) plantar strap of the bony endoskeleton foot simulates the "tie beam" and "windlass" action of the plantar aponeurosis (PA) of the living foot during dorsiflexion.

dinate multiarticular movement, and stabilize the foot during deformation. Such modulation is evidenced by the leveling off of deformation on sequential loading. X-rays taken in different stages of deflection *vis-a-vis* dorsiflexion, plantar flexion, inversion, eversion, and axial rotation suggest that the various joints contribute to achieve an integrated movement. (These studies will be reported separately.)

The configuration and arched arrangement of the intertarsal joints, and the "tie beam" and "windlass" actions of the plantar tire cord strap in the bony endoskeleton prosthesis allow for flexibility in the early stance phase, but confer it with rigidity in the late stance phase. The heel of the prosthesis is comprised essentially of the natural calcaneum which, when loaded, deflects backward and upward with simultaneous plantar flexion of the forefoot as in the living foot on heelstrike. In the late stance phase, when the forefoot is loaded, the tie-beam and windlass action of the plantar tire cord strap of the bony endoskeleton foot convert the arched skeleton into a rigid lever, thereby facilitating movements of dorsiflexion and axial rotation through the ankle and subtalar joints respectively.

In contrast, the Jaipur foot (7), SAFE foot (1), and STEN foot (8) have a compressible endoskeleton whose flexibility provides for simulated movements only. The single axis, Greissinger, and Flex-Foot provide true plantar flexion (2,8) but, like most prosthetic feet other than the Jaipur foot, are expensive. At our workshop, the endoskele-

ton foot costs \$6 inclusive of labor. According to a recent price list (Durr Fillauer Medical, Inc., Chattanooga, TN, 1989), currently available prosthetic feet vary in cost from \$40 for a SACH foot to \$200 for a Carbon II foot. The Greissinger Multi-axis foot costs \$91. Thus, the endoskeleton foot, although as, if not more, versatile than the Greissinger foot, is 15 times less expensive.

Apart from its prosthetic utility and low cost, we believe the bony endoskeleton foot would serve as an ideal experimental model for the study of complex, integrated joint movements under natural loading conditions. It is more natural in construction and we have found it easier to fabricate and operate than some other existing models, such as those used by Inman (5).

A minor problem is a shortage of cadaveric feet. This can be overcome by using surgically amputated limbs. Indeed, such limbs may be used for the very individuals from whom they were removed. This may have salutary psychological implications for the person, since a part of the anatomy hitherto considered irretrievable is being used in his or her rehabilitation. Since the leading indication for amputation today is peripheral ischemia, such amputated limbs will, in many cases, be suitable for fabrication. Use of the patient's own amputated limb is devoid of the ethical questions that surround the use of cadaveric feet. Freshly amputated limbs may be placed in 10 percent formalin for pathological studies and thereafter be used for fabrication. We are currently evaluating three prostheses fabricated in this way, and expect they will behave like cadaveric endoskeleton feet.

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