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Functional and clinical evaluation at 5-year follow-up of a three-component prosthesis and osteochondral allograft transplantation for total ankle replacement

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ABSTRACT

Background: Severe ankle arthritis is a life-limiting condition which often requires surgery. Ankle arthroplasty via artificial or "biological" reconstruction is a viable option in those patients who are not comfortable with arthrodesis. More functional studies are needed to compare the performance and outcomes of the two function-preserving arthroplasties.
Methods: In this study two groups of 10 patients affected by severe ankle arthritis were treated either with a 3-component ankle prosthesis or with bipolar fresh osteochondral allograft transplantation. Patients were evaluated pre-operatively and at 5-year follow-up. The American Orthopaedic Foot and Ankle Society score was used for clinical evaluation, and gait analysis for functional assessment. Activation pattern of lower limb muscles was obtained by surface electromyography (EMG). In each group, kinematic, kinetic, and EMG data were compared between pre-op and follow-up assessments, and also versus corresponding data from a 20 healthy subject control group.
The median clinical score significantly increased between pre-op and follow-up from 53 to 74.5 in the transplantation and from 28.5 to 80 in the prosthesis group. Spatio-temporal parameters showed a statistically significant improvement in cadence and cycle time. Improvement of gait speed was also observed only in the prosthesis group. EMG patterns at follow-up were strongly correlated with the corresponding control data for both groups.
Although no significant amelioration in the joints' range of motion was detected in either surgical procedure, preservation of the functional conditions at medium-term, along with significant improvement of the clinical score, may be considered a positive outcome for both techniques.

1. Introduction

Severe ankle arthritis, including the most frequent post-traumatic, is by far the most common cause of degeneration and disability of the ankle joint (Valderrabano et al., 2009). Necrosis of the talus bone and varus hindfoot is frequently observed in post-traumatic ankle arthritis (Valderrabano et al., 2009). Ligament lesions, fracture of the tibial shaft and diaphysis, malleolar fractures and recurrent subluxations of the ankle are among the most common causes. Because of the type and nature of these injuries, this condition affects mainly the younger and the more active patients.

In most cases of severe ankle arthritis, surgery is the option ensuring the best outcomes, and ankle fusion is the preferred surgical treatment (Grunfeld et al., 2014). However, arthroplasty of the articular surfaces via two- or three-component ankle prostheses has become a promising alternative for those patients who are uncomfortable with the option of a fused articulation (Daniels et al., 2014). From a functional and biomechanical perspective, joint arthroplasty allows a range of motion (RoM) in the three anatomical planes compared to arthrodesis, thus this can be defined as function-preserving procedure (Valderrabano et al., 2009). Increased range of motion at the ankle, hip and knee joints, and faster gait speed at four years following ankle arthroplasty have been reported (Brodsky et al., 2011). But the same prosthesis did not show any major difference in gait parameters when compared to ankle fusion at 1-year follow-up (Flavin et al., 2013). In another study, a three-component ankle prosthesis performed slightly better than ankle fusion in restoring normal gait patterns (Singer et al., 2013). Despite the improved clinical

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scores and function (Detrembleur and Leemrijse, 2009; Ingrosso et al., 2009; Valderrabano et al., 2007) and some restoration of the main gait parameters (Detrembleur and Leemrijse, 2009; Rouhani et al., 2012; Valderrabano et al., 2007), current total ankle prostheses do not seem able to re-establish gait symmetry and normal joint function fully (Leardini et al., 2014; Queen et al., 2014).

Over the last decade, bipolar fresh osteochondral allograft (BFOA) transplantation was introduced as a viable alternative to treat severe ankle arthritis particularly in the younger and more active patients (Giannini et al., 2010a; Kim et al., 2002). A major strength of this approach is the restoration of anatomical contact surfaces at the tibiotalar joint. However this treatment is still relatively new, its reliability lacks strong evidence from the literature, and mainly short-term follow-ups have been published (Labib et al., 2013). The first study on BFOA transplantation reported a failure rate of 42% of the cases over a minimum follow-up of 7 years, with the remaining 58% not showing any statistically-significant improvement from the pre-operative evaluation (Kim et al., 2002). Two further studies from the same Institution, which assessed different tibial and talar bone cuts, mainly confirmed the same failure rate at short-term (Meehan et al., 2005; Tontz et al., 2003). However, about half of the treated patients showed improved gait and function and reduced pain. Whereas the same cutting jigs were also used in a different Institution (Jeng et al., 2008), a final success rate of just 31% of the patients was reported at 2-year follow-up. The most frequently reported issues associated with BFOA transplantation were graft collapse, allograft fracture, and radiographic degenerative changes at the ankle joint. More recently, BFOA transplantation has demonstrated to be a promising alternative to ankle prosthesis (Berti et al., 2013; Giannini et al., 2014; Pimenta et al., 2012). In general, appropriate graft size, good adaptation, stable fixation, and delayed weight-bearing appear to contribute to increasing the success rate of this procedure (Giannini et al., 2010a, 2014).

While BFOA transplantation has proved to be effective in reducing pain and increasing function at the ankle joint, a number of failures and revisions have been reported and long-term evidence is still required (Labib et al., 2013). In fact, functional and clinical assessments of arthrodesis and joint prosthesis for the treatment of the ankle with severe arthritis have been investigated extensively (Brodsky et al., 2011; Flavin et al., 2013; Leardini et al., 2014; Singer et al., 2013), whereas only one study has thus far reported the effects of BFOA transplantation on gait function at short-term follow-up (Berti et al., 2013). This technique is still considered "experimental" thus more quantitative information for the assessment and validation at medium- and long-term are highly sought by clinicians in order to make more accurate and evidence-based decisions in the treatment of severe ankle arthritis. Furthermore, different methodologies and inconsistent functional parameters reported in the literature prevent the comparison of functional outcomes across different studies. Therefore, the aim of this study is providing a side-by-side functional evaluation, via the same gait-protocol, of the two function-preserving arthroplasties (i.e. BFOA transplantation and prosthesis) for the treatment of severe ankle arthritis, performed in the same Institution by the same surgeon. While these two surgical options are not always applicable to all patients, either of them may be used to treat ankle arthritis in those patients with an active lifestyle and for which arthrodesis is not accepted.

2. Methods

2.1. Subjects

The two subject cohorts that participated in the study consist of patients treated for severe ankle arthritis at the authors' Institution between March 2004 and March 2007. During this period, ten patients (2 F, 8 M; mean age 38 years; range 20–55; mean BMI 24.0, range 19–29) underwent BFOA transplantation according to what was described in Berti et al. (2013), and ten patients (PROS group; 5 F, 5 M; mean age 55 years, range 36–70; mean BMI 25.7, range 23–39) underwent joint replacement via a three-component ankle prosthesis (BOX Ankle, Finsbury Orthopaedics Ltd, Leatherhead, UK) implanted according to details as in Giannini et al. (2010b, 2011). The patients were treated with either BFOA transplantation or ankle prosthesis following the refusal to undergo ankle arthrodesis, and according to the current recommendations at the orthopedic department of the authors' Institution. Accordingly, provided that the bone graft of the correct size is available in the bone bank, the preferred surgical option for young patients with severe ankle arthritis is BFOA. The patient groups had different ages ($P < 0.05$) and similar BMI ($P > 0.05$). All patients were assessed pre-operatively and at a similar follow-up period of 73 (11) and 60 (1) months for the BFOA and PROS groups, respectively. Patients reporting painful unilateral ankle arthritis (grade III), unresponsive to a minimum of six months of medical and physical therapies, and limiting the activities of daily living, were included in the study. Exclusion criteria were: ankle anatomy disruption, osteopenia, rheumatoid arthritis, infections, and vascular and neurological diseases. Informed consent was obtained from all patients after extensive discussion about the various risks and benefits of the selected surgical option. The study was approved by the Ethics Committee of the authors' Institution.

2.2. Testing protocol

Patients were clinically evaluated pre- and post-operatively using the American Orthopaedic Foot and Ankle Society (AOFAS) score, and functionally by state-of-the-art gait analysis. As for the latter, rotations and torques of the main lower limb joints were obtained using an established gait analysis protocol (Leardini et al., 2007). An eight-camera motion capture system (Vicon 612, Vicon Motion Capture, Oxford, UK) sampling at 100 Hz was used to track twelve reflective markers on the pelvis, thighs, shanks and feet during barefoot level walking at self-selected normal speed. Each patient performed a minimum of three repetitions of a full gait cycle along a 15 m long walkway. Rotations in the three anatomical planes were calculated at each joint in the lower limb throughout a normalized gait cycle. In particular, dorsi/plantarflexion, inversion/eversion and ab/adduction, respectively in the sagittal, frontal, and transverse planes, were measured for the ankle joint. Simultaneously, two dynamometric platforms (Kistler Instruments, Einterthur, Switzerland) measured the ground reaction forces at 2000 Hz. Internal joint torques during the stance phase of walking were calculated as the vector product of this force and the position vector of the joint center. A wireless electromyographic system (Zerowire, Cometa, Milan, Italy) sampling at 2000 Hz recorded the myoelectric activity of the rectus femoris, long head of biceps femoris, medial head of gastrocnemius and tibialis anterior muscles. The surface dynamic EMG data were automatically processed by a custom single-threshold algorithm as to obtain on–off patterns of muscle activity. In order to provide a global representation of the muscle activation patterns, these were shown as percentage of trials, across all subjects of each group, which recorded muscle activity for each time frame of the normalized gait cycle. Spatio-temporal parameters, together with those extracted from the kinematic and kinetic gait patterns (Benedetti et al., 1998), were used for statistical analysis.

2.3. Statistical analysis

The terms "improvement" and "worsening" of a kinematic/kinetic variable are here associated with statistically significant differences between pre- and post-op evaluations, where the post-op data was becoming respectively more similar to or more different from the control group corresponding values. The Wilcoxon non-parametric test, calculated by an exact method for small samples, was used to compare pre-operative and post-operative AOFAS scores. The Kolmogorov Smirnov test was at first performed to assess normality of gait analysis data. Pre- and post-operative gait data were compared using the Mann–