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**Colophon**

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1. BACKGROUND

1.1 INTRODUCTION

As with the hip and knee, the ankle joint may be disabled by inflammatory arthritis, degenerative arthritis or post-traumatic arthritis. Ankle arthritis may become so severe that it can lead to significant functional disturbances and to a disturbed gait. End-stage ankle arthritis can lead to ankle deformities and also to additional stress on the knee and hip joint, which in turn could cause damage in these joints (1,2).

1.2 FUSION OR ARTHROPLASTY?

Until recently, fusion has been the primary mode of treatment for most of the disabling conditions of the ankle joint (3,4,5). The influence of a fused ankle on the adjacent joints should, however, not be underestimated (6,7). Fixed-bearing implants have shown disappointing results and are known to have a high rate of early failures (8,9,10,11). This elevated failure rate is caused by both the high stresses across the ankle joint and a lack of adequate unconstrained ankle motion, each jeopardizing implant fixation and resulting in polyethylene wear and early component loosening (72).

Buechel and Pappas developed in 1981 the LCS mobile bearing ankle prosthesis to counter the problems with fixed bearing total ankle replacement. In 1989 they modified this design into the B-P mobile bearing total ankle prosthesis. The clinical experience with the latter design showed good to excellent results (13,14).

1.3 MOBILE-BEARING DESIGN

A mobile-bearing design is probably the key factor for successful ankle replacement. During normal gait, stresses on the ankle are high with tibio-talar forces estimated to be 4-7 times body weight (14,15). Axial rotation varies from 5° internal rotation to 3° of external rotation (16). A replaced ankle should allow dorsiflexion (13°-17°) and plantarflexion (6°-16°) for unrestricted level of walking. In ankle designs that do not allow unrestricted motions, the intrinsic constraints cause the load forces to be transmitted to the implant-bone interface and implant loosening and/or bone fracture will most likely occur.

1.4 POLYETHYLENE WEAR

Polyethylene wear has been identified as a major cause of failure of total joint arthroplasties in the hip and knee. The compressive forces on the ankle joint are similar to those of the knee joint and the amount of abrasive wear in fixed-bearing ankles is identical to that of fixed-bearing knees (77).

The polyethylene wear in mobile-bearing implants, knees and ankle alike, is reduced significantly by the full congruency between the articulating surfaces. Mobile-bearing ankle implants have shown to be successful due to their ability to maintain low contact stresses while providing a complex ankle motion (13,14,16,17). Congruency of the articulating surfaces provide reduced contact stresses, which diminishes the strain on the implant-bone interface and reduces the amount of abrasive and fatigue wear of the polyethylene.
The CCI Evolution total ankle replacement is a three-component mobile-bearing design.

2.1 TIBIAL COMPONENT

Trapezoidal design: although the ankle joint has three sets of articular surfaces, the tibio-talar joint bears the majority of the body weight and the forces on the ankle. The shape of the human tibial surface is a trapezoid with an anterior-posterior ratio (B:A) of 1.4 to 1. The CCI Evolution prosthesis has the same AP-ratio in the Tibial Component.

Fixation fin: the fixation fin requires a small slot and does not require a window in the tibia to accommodate a stem (as seen in other contemporary designs). This allows for minimal bone resection.

2.2 TALAR COMPONENT

Triple V-design: three V-shaped surfaces build the implant-bone interface of the talar component. This allows for instrument-guided cutting of the bone and, more importantly, provides optimal rotational stability combined with minimal bone resection. The two pins for fixation reduces the risk of talar fracture and will help to easily seat and stabilize the implant at impaction.

Deep sulcus: the mobile-bearing concept allows for ligament-guided motion. The design of the talar component includes a deep sulcus, conforming the distal articulating surface of the polyethylene bearing, providing medial-lateral stability. A deep sulcus also allows for a thicker polyethylene in the central part of the bearing. The fixation pegs are placed at the side of the sulcus, so as not to endanger the vascularisation of the talus.

2.3 POLYETHYLENE

The bearing is designed for optimal congruency with the talar component, so as to minimize contact stresses and maximize stability. There are 5 heights of bearings available. The strict congruency between the talar component and the bearing also means that these two components must always be of a corresponding size. Upsizing of the tibial component by 1 size is preferable. The polyethylene bearing is ethylene oxide sterilised to avoid the degradation resulting from gamma radiation.

2.4 CEMENTLESS APPLICATION

The CCI Evolution has a Titanium Plasma Spray surface structure at the implant-bone interface. The Bonit® calcium phosphate coating on top of this Titanium Plasma Spray surface provides an optimal environment for osseointegration, allowing for a reliable cementless fixation.

2.5 TITANIUM NITRIDE COATING

The articulating surface of the CCI Evolution is coated with a Titanium Nitride (TiN) coating. TiN is a technical ceramic, and forms a secure ionic bond with the CoCrMo metal of the CCI Evolution tibial and talar components. The ultra-hard TiN layer forms a supremely smooth surface and covers any protruding metal block carbides, thus preventing scratching of the opposite polyethylene articulating surfaces. The TiN ceramic enhances the wear characteristics and reduces metal ion release from implant components in the event of metal hypersensitivity.

2.6 MINIMAL BONE RESECTION

The CCI Evolution has specifically been designed to minimise bone resection. This is reflected by a number of characteristics of the components:

- The tibial component basically requires only a 2.8mm resection of the distal tibia.
- The fixation of the tibia component is achieved with one central fin. No stems or cylinders are needed.
- The talar component, with its triple V design, will smoothly follow the anatomical shape of the talus, necessitating as little resection as possible.
3. CCI EVOLUTION: OVERVIEW OF COMPONENTS

The size of the polyethylene bearing to be used is determined by the size of the talar component. For each polyethylene bearing the same size tibial component can be used or, preferably, one size bigger as shown here schematically. The CCI Evolution Ankle Prosthesis is designed for cementless implantation only.

TIBIAL COMPONENTS:
- STANDARD
- STANDARD PLUS
- LARGE
- LARGE PLUS

BEARINGS:
- STANDARD
  - Heights: 4, 5, 6, 8, 10 mm
- STANDARD PLUS
  - Heights: 4, 5, 6, 8, 10 mm
- LARGE
  - Heights: 4, 5, 6, 8, 10 mm

TALAR COMPONENTS:
- STANDARD
- STANDARD PLUS
- LARGE
4. INDICATIONS AND CONTRA-INDICATIONS

The etiology of ankle arthritis differs from arthritis of the hip and knee as there is a low rate of degenerative arthritis and a predominance of posttraumatic arthritis and inflammatory joint disease. Posttraumatic arthritis can develop secondary to intra-articular ankle fractures, to lower leg fractures or to ligament injury. End-stage ankle arthritis occurs usually at a younger age and is known to have an important negative influence on quality of life and on the ability of patients to perform their occupational and recreational activities. If conservative treatment fails surgical reconstruction usually becomes necessary. Then the choice has to be made between ankle fusion and total ankle arthroplasty (TAA). Although ankle fusion usually gives a satisfactory clinical result, gait will remain somewhat disturbed and it is also known that with longer follow-up there is an increased risk of secondary hindfoot arthritis. Over the last years good medium to long term results with third-generation mobile-bearing implants have been reported. Therefore, the interest in TAA has grown considerably. This is reflected by the increasing number of total ankle replacements performed by an increasing number of surgeons and also by an increase in scientific publications on total ankle replacement. Until today, the choice between ankle fusion and TAA is not only made on clear clinical arguments, but also frequently depend on the experience and the preference of the surgeon and, to some extent, on the preference of the patient. This is mainly due to the fact that some uncertainty remains about the long term outcome of TAA. This study showed that patients treated by mobile-bearing TAA had a somewhat better function and equivalent pain relief compared to a control group of patients treated by ankle fusion. Haddad et al. found, in a systematic review of the literature, similar clinical results and revision rates between the two procedures at 5 to 10 years. Their strong clinical argument in favor of TAA was the lower below-knee amputation rate: 1 per cent for TAA versus 5 per cent for ankle fusion. This lower amputation rate after TAA compared to the amputation rate after ankle fusion has also been reported by Saltzman et al. and SooHoo et al.

Since the pathology of the arthritic ankle may differ substantially between individual cases and between different etiologic entities, TAA can usually not be considered an out-of-the-box procedure like endoprosthetic replacement of the hip or the knee. The ideal indication for TAA is end-stage arthritis with no or limited deformity, with a normal foot, good bone stock and a good range of motion. This situation occurs most frequently in postfracture ankles and in primary degenerative arthritis. Bilateral ankle arthritis and inflammatory joint disease can also be regarded good indications for TAA. Deformity, stiff ankles and younger age are among the controversial indications, although in experienced hands good results can be expected. The most important contraindications for TAA are high-demand and noncompliant patients, perarticular bone loss, severe deformity, active or latent infection, vascular disease (e.g. heavy smokers, long-standing diabetes), and neurological impairments.

5. PRE-OPERATIVE PLANNING

5.1 ROUTINE

The following weight bearing views should be made: AP Ankle, Lateral Ankle + whole Foot, and a DP Foot. Check for any deformity in the frontal or sagittal plane.

In the event of bone loss or (suspected) cystic changes, a Computer Tomography Scan + Reconstruction should be made.

5.2 ON INDICATION

MRI
- Soft tissue lesions
- History of infection
6. KEY ISSUES OF SURGICAL PROCEDURE

Goal is to achieve a stable and well-aligned ankle and hind foot.

Maximal coverage of distal tibia
- Wide AP resection, so start medially

Correction of deformity in frontal + sagittal plane
- Talocrural varus: medial release or medial malleolar sliding osteotomy
- Hindfoot deformity: fusion or osteotomy
- No tibiotalar anterior subluxation, 0° (max. 5°) anterior slope of tibial component

No PE edge-loading
- Preferably oversized tibial component
- Non-oversized talar component

No prosthetic impingement + talomalleolar symptoms
- Debridement of talomalleolar joints
- Non-oversized talar component

Dorsiflexion ≤ 5°-10°
- Achilles tendon lengthening

7. REQUIRED INSTRUMENTS

- CCI Evolution Set of Instruments Version 2.0 (please see the full overview of the instruments in section 12, on page 19)
- Reciprocating saw (Tukey saw recommended)
- Oscillating saw with tapered saw blade: saw blades should have a thickness of 0.9mm, a width of 15mm, and a length of 70mm
- Drill 2.5 mm for drilling the talar spike hole
- Drill 3.5 mm for pre-drilling the tibial slot, an additional 4.5 mm drill may be used in the event of sclerotic bone
- V-shaped chisel
- Laminar spreader
- Osteotomes
- Discectomy Luer
8. SURGICAL TECHNIQUE

As recommended by Dr H.C. Doets MD PhD, Amsterdam the Netherlands

Please note that the reference numbers (A1 until A17) refer to the appropriate instruments, which are displayed on each page as well as in the instrument overview in section 12, page 19 (CCI Evolution Set of Instruments 2.0)

8.1 PREPARATION AND OPENING

Assuming adequate mobility of the other joints in both lower limbs the patient is positioned supine on the operating table. The patient’s leg is placed in a leg holder (Fig. 1) allowing the knee to be flexed and to rotate the lower leg to a neutral position. Standard skin preparation is performed. A surgical glove is used as an additional barrier in order to prevent any bacterial or fungal infection originating from the foot. The glove is included in the transparent adhesive surgical drape.

The procedure is started with the tourniquet deflated. The tourniquet should be inflated when bleeding prevents a good view of the ankle during surgery (generally, after arthrotomy). For promotion of wound healing, maximum tourniquet time should be set to 75-90 minutes. A straight anterior midline incision is used (Fig. 2). Branches of the superficial peroneal nerve (Fig. 3, see arrow) should be identified and, if necessary, mobilised laterally.

After incision of the extensor retinaculum, the interval between the anterior tibial and the extensor hallucis tendons (Fig. 4) is used to reach the anterior capsule.
8. SURGICAL TECHNIQUE (CONTINUED)

8.2 TIBIAL RESECTION

Determine the level of tibial pathology. Remove anterior osteophytes.

Prior to the horizontal distal tibia resection, a small vertical cut in the medial corner (just medial from the talus) should be made. This will protect the medial malleolus during the distal tibial resection and marks the medial limit of the distal tibia resection.

Use a reciprocating saw to make this vertical cut (Fig. 5). As an alternative, it is possible to drill a pilot hole first, and then make the vertical cut with a reciprocating saw. The cut should be made towards the drilled pilot hole. In this case, it is necessary to place the Modular Resection Guide (A1) first, in order to use the drill hole (on the medial side) of the Tibial Resection Block (A2).

The Modular Resection Guide, combined with the Tibial Resection Block is placed in line with the anatomical axis of the tibia. The tibial tuberosity should be used as a reference point for the proximal part of the Tibial Resection Guide. Use the Tibial Resection Stylus (A3), fixed on the Tibial Resection Block, to determine the height of the resection (Fig. 6). The Resection Guide is fixed to the tibia using 1 pin distally and a spring proximally.
8.2 Tibial Resection (Continued)

Use the Tibial Resection Block (A2) on the Modular Resection Guide (A1) to resect the distal tibia (Fig. 7), aiming for a 0 degree slope. Attention should be paid not to undercut the medial or lateral malleolus in order to prevent fracture. First mark the level of the distal tibial resection with the oscillating saw, temporarily remove the Tibial Resection Block, and, in the event of a too minimal resection, reposition the Modular Resection Guide one level (2 mm) higher. After a complete horizontal osteotomy of the distal tibial articulating surface, remove the Tibial Resection Block with the Resection Block Handle / Joystick (A4) and extract the distal tibial fragment. Usually it is necessary to perform a piecemeal removal. In order to do so, split the fragment, remove the anterior part first, and use a small rongeur or discectomy luer for removal of the dorsal fragments. Use of the laminar spreader is very helpful for distraction of the joint space and for a better view on the dorsal compartment. However, a complete removal of the posterior fragments of the distal tibia can best be done when the superior V resection of the talus has been carried out (see 8.3). After resection of the distal tibia (Fig. 8), sizing of the distal tibia is done (Fig. 9) with use of the Tibial Templates (A5), both in the medial-lateral and in the anteroposterior direction. These Templates should also be used to check whether the distal tibial surface does not have any irregularities.
8. SURGICAL TECHNIQUE (CONTINUED)

8.3 TALAR PREPARATION

After tibial resection, the V-shaped resection of the talus is prepared. When the ankle joint has a good alignment without signs of a varus or valgus deformity, the upper part of the V-shaped resection can be carried out through the Talar Resection Block (A6), which should be connected on the Modular Resection Guide (Fig. 10). The foot should preferably be held in 10-degree plantarflexion to create a posterior slope of the upper V resection.

In the event of a varus or valgus deformity the use of the Free-Hand Talar Resection Guide (A7) may be an alternative to perform the upper part of the V-shaped resection. Before using the Free-Hand Talar Resection Guide; remove any anterior and posterior osteophytes, especially in the central aspects. However, in the event of a coronal plane deformity, it is better to do a thorough debridement of the medial and lateral gutters first, then reposition the talus into a neutral position in the ankle mortise and continue with the superior V resection of the talus with use of the Talar Resection Block (A6). It is recommended to mark the level of the talar resection with the oscillating saw, then remove the Talar Resection Block with the Resection Block Handle (A4) to check the correct level and orientation of the resection, then reposition the Talar Resection Block and finish the superior V resection with use of a reciprocating saw or a small saw blade on an oscillating saw.

The V-shaped resection can be refined with the V-Shaped Chisel (A8). After the superior V-shaped resection has been done, place the Talar Posterior Resection Guide (A9) in the newly made V-shaped groove, fixing the hooks behind the talus. Use the V-Shaped Chisel to perform the posterior V-shaped resection (Fig. 11 & 12), guided by the Talar Posterior Resection Guide while holding the foot in maximal plantarflexion (about 40°). Next, perform the anterior V-shaped resection with the V-shaped Chisel (Fig. 13) holding the foot again in maximal plantarflexion (about 40°).
Prepare the talus in such a way that the Talar Drill Guide (A10) has optimal bony contact (Fig. 14). The appropriate size of the talar component can be determined with the use of the Talar Drill Guide. There should be no overhang of the Talar Drill Guide medially and laterally over the borders of the talus in order to prevent impingement of the talar component or the bearing with the malleoli. With the correct size Talar Drill Guide in place, the two spike holes are drilled with a 2.5 mm drill (Fig. 15). After drilling of the first hole, a drill can be left in place to keep the Drill Guide in position. The Talar Drill Guide should furthermore be kept in position with use of the laminar spreader.

Talar preparation and implant stability is then checked with the Talar Trials (A11). Use the Talar Impactor (A12) to seat the Talar Trial. Correct orientation of the Talar Trial is achieved when the handle of the Talar Trial is in line with the 2nd metatarsal and has a 10° posterior slope with the plantar side of the foot. The Talar Trial (Fig. 16) should remain in place for a correct orientation of the tibial slot preparation (Talus First Philosophy).
8. SURGICAL TECHNIQUE (CONTINUED)

8.4 SIZING AND SLOT PREPARATION FOR THE TibIAL COMPONENT

The correct size of the tibial component should be determined with use of the Tibial Templates (A5). Preferably, the tibial component is one size bigger than the talar component. With the correct Tibial Template in place, the center of the distal tibia is marked on the anterior cortex (Fig. 17). The Tibial Drill Guide (A13) is then placed on the anterior tibia (Fig. 18). Keep the handle of the Tibial Drill Guide over the handle of the Talar Trial (A11) for a proper orientation of the rotation of the Tibial Trial Component. Predrill the tibial slot with a 3.5 mm drill with use of the Tibial Drill Guide. In the event of sclerotic bone in the distal tibia a 4.5 mm drill can be used for an easier preparation of the tibial slot. The drill holes are interconnected with use of the drill, the reciprocating saw (Fig. 19), a burr or a sharp curette. The final preparation of the slot for the fixation fin is made by using the Tibial Slot Chisel (A14). The flat part of the Tibial Slot Chisel should be in line with the anterior cortex of the distal tibia (Fig. 20). Extra check with the tibial templates; conduct an optical check through the newly made slot if the template (A5) has optimal coverage with the distal tibia.
8.5 TRIAL IMPLANTS

With the Talar Trial in place, insert the Tibial Trial (A15) into position (Fig. 21). Final seating of the Tibial Trial against the distal tibia can be done with use of the laminar spreader. Then insert the appropriate Trial Bearing (A16) between the Talar and Tibial Trials to determine the correct ligament tension and alignment of the ankle-hindfoot complex (Fig. 22). Unrestricted motion is checked with the Trial Bearing in place. Maximum bearing thickness is recommended for an adequate ligament tension and for distraction of the medial and lateral talar-malleolar joints.

Final checks to be done with the Trial Components:

- Coronal Plane: Neutral Alignment of the ankle + central orientation of the Tibial Trial over the Talar Trial (Talus First Philosophy)
- Sagittal Plane: Tibial Component in 0°-5° Anterior Slope; Talar Component in 10° (5°-15°) Posterior Slope
- Minimum 10° dorsiflexion of the ankle. If this is not possible, then either a gastrocnemius recession or a percutaneous achilles tendon lengthening should be performed.
- No Talar Component Overhang (no overstuffing of the ankle and no risk of bearing impingement)
- Full Debridement of the posterior compartment and the medial and lateral Talar-Malleolar joints. It may be helpful to check if the posterior part of the tibial component is fully seated against the distal part of the tibia with use of fluoroscopy (mobile C-arm) after all trial components have been put into place.
8.6 IMPLANTING THE TALAR AND TIBIAL COMPONENTS

First the talar component is implanted using the Talar Impactor (A12). The angle under which the two fixation pins are placed will facilitate the correct insertion. The component is forced downwards while impacting it (Fig. 23). Next, place the tibial component into position (Fig. 24) with the Tibial Component Impactor (A17).
8.7 TRIAL BEARING CHECK

Place the thickest Trial Bearing (A16) possible between the tibial and talar component for a final check and to obtain a full seating of the tibial component (Fig. 25). The Trial Bearing can be used as a lever to fully seat the tibial component against the distal tibia.

Check with an anterior drawer test that no anterior subluxation exists.

8.8. IMPLANTING THE POLYETHYLENE BEARING

Insert the appropriate polyethylene bearing between the talar and the tibial component by distracting the ankle joint (Fig. 26).

It may be helpful to check the position of the components, especially whether the posterior part of the tibial component is fully seated against the distal part of the tibia, using fluoroscopy (mobile C-arm) after definite implantation of all components.

8.9 BALANCING / CORRECTION OF DEFORMITY

Articular Varus: correction should be performed at the level of the ankle joint by a thorough debridement of the medial talar-malleolar joint, if necessary a release of the deep part of the medial ligament. When a bearing subluxation still exists a lengthening osteotomy of the medial malleolus is recommended, if necessary followed by an additional corrective osteotomy of the hindfoot. This medial malleolar osteotomy should be performed after implantation of the talar and tibial components, and just prior to the insertion of the polyethylene bearing.

Valgus: a fixed valgus deformity at the level of the ankle joint is infrequent and can usually be corrected by a thorough debridement of the talar-malleolar joints. A valgus deformity of the hindfoot should be corrected after implantation of the ankle prosthesis.

Equinus: an equinus deformity should be corrected by an achilles tendon lengthening procedure. A percutaneous tendon lengthening is preferred. If indicated, a gastrocnemius recession should be done as an alternative to achilles tendon lengthening.

8.10 WOUND CLOSURE AND IMMEDIATE POSTOPERATIVE REGIME

The wound is irrigated and a wound drain inserted. Routine wound closure is done with careful suturing of the extensor retinaculum with #1 resorbable sutures, then the skin with 3-0 nonresorbable sutures.

8.11 CAST

Applying a polstered below-knee cast with the ankle in maximum dorsiflexion finishes the procedure.
9. RECOMMENDED AFTERTREATMENT

With normal bone-stock and good primary stability of the implant weight bearing to tolerance can be allowed for.

Immobilization in a below-knee walking cast is recommended for a period of 3-6 weeks, depending on the quality of the bone-stock and the patient’s pathology. Generally, it is recommended to have:

- 3-4 weeks of (walking) cast with patients with a diagnosis of posttraumatic arthritis
- 6 weeks of (walking) cast with patients with a diagnosis of rheumatoid and instability arthritis

10. SUMMARY

FINAL REMARKS:

- Preoperative workup is important for a good end result
- Patient selection
- Accurate assessment of osseous and soft-tissue pathology
- A delicate surgical technique is mandatory with attention for detail
- Adequate distal tibial resection
- Talar preparation
- Orientation of tibial component in alignment with talar trial
- Correction of any deformity in frontal + sagittal plane
## 11. PRODUCT CODES AND INSTRUMENT CODES

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12. CCI EVOLUTION SET OF INSTRUMENTS 2.0

A1
Modular Resection Guide
ref. no 0020-3010

A2
A2 Tibial Resection Block
ref. no 0020-3009
A3 Tibia Resection Stylus
ref. no 0020-3800

A3
Modular Resection Block Handle
ref. no 0020-3013

A4

A5
Tibial Templates
ref. no 0020-4111
ref. no 0020-4113

A6
Talar Resection Block
ref. no 0020-3008

A7
Free-Hand Talar Resection Guide
ref. no 0020-3012

A8
V-shaped chisel
ref. no 0020-3007

A9
Talar Posterior Resection Guide
ref. no 0020-3300

A10
Talar Drill Guides 2.5 mm
STD: ref. no 0020-3401
STD+: ref. no 0020-3402
LG: ref. no 0020-3403

A11
Talar Trials
STD: ref. no 0020-3001
STD+: ref. no 0020-3002
LG: ref. no 0020-3003

A12
Talar Impactor
ref. no 0020-4121

A13
Tibial Drill Guide 3.5 mm
ref. no 0020-3011

A14
Tibial Slot Chisel
ref. no 0020-3000

A15
Tibial Trials
STD: ref. no 0020-3111
STD+: ref. no 0020-3112
LG: ref. no 0020-3113
LG+: ref. no 0020-3114

A16
Trial Bearing
STD: ref. no 0020-3104/3110
STD+: ref. no 0020-3204/3210
LG: ref. no 0020-3304/3310

A17
Tibial Component Impactor
ref. no 0020-4123
REFERENCES

15. Kaptein BL, Valstar ER, Garling EH. Accuracy of Model-based RSA of the CCI Ankle Proposal for a phantom study under simulated in vivo conditions (on file).