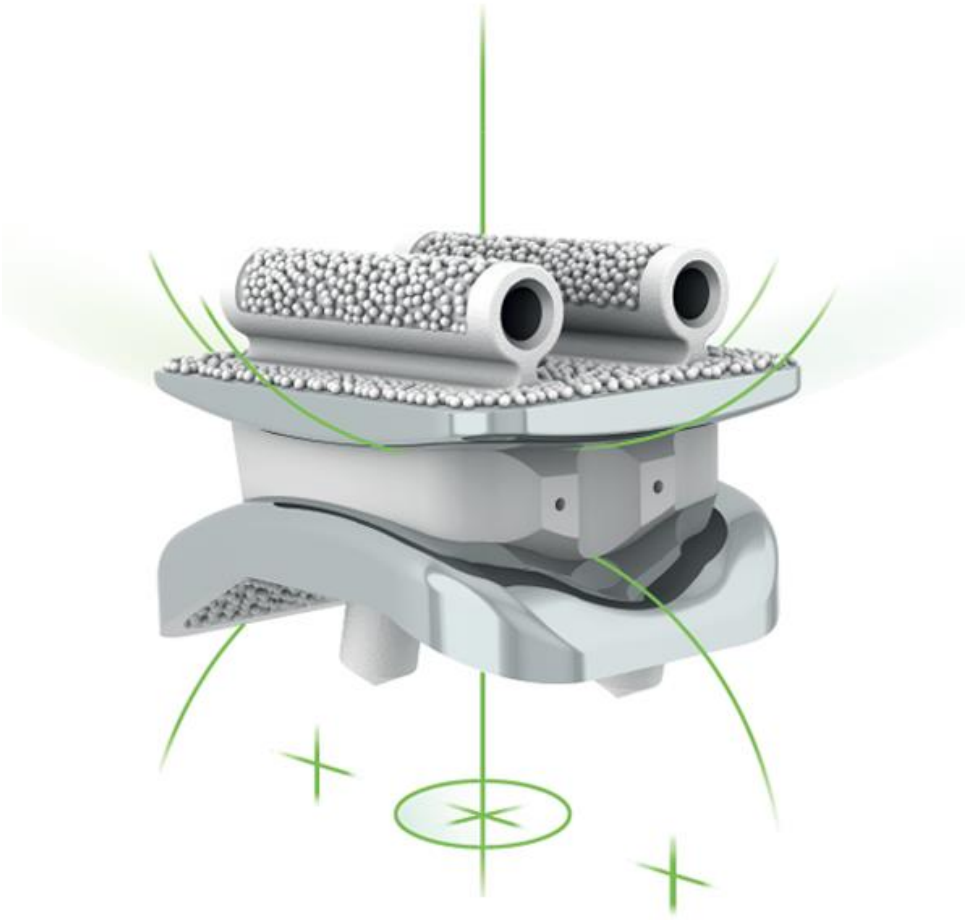
MatOrtho®



BOX®
Total Ankle Replacement

Clinical Data Summary

Balanced Natural Movement

Forever Active

Contents

1 Summary overview of clinical data

Treatments for end-stage ankle arthritis

Patients with end-stage arthritis can be treated with arthrodesis or total ankle replacement (TAR). Although arthrodesis is the more common treatment, it has some disadvantages. Despite being so well established, painful complications are common. Non-unions are observed in about 10% of cases, most requiring further surgery. Five percent require below knee amputation, primarily due to non-union[1]. Of those that do fuse, loss of ideal position (during or after surgery), malunion or delayed union is common[2]. When arthrodesis is successful there are still some disadvantages, including loss of motion and permanent disturbance of normal gait. Loss of mobility at the tibiotalar joint affects the kinematics of neighbouring joints and for most patients this results in advancing arthritis, including in the subtalar and midfoot joint[3,4,5].

TAR is intended to achieve pain relief with preservation or improvement in joint motion, thereby maintaining normal gait and function and avoiding accelerated arthritis in the adjacent joints.

While some 2nd and 3rd generation TAR designs do show improvements in function and ROM[6,7], their merits do not consistently exceed those of arthrodesis[8]. A limitation of all such devices is the extent to which they accommodate normal degrees of freedom: two-part designs impose a fixed sagittal axis; three-part designs reproduce the shape of the talar dome but with a flat tibial articulation intended to allow a rolling and sliding motion with internal-external (IE) rotation. As such, relief for the neighbouring joints is partial; the instantaneous centre of rotation of the natural joint translates AP and changes inclination during flexion and normal activities. **Without accommodating coupled rotations in all three anatomical axes, including inversion and eversion, TAR devices are unlikely to restore a physiologically compatible characteristic movement of the tibio-talar joint[9,10,11].**

Principles of the BOX® Ankle design

Physiological movement

The BOX® Total Ankle Replacement is different to all other designs currently available. It was designed specifically to allow a more natural tibiotalar freedom of movement for a more normal gait[12]. Guided by the ligaments, physiological AP translation and changing inclination of the instantaneous centre of rotation is enabled[9,10,12]. By accommodating the natural function of the ligaments in controlling passive mobility, their role in joint stability is also restored[13]. Translation of the flexion axis also modifies the effective lever arm during flexion, optimising the mechanical advantage of the muscle forces during level walking[14].

Long-term function

A high revision rate in early TAR designs was largely due to failure of fixation[15]. Although survivorships have markedly improved with up to 89% at 10 years, loosening and/or subsidence remains the most common reason for revision[1]. A number of factors can contribute to this, including increased stresses at the implant-bone interface associated with limited freedom of movement[11]. The BOX® Ankle is designed to address this by allowing for all physiological degrees of freedom[11].

By allowing the right freedom of movement, the biconcave bearing of the BOX® Ankle maintains full conformity throughout the ROM and in all functional positions[16,17]. This infers very low contact stresses and low wear rates[16,17], minimising early loosening due to lysis. Full conformity also means that a thick polyethylene component is not required[12] and with the unique tensioning instrument supplied with the BOX® Ankle, the overall construct remains low profile. Resections are limited to those necessary to resurface the articular regions and retain optimum quality bone for fixation. The tensioning instrument also provides restoration of the joint space and separation of the malleoli from the talus.

The BOX® Ankle features the most theoretically attractive cementless bone ingrowth interface[11] with a clinically proven[18] combination of beads and hydroxyapatite (HA). This low-profile primary resurfacing design requires no gross bone removal or routine grafting.

Implant-bone micromotion and peri-implant bone strains of the tibial and talar components when optimally positioned and when malpositioned has been studied for TAR designs including the BOX® Ankle. Such work has found that micromotion was lowest for the BOX® Ankle and that the BOX® Ankle is less affected by malpositioning when compared to the alternative designs[28].

Clinical use of the BOX® Ankle

The BOX® Ankle has been in clinical use since 2003[24] and over 2,100 BOX® Ankles have been implanted worldwide

The annual report of the National Joint Registry (NJR) reports a continued steady increase in use of the BOX® Ankle. The BOX® Ankle accounted for 22% of all TARs implanted in the UK in 2015[26]. The BOX Ankle is the second most used TAR device in the UK making up 18% of all TAR procedures in the last reporting year[26].

ROM and gait outcomes

With the BOX® Ankle's unique bearing design, clinical studies have consistently observed significant increases in ROM of the tibiotalar joint[19,20,21,22], contributing to increased ROM of the foot-ankle complex[21,22,23,24,25].

X-ray, fluoroscopy and gait studies with BOX Ankle patients have shown that nearly normal function is restored, with large coupled motions in three anatomical planes during active flexion[21], stair climbing and descending[21,22] and walking[19]. Corresponding AP translations of the meniscus[20,22,24] actively demonstrate the adoption of a physiological non-fixed axis of rotation. As a result, significant improvement has been observed in all spatial-temporal parameters during gait with reduced compensation at toe-off indicating good restoration of function and improved strength of the plantarflexor muscles[19].

Functional outcomes

In all reports of the BOX® Ankle, AOFAS scores improved significantly, ranging from an increase of 31.8[22] and 36.7[20] at 1 year to over 42 points 2-4 years post operatively[21,24,25]. This includes an independent single surgeon study reporting on the surgeon's earliest experience with the new device, which also found a high rate of patient satisfaction[25].

Survivorship

Summary NJR data provided to MatOrtho® as the manufacturer of the BOX® Ankle includes 606 procedures (588 patients) with a maximum implantation time of 7.8 years (mean 2.8 years)[27]. There is no statistical significance in the total number revised for BOX® Ankle (31 revisions, 5.1%) against the expected number according to all other TAR in the NJR.

However there are differences in the type of revision:

For all other TAR in the NJR, 69.4% of revisions include revision of both tibial and talar components i.e. complete removal of the device[27]. For the BOX® Ankle only 22.6% of revisions include complete removal of the implant[27]. In other words, when considering failure as complete removal of the implant, the BOX® Ankle is reported with a total of 1.16% failed ankles.

The expected number of revisions recorded specifically for aseptic loosening of the tibial or talar component of the BOX® Ankle is fewer than half the expected number based on all other TAR in the NJR ($p = 0.85$)[27]. Further to removal of both components , exchange of one metal component (tibial or talar) accounts for 12.9% of revisions (0.7% of primary BOX® Ankles) which compares well to the reported 14.8% of revisions for all other TARs in the NJR[27]. Overall this clinical data shows that fixation of the BOX® Ankle is successful, in support of the independent study of TAR fixation characteristics[28].

When considering the polyethylene component alone, 64.5% of BOX® Ankle revisions are for a bearing exchange only (3.3% of all ankles), compared to 13.7% for all other TAR in the NJR[27]. Various reasons for revision are recorded for these cases so no specific issue is identified. However, this demonstrates that surgical management of ankles can be carried out when required with insertion of a new bearing and retention of the well-fixed metal components, and patients can continue to benefit from their functioning primary implant.

Data published by the National Joint Registries tends to indicate higher revision rates for TARs than the literature[6]. However, registry data for the BOX® Ankle[26] is consistent with published results from a multicentre study of 158 ankles in 9 operating centres, which reported a survivorship of 96.1% at 4 years[24]. A single surgeon's early experience study did report a slightly higher revision rate[25]; however, successful arthrodesis was achieved in the 4 cases where the implant was removed. None of the studies found progressive radiolucencies[24,25].

Summary

The BOX® Ankle has been in clinical use since 2003 and is demonstrated to achieve good survivorship[24, 27] and improvements in functional scores, patient satisfaction, ROM and gait[19,20,21,22,23,24,25].

By enabling physiological coupled rotations in all degrees of freedom, neighbouring joints are relieved from degenerative effects associated with loss of mobility, setting the BOX® Ankle apart from other TARs.

The BOX® Ankle is demonstrated to have markedly fewer revisions than other TARs with endpoint being removal of Tibial and Talar components[27].

Combining all key principles for long-term stable fixation with full congruency throughout ROM for stability and low wear[12,24,16,17,11], the BOX® Ankle sets a new benchmark for the success of TAR.

2 Key BOX® Ankle literature

Leardini et al. CORR. 2004; 424: 39-46

The authors describe fundamental features and rationale of the BOX® Ankle design following a comprehensive study of the role of the ligaments in guiding joint motion in intact and replaced joints. Early experience with the BOX® Ankle in two patients is also reported. The authors reported that the instrumentation worked well and allowed accurate implantation of the three components. After implantation, components were observed to move as expected from prior study data and complete congruence among the three components was maintained in all joint positions.

Abstract

Our prior research has shown that currently available total ankle implants fail to restore physiologic ankle mobility. Most of the modern mobile-bearing designs that feature a flat tibial component and a talar component with anatomic curvature in the sagittal plane function non-physiologically with the natural ligament apparatus. To establish a more natural relationship between the implanted components and the retained ankle ligaments, we have developed a new design. According to our prior research, we suggest that physiologic ankle mobility is reproduced best with a design featuring a spherical convex tibial component, a talar component with radius of curvature in the sagittal plane longer than that of the natural talus, and a fully conforming meniscal component. Our preliminary observations in trial implantation and in a few patients suggest that while reproducing physiologic ankle mobility, the new design is capable of maintaining complete congruence at the two articulating surfaces of the meniscal bearing over the entire motion arc, with the prospect of minimizing wear of this component.

Leardini et al. J Foot Ankle Res. 2014; 7:8 (Open Access)

The following is a recent review of relevant literature concerning the biomechanics of the natural, arthritic and replaced human ankle joint, with a particular focus on the requirement for a TAR to reproduce a natural movement with interactions between the articular surfaces and ligaments guiding and stabilising motion at the ankle.

Abstract

The human ankle joint complex plays a fundamental role in gait and other activities of daily living. At the same time, it is a very complicated anatomical system but the large literature of experimental and modelling studies has not fully described the coupled joint motion, position and orientation of the joint axis of rotation, stress and strain in the ligaments and their role in guiding and stabilizing joint motion, conformity and congruence of the articular surfaces, patterns of contact at the articular surfaces, patterns of rolling and sliding at the joint surfaces, and muscle lever arm lengths. The present review article addresses these issues as described in the literature, reporting the most recent relevant findings.

Giannini et al. CORR. 2010; 468(10): 2746-53

Giannini et al. J FootAnkleSurg. 2011; 50: 641-7

These two papers assessed scores, function and survivorship of 51 and 158 prostheses respectively. The later paper (Giannini 2011) presents results and with an extended cohort compared to the earlier paper (2010) and extended to 9 centres, with the former concerning 7 centres. The BOX® Ankle has a Kaplan-Meier survivorship of over 97% at 3 years and over 96% remaining functional at 4 years and more. Patient reported outcomes were improved and sustained over the follow-up period.

Abstract (2010)

Background: A three-part ankle replacement was developed to achieve compatibility with the natural ligaments by allowing fibres on the medial and lateral sides to remain isometric during passive motion. Unlike all current prostheses, the new design uses non-anatomically shaped components on the tibia and talus and a fully conforming interposed meniscal bearing. Questions/ Purposes: Does this new design restore ankle mobility, improve clinical score, and result in low complication and early revision rates?

Patients and Methods: We reviewed 51 patients in whom 51 prostheses were implanted in a seven-centre trial from July 2003 to July 2006. The mean age of the patients at surgery was 61.5 years (range, 35.1-82.5 years). We used the AOFAS score to assess clinical outcome. We used lateral radiographs to assess function. The minimum follow-up was 24 months (mean, 30 months; range, 24-48 months). Results: The mean preoperative AOFAS score of 38.5 increased to 76.9, 79.1, 76.4, and 79.0 at 12, 24, 36, and 48 months, respectively. We observed a correlation between meniscal bearing movement on the tibial component (mean, 3.4 mm; range, 2-12 mm) and range of flexion at the replaced ankle (mean, 27.4º; range, 16º-53º). We revised one arthroplasty in the second postoperative year for lateral impingement, providing a 3-year cumulative survival rate of 97% and performed one other secondary operation for hindfoot pain. Conclusions: These data suggest the new prosthesis can provide short-term restoration of ankle mobility, a good clinical score, and low complication and failure rates. Longer follow-up with larger numbers is required.

Abstract (2011)

A new design for a 3-part ankle replacement was developed in an effort to achieve compatibility with the naturally occurring ligaments of the ankle by allowing certain fibers to remain isometric during passive motion. In order to test the design concept clinically, 158 prostheses were implanted in 156 patients within a 9-center trial and were followed up for a mean of 17 (range 6 to 48) months. The mean age at the time of surgery was 60.5 (range 29.7 to 82.5) years. Outcome measures included the American Orthopaedic Foot & Ankle Surgery hindfoot-ankle score and range of motion measured on lateral radiographs of the ankle. The preoperative American Orthopaedic Foot & Ankle Surgery score of 36.3 rose to 74.6, 78.6, 76.4, and 79.0, respectively, at 12, 24, 36, and 48 months. A significant correlation between meniscal bearing movement on the tibial component (mean 3.3 mm; range 2 to 11 mm) and range of flexion at the replaced ankle (mean 26.5°; range 14° to 53°) was observed in radiograms at extreme flexions. Two (1.3%) revisions in the second and third postoperative years necessitated component removal (neither were for implant failure), and 7 (4.4%) further secondary operations were required. The results of this investigation demonstrated that non-anatomic-shaped talar and tibial components, with a fully conforming interposed meniscal bearing, can provide safety and efficacy in the short term, although a longer follow-up period is required to more thoroughly evaluate this ankle implant.

Zaidi et al. Bone Joint J. 2013;95-B:1500–7

This comprehensive review of available clinical data on TARs confirms that TAR has a positive impact on patients' lives with benefits lasting [at least] 10 years. The review included presentation of functional data on the BOX® Ankle, with comparable improvements to state of the art devices. The review discusses the prevalence of radiolucencies in other devices; this has not been reported for the BOX® ankle.

Abstract

We performed a systematic review and meta-analysis of modern total ankle replacements (TARs) to determine the survivorship, outcome, complications, radiological findings and range of movement, in patients with end-stage osteoarthritis (OA) of the ankle who undergo this procedure. We used the methodology of the Cochrane Collaboration, which uses risk of bias profiling to assess the quality of papers in favour of a domain-based approach. Continuous outcome scores were pooled across studies using the generic inverse variance method and the random-effects model was used to incorporate clinical and methodological heterogeneity. We included 58 papers (7942 TARs) with an interobserver reliability (Kappa) for selection, performance, attrition, detection and reporting bias of between 0.83 and 0.98. The overall survivorship was 89% at ten years with an annual failure rate of 1.2% (95% confidence interval (CI) 0.7 to 1.6). The mean American Orthopaedic Foot and Ankle Society score changed from 40 (95% CI 36 to 43) pre-operatively to 80 (95% CI 76 to 84) at a mean follow-up of 8.2 years (7 to 10) ($p < 0.01$). Radiolucencies were identified in up to 23% of TARs after a mean of 4.4 years (2.3 to 9.6). The mean total range of movement improved from 23° (95% CI 19 to 26) to 34° (95% CI 26 to 41) ($p = 0.01$).

Our study demonstrates that TAR has a positive impact on patients' lives, with benefits lasting ten years, as judged by improvement in pain and function, as well as improved gait and increased range of movement. However, the quality of evidence is weak and fraught with biases and high quality randomised controlled trials are required to compare TAR with other forms of treatment such as fusion.

Ingrosso et al. Gait & Posture. 2009; 30: 132-7

A follow-up of 10 patients focussing on gait analysis that confirms the design of the BOX® Ankle provides improvements in gait. Gait analysis and functional scores were reported pre-operatively and at 6 and 12 months post-operatively. The authors report a significant increase in ROM, considerable improvements in all spatio-temporal parameters and observed more normal patterns and ranges of rotations and moments in the three anatomical planes of the replaced ankles, with recovery of muscle activation contributing to plantarflexion at 6 months. Improvements in these and outcome scores were maintained at 12 months.

Abstract

A new three-part total ankle prosthesis was designed recently to restore natural joint motion while maintaining full congruity of the articulating surfaces. This was achieved by replicating natural function for the ligaments. Early functional recovery was assessed in the present study in patients who underwent replacement with this prosthesis. This was undertaken using the AOFAS clinical scoring system and gait analysis, performed preoperatively and at 6 and 12 months from surgery. The 10 patients had, at the time of operation, a mean age of 57.4 years (range 45-72), and BMI 25.8 (range 20.4-34.1).

A recently proposed protocol for three-dimensional and anatomically based analysis of joint kinematics and kinetics was used. The AOFAS score rose from 44.3 pre-op to 81.5 and 81.0 respectively at 6- and 12-month follow-up, with particular improvement in function.

Spatio-temporal parameters improved considerably already at 6 months. More normal patterns and ranges of rotations and moments were observed in the three anatomical planes of the replaced ankle at 6 months and maintained at 12 months. In particular the improvement in dorsi-plantar flexion range in stance was significant, though a limited plantarflexion in swing occurred. EMG revealed a good recovery of physiological activity for the biceps femoris at 12-month follow-up. The new ankle prosthesis contributed to early functional recovery at 6 months, maintained at 1 year.

Cenni et al. Int.Orth. 2012; 36: 571-8

The authors report on a radiographical assessment of range of motion for 14 patients, 7 and 13 months postoperatively. Range of motion and scores improved pre-to-postoperatively. ROM correlated with AP movement of the meniscus within the construct, in accordance with the unique design of this prosthesis. The study also demonstrated that the positioning of the talar component can influence ROM, but that a satisfactory ROM was achieved in all patients, including those where recommended location could not be achieved because of the size of the original joint deformity.

Abstract

Purpose In some cases of total ankle replacement, perfect alignment of the prosthetic components is not achieved. This study analyses the extent to which component positioning is critical for the final range of motion.

Methods Fourteen patients undergoing total ankle replacement were assessed preoperatively and postoperatively at seven and 13 months follow-up. X-ray pictures of the ankle were taken in static double leg stance, i.e. at neutral joint position, and in maximum plantarflexion and dorsiflexion.

Measurements were obtained by a specially devised computer program based on anatomical reference points digitised on the radiograms. These allowed calculation of the position and orientation of the components in the sagittal and coronal planes, together with the joint range of motion.

Results The mean range of motion was about 34 degrees at the first follow-up and maintained at the second. Tibial and talar components were more anterior than the mid-tibial shaft in 11 and nine patients, respectively. Mean inclination was about four degrees posterior for the tibial component and nearly one degree anterior for the talar component. A significantly larger range of motion was found in ankles both with the talar component located and inclined more anteriorly than the tibial.

Conclusions Correlation, though weak, was found between motion at the replaced ankle and possible residual subluxation and inclination of the components. However, a satisfactory range of motion was also achieved in those patients where recommended locations for the components could not be reached because of the size of the original joint deformity.

Cenni et al. Foot Ankle Int. 2012; 33(4): 290-300

The authors report on a three-dimensional video-fluoroscopic analysis of 12 patients at 6 months, 1 and 2 years postoperatively for maximum flexion and extension separately with foot on the ground and raised, stair climbing and stair ascending. The focus of the study was evaluation of rotations in all three axis: planter-dorsiflexion, inversion-eversion and internal-external rotation. Translations of the components with respect to each other were also analysed. The results found replaced joints showed satisfactory recovery of the natural overall motion at the three anatomical planes even at 6 months postoperatively, with apparent restoration of the natural position and inclination of the axes of joint rotation.

Abstract

Background Careful kinematic analysis of ankle joints with newly developed prostheses should be carried out to assess the actual performance in vivo. This study analyzed the pattern of motion of the three components of a ligament-compatible ankle replacement, developed to replicate normal joint kinematics.

Materials and methods Twelve patients treated with this design were analyzed at 6, 12, and 24 months followup. A series of images were acquired by videofluoroscopy at extremes of the range of motion, and during flexion/extension against gravity and stair-climbing/descending. Three-dimensional positions and orientations of the tibial and talar metal components and of the polyethylene mobile-bearing were obtained from the images by a standard shape-matching procedure. Motion between the three components was calculated and descriptively analyzed.

Results Large tibiotalar joint mobility of the replaced ankle was observed in all three anatomical planes, particularly in the sagittal. In flexion/extension against gravity, the mean range of flexion was 17.6, 17.7, and 16.2 degrees, respectively, over the three followups. The inclination angle of the mean axis of joint rotation was 3.7 degrees down and lateral in the frontal plane and 4.7 degrees posterior and lateral in the transverse plane, similar to those in the normal ankle. The corresponding antero-posterior translation of the meniscal bearing with respect to the tibia was 3.3, 3.3, and 3.2 mm, with statistically significant correlation with joint flexion. Conclusion: Physiological motion can be achieved in ligament-compatible ankle joint replacements. The considerable antero-posterior bearing-to-tibial motion and its coupling with flexion support the main original claims of this design.

Cenni et al. Clin Biomech. 2013; 28: 79-87

The authors report on summary results of the BOX® Ankle combining fluoroscopic and gait analyses. The results showed consistent and smoothed paths of motion with large coupled rotations and AP translation of the meniscus, confirming that the design permits more natural translations and changing inclination of the flexion axis for the tibiotalar joint.

Abstract

Background A thorough assessment of patients after total ankle replacement during activity of daily living can provide complete evidence of restored function in the overall lower limbs and replaced ankle. This study analyzes how far a possible restoration of physiological mobility in the replaced ankle can also improve the function of the whole locomotor apparatus.

Methods Twenty patients implanted with an original three-part ankle prosthesis were analyzed 12 months after surgery during stair climbing and descending. Standard gait analysis and motion tracking of the components by three-dimensional fluoroscopic analysis were performed on the same day using an established protocol and technique, respectively.

Results Nearly physiological ankle kinematic, kinetic and electromyography patterns were observed in the contralateral side in both motor activities, whereas these patterns were observed only during stair climbing in the operated side. Particularly, the mean ranges of flexion at the replaced ankle were 13° and 17° during stair climbing and descending, respectively. Corresponding 2.1 and 3.1mm antero/posterior meniscal-to-tibial translations were correlated with flexion between the two metal components ($p<0.05$). In addition, a larger tibiotalar flexion revealed by fluoroscopic analysis resulted in a physiological hip and knee moment.

Conclusion The local and global functional performances of these patients were satisfactory, especially during stair climbing. These might be associated to the recovery of physiological kinematics at the replaced ankle, as also shown by the consistent antero/posterior motion of the meniscal bearing, according to the original concepts of this ankle replacement design.

Reggiani et al. J Biomech. 2006; 39: 1435-43

This study used finite element analysis to assess the kinematics and contact pressures associated with simulated passive and active function for the BOX® Ankle. The study demonstrated the capacity for all tibial-meniscal and meniscal-talar interfaces to remain fully conforming throughout the range of motion and in all positions, resulting in low peak contact pressures in the device.

Abstract

Total ankle replacement (TAR) designs have still several important issues to be addressed before the treatment becomes fully acceptable clinically. Very little is known about the performance, in terms of the contact pressures and kinematics of TAR when subjected to daily activities such as level gait. For this purpose, an explicit finite element model of a novel 3-component TAR was developed, which incorporated a previously validated mechanical model of the ankle ligament apparatus. The intermediate mobile polyethylene meniscal bearing was modelled as an elastic-plastic continuum while the articulating surfaces of the tibial and talar metal components as rigid bodies. Overall kinematics, contact pressures and ligament forces were analysed during passive, i.e. virtually unloaded, and active, i.e. stance phase of gait, conditions. Simulation of passive motion predicted similar kinematics as reported previously in an analytical four-bar linkage model. The meniscal bearing was observed to move 5.6 mm posteriorly during the simulated stance and the corresponding antero-posterior displacement of the talar component was 8.3 mm. The predicted pattern and the amount (10.6 degrees) of internal-external rotation of the ankle complex were found to be in good agreement with corresponding in vivo measurements on normal ankles. A peak contact pressure of 16.8 MPa was observed, with majority of contact pressures below 10 MPa. For most ligaments, reaction forces remain within corresponding physiological ranges. A first realistic representation of the biomechanical behaviour of the human ankle when replaced by prosthetic joints is provided. The applied methodology can potentially be applied to other TAR designs.

Affatato et al. J Biomech. 2007; 40: 1871-76

Four small (worst-case) BOX® Ankle devices were evaluated for wear in a four-station wear simulator able to reproduce load-motion patterns typical of a replaced ankle. The study found that the BOX® Ankle produced a smooth motion throughout, with full conformity maintained between components and corresponding very low level of wear.

Abstract

Despite the fundamental value of wear simulation studies to assess wear resistance of total joint replacements, neither specialised simulators nor established external conditions are available for the human ankle joint. The aim of the present study was to verify the suitability of a knee wear simulator to assess wear rates in ankle prostheses, and to report preliminary this rate for a novel three-component total ankle replacement design. Four intact 'small' size specimens of the Box ankle were analysed in a four-station knee wear simulator. Special component-to-actuator holders were manufactured and starting spatial alignment of the three-components was sought. Consistent load and motion cycles representing conditions at the ankle joint replaced exactly with the prosthesis design under analysis were taken from a corresponding mechanical model of the stance phase of walking. The weight loss for the three specimens, after two million cycles, was 32.68, 14.78, and 62.28mg which correspond to a linear penetration of 0.018, 0.008, and 0.034mm per million-cycle, respectively for the specimens #1, #2, and #3. The knee wear simulator was able to reproduce load-motion patterns typical of a replaced ankle. Motion of the meniscal bearing in between the tibial and talar components was smooth, this component remaining in place and in complete congruence with the metal components throughout the test.

Bianchi et al. JBJS-Br. 2012; 94(6): 793-8

The authors of this study report on outcomes for a mean 3.5 years post-operatively from a single non-designer surgeon's earliest experience with the BOX® Ankle (62 procedures; 60 patients). AOFAS scores increased by over 40 points and there was a significant improvement in satisfaction Visual Analogue Scale (VAS). Over 78% of patients were satisfied or very satisfied with their outcome. Five devices required revision with reasons including infection and being attributed by the authors to the learning curve. However, all were successfully converted to arthrodesis which is in line with the design intent of maximising retention of bone stock.

Abstract

The Bologna-Oxford (BOX) total ankle replacement (TAR) was developed with the aim of achieving satisfactory pain-free movement of the ankle. To date, only one single multicentre study has reported its clinical results. The aim of this study was to conduct an independent review of its mid-term results. We retrospectively reviewed a total of 60 prospectively followed patients in whom 62 BOX® TARs had been implanted between 2004 and 2008. We used the American Orthopedic Foot and Ankle Society (AOFAS) score to assess the clinical results. Standardised radiographs taken at the time of final follow-up were analysed by two observers. The overall survival was 91.9% at a mean follow-up of 42.5 months (24 to 71). The mean AOFAS score had improved from 35.1 points (sd 16.6; 4 to 73) pre-operatively to 78.0 (sd 10.7; 57 to 100) at final follow-up ($p < 0.01$). Tibial radiolucencies < 2 mm in width were seen around 16 TARs. Talar radiolucencies < 2 mm were seen around four TARs. A total of 47 patients (78.3%) were very satisfied or satisfied with the outcome. Five patients required revision for functional limitation or continuing pain.

Sopher RS, Amis AA, Calder JD, Jeffers JRT

Med Eng Phys. 2017 Apr; 42: 80–90

Abstract

Implant loosening – commonly linked with elevated initial micromotion – is the primary indication for total ankle replacement (TAR) revision. Finite element modelling has not been used to assess micromotion of TAR implants; additionally, the biomechanical consequences of TAR malpositioning – previously linked with higher failure rates – remain unexplored. The aim of this study was to estimate implant-bone micromotion and peri-implant bone strains for optimally positioned and malpositioned TAR prostheses, and thereby identify fixation features and malpositioning scenarios increasing the risk of loosening. Finite element models simulating three of the most commonly used TAR devices (BOX®, Mobility® and Salto®) implanted into the tibia/talus and subjected to physiological loads were developed. Mobility and Salto demonstrated the largest micromotion of all tibial and talar components, respectively. Any malpositioning of the implant creating a gap between it and the bone resulted in a considerable increase in micromotion and bone strains. It was concluded that better primary stability can be achieved through fixation nearer to the joint line and/or while relying on more than a single peg. Incomplete seating on the bone may result in considerably elevated implant-bone micromotion and bone strains, thereby increasing the risk for TAR failure.

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