TOTAL ANKLE ARTHROPLASTY: BRAZILIAN EXPERIENCE WITH THE HINTEGRA PROSTHESIS

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ABSTRACT
Ankle arthrosis is becoming more and more common. The search for solutions that preserve joint function has led to a new generation of prosthesis with three components and more degrees of freedom. This paper presents the results achieved for ten patients treated with the HINTEGRA Prosthesis (Integra, New Deal), through collaborative action between the Foot and Ankle Groups of the Orthopedics and Traumatology divisions of Escola Paulista de Medicina, Unifesp, and the School of Medicine of the University of São Paulo (USP). The ten patients (six women and four men, aged between 29 and 66 years), underwent a surgical procedure consisting of Hintermann’s technique, between January and June 2005. They were evaluated at prearranged intervals, and the data were subjected to statistical analysis. The surgery led to a significant improvement in ankle mobility. Radiological evaluation showed no signs of loosening or failure in the prosthetic components in any of the patients studied. Although the complication rate in our sample was high, it was equivalent to the rates found by other authors, and directly represents the learning curve associate with this kind of procedure. Four years after the procedure, it was found that the patients’ pain levels had significantly decreased, and that their functional patterns had significantly improved, with AOFAS and Hintermann scores indicating results that were excellent for 20%, good for 70% and poor for 10%. Treatment of ankle arthritis by means of total arthroplasty using the HINTEGRA prosthesis was capable of providing good results over an average observation period of four years.

Keywords – Ankle joint; Arthrodesis; Osteoarthritis; Arthroplasty; Prostheses and implants

INTRODUCTION
Although the frequency of primary arthrosis of the ankle is not a matter of special concern within our setting, its post-traumatic and inflammatory forms are presenting increasing incidence here in Brazil and around the world. Ankle arthrodesis, which is considered to be the gold standard for treating arthrosis of any etiology, has been increasingly questioned, especially when we have been faced with occurrences of bilateral cases and cases among young individuals. Our work always involves a spectrum of overload on adjacent joints and the sequelae resulting from this, with consequent deterioration of patients’ functional quality(1).

Despite the high failure rates experienced with the first generations of total ankle prostheses(2), several groups continued to conduct research. Today, a variety of implants are available, and their refinements come close to the anatomical and functional requirements of this joint.

Analysis of the literature indicates that the most important advance has been the concept of “mobile support”, in which the prosthetic components correlate with various degrees of freedom, without involving joint constriction. Third-generation prostheses consist-

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ing of the three elements of tibial, talar and intermediate components have been the most successful prostheses so far (3-5).

Within this scenario, which is highly unfavorable for third-world countries because of the high cost and complexity of the production, distribution and commercialization of surgical material of such sophistication, the Foot and Ankle Groups of the Department of Orthopedics and Traumatology, Escola Paulista de Medicina, Unifesp, and the Institute of Orthopedics and Traumatology, School of Medicine of the University of São Paulo, joined forces to seek deeper knowledge, achieve desirable training and introduce total ankle arthroplasty into our setting. The HINTEGRA prosthesis (Integra Group, USA, and New Deal, France) was chosen as the one that we would work with, because of its quality, performance, ease of access and availability (5).

The aim of this study was to present the results obtained from the first ten cases treated with the HINTEGRA total ankle prosthesis in Brazil.

METHODS

Between January and June 2005, ten total ankle arthroplasty procedures were performed by the surgical groups in the two institutions. The patients were reassessed in April 2009, and clinical and radiographic data was obtained from all of them. With these observations, a mean follow-up period of four years was attained.

Our sample was composed of six women and four men, with ages ranging from 29 to 66 years and a mean age of 50.2 years. The side affected was evenly distributed. The mean length of time for which the patients had been suffering pain and the disease was 10.1 years, with a range from two to 29 years.

With regard to the etiology of the ankle arthrosis, there were three cases of post-traumatic arthrosis, six cases of inflammatory arthrosis and one case of post-infection arthrosis. In this last case, the patient had suffered a condition of septic arthritis 28 years earlier.

Table 1 presents the demographic data relating to the patients of our sample.

All of the patients were enrolled in a study protocol and underwent surgical treatment that strictly followed the technique devised and disseminated by Beat Hintermann for the HINTEGRA prosthesis (New Deal, France) (6).

The patients’ records were consulted to obtain data relating to immediate and late-stage complications, and a series of radiographs was evaluated and measured in order to search for signs of misalignment, wear and loosening of the prosthetic components. In addition, the conditions of bone specimens and specimens of tissue from around the prostheses were evaluated.

We used the criterion of “three weeks” to analyze the integrity of the soft-tissue envelope in the ankle region and to determine occurrences of complications of the surgical wound (7). According to this criterion, minor complications include small-scale dehiscence of the wound, necrosis limited to the edge of the incision and signs of superficial infection that can treated by means of a series of dressings. Major complications include all complications that require some type of surgical treatment for debridement, drainage or skin coverage.

Table 1 – Order, date of operation, length of follow-up, service of origin, initials, age, sex, color, side, length of time with disease and type of arthrosis, among the patients who underwent the operation

| No. | Date | Length of follow-up | Service  | Name  | Age | Sex | Color | Side  | Length of time with disease | Type               |
|-----|------|---------------------|----------|-------|-----|-----|-------|-------|-----------------------------|--------------------|
| 1   | 20/01| 4y2m                | Unifesp  | EDS   | 66  | F   | white | R     | 2y                          | Post-traumatic     |
| 2   | 28/01| 4y2m                | Unifesp  | ARR   | 29  | M   | white | L     | 14y                         | Inflammatory       |
| 3   | 03/02| 4y2m                | Unifesp  | ADC   | 49  | M   | white | R     | 4y                          | Post-traumatic     |
| 4   | 10/02| 4y1m                | Unifesp  | SRH   | 43  | F   | white | F     | 28y                         | Inflammatory       |
| 5   | 02/03| 4y1m                | Unifesp  | LMTR  | 52  | F   | white | R     | 3y                          | Inflammatory       |
| 6   | 11/03| 4y1m                | USP      | MMRR  | 53  | F   | black | R     | 5y                          | Inflammatory       |
| 7   | 18/03| 4y1m                | USP      | CL    | 57  | M   | white | L     | 9y                          | Inflammatory       |
| 8   | 01/04| 4y                  | USP      | MLM   | 58  | F   | black | L     | 29y                         | Inflammatory       |
| 9   | 27/04| 4y                  | USP      | NGB   | 45  | F   | white | L     | 2y                          | Post-traumatic     |
| 10  | 29/06| 3y9m                | Unifesp  | RAF   | 50  | M   | mixed | L     | 5y                          | Inflammatory       |
|     |      |                     |          |       |     |     |       |       |                             | Mean               |
| Mean|      |                     |          |       |     |     |       |       |                             | 50.2               |

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In the clinical evaluation, we used a visual analog scale for pain, Hintermann’s clinical criterion for total ankle arthroplasty (8) (Table 2) and the AOFAS scale for the ankle and rear part of the foot (9).

The radiographic evaluation was performed using radiographs of the ankle in anteroposterior and lateral views that were obtained with the patient in the orthostatic position. The parameters suggested by Hintermann et al. were measured (5, 8, 10).

Distance “a”: Distance in millimeters measured between the anterior extremity of the talar component of the prosthesis and the line tangential to the upper edge of the navicular and the upper eminence of the posterior tuberosity of the calcaneus.

Distance “b”: Distance in millimeters measured between the posterior extremity of the talar component of the prosthesis and the line tangential to the upper edge of the navicular and the upper eminence of the posterior tuberosity of the calcaneus.

The real mobility of the ankle was measured in our patients. This was defined as the range of motion measured between the tibial and talar components on lateral radiographs, at maximum flexion and extension.

Radiolucent lines were defined as dark lines of variable width that appeared around the prosthesis components. Their occurrence was not directly associated with loosening of the components and could resolve spontaneously.

Loosening of the tibial component of the HINGE prosthesis was diagnosed when there were changes of more than two degrees in the alpha and beta angles, or when radiolucent lines of more than 2 mm in thickness appeared.

Loosening of the talar component of the HINGE prosthesis was diagnosed when deepening of the talus body greater than 5 mm occurred (distances “a” and “b”), or when the theta angle underwent changes greater than five degrees. It is very difficult to evaluate radiolucent lines around the talar component.

The intermediate component, which is made of polyethylene, may become worn. This is characterized by tapering or fracturing, with loss of support and locking or instability of the prosthesis. The radiographs on all the patients in this series were examined to look for such signs.

Table 2 – Hintermann’s clinical criteria (8)

| Grade   | Pain                     | Limitation on recreational activities | Limitation on daily activities | Need for support | Use of footwear |
|---------|--------------------------|---------------------------------------|-------------------------------|------------------|-----------------|
| EXCELLENT | None                     | None                                  | None                          | None             | Free            |
| GOOD    | Slight/occasional        | Slight                                | None                          | None             | Slight restriction |
| REGULAR | Moderate/frequent         | Yes                                   | Yes                           | One crutch       | Serious restriction |
| POOR    | Intense/daily            | Significant                           | Important                     | Walking frame/orthosis | Orthopedic shoes  |

Figure 1 – Radiological parameters for evaluating the HINGE model of total ankle prosthesis – see text
The initial and final numerical data from the angular and linear measurements on all the patients were subjected to statistical analysis using Student’s t test. We defined the level for rejection of the nullity hypothesis as 5% (alpha error = 5; p = 0.05).

RESULTS

Table 3 presents the range-of-motion values for the ankles before the operation and at the final postoperative assessment (four years). The real mobility was positive in 80% of the patients, who improved by an average of 17 degrees.

The statistical analysis did not detect any significant differences in the other parameters evaluated (alpha, beta and theta angles and distances “a” and “b”), which only underwent small changes within the acceptable limits that had been defined previously, after four years of follow-up.

For two patients (20%), other surgical procedures had to be performed in association with the main procedure of total ankle arthroplasty. For patient #6, arthrodesis of the subtalar joint and stretching of the Achilles tendon were performed; and for patient #10, only stretching of the Achilles tendon was needed.

Analysis on the radiographs that were obtained at preestablished intervals from all the patients indicated that radiolucent lines appeared in four patients (40%): in patient #1, the lines appeared in the fibula and talus on radiographs produced after two years; in patient #3, the lines were around the tibial component on radiographs produced after four years; in patient #4, the lines were in the contact area between the tibial component and fibula on radiographs produced after three months (Figure 2); and in patient #5, the lines were around the talus and tibia on radiographs produced after one year. These lines did not progress with time and did not represent signs of loosening of prosthetic components in the patients of this sample.

Three cases (30%) of radiographic misalignment of the prosthetic components were identified: in patient #1, misalignment between the components in the coronal and transverse planes was noted on radiographs produced after two years of follow-up; in patient #2, slight misalignment of the talar component in the transverse plane was already noted on the initial radiographs, and this positioning did not change with time; in patient #5, there was deepening of the tibial and talar components without any perceptible change to their alignments on radiographs produced four years after the operation (Figure 3).

Table 4 brings together the final results from the ten patients included in this study. Arthroplastic replacement of the ankle gave rise to a significant reduction in pain levels, which went from an average of 7.9 before the operation to 2.0, four years after the operation.

According to the clinical scores, good results (70%) predominated over excellent results (20%) and poor results (10%).

The differences between the initial values measured on radiographs produced one month after the operation and the final values measured on radiographs produced at the end of the observation period, with regard to alpha, beta and theta angles and the distances “a” and “b”, are also presented.

There was a significant difference in the mean value for range of ankle motion, from before to after the surgery, thus indicating that the procedure gave rise to a substantial improvement. Except for one patient (#3), the others presented range-of-motion values that were considered functional for total ankle arthroplasty (30 degrees).

Although not presented in the table, comparative analysis on subtalar mobility and rear foot valgus did not show any significant difference from before to after the surgery (p = 0.343).
Figure 2 – Patient #4: Radiographs in anteroposterior and lateral views of the right ankle at four different times: initial, three months after the operation, one year after the operation and four years after the operation. Despite good positioning of the prosthetic components, a radiolucent line appeared three months after the operation, in the contact area between the tibial component and the medial edge of the fibula. This line continued to be present one year after the operation and had regressed by the time of the fourth-year assessment, while the patient presented a clinical result that was considered good. See also the joint mobility of this patient demonstrated in Figure 6.

Table 4 – Final results according to evolution of pain, AOFAS score and Hintermann's clinical criterion for PTT

| No. | Initial pain | Final pain | AOFAS before | AOFAS after | Clinical result |
|-----|--------------|------------|--------------|-------------|----------------|
| 1   | 8            | 4          | 37           | 71          | Good           |
| 2   | 9            | 2          | 42           | 81          | Good           |
| 3   | 8            | 1          | 27           | 85          | Good           |
| 4   | 8            | 0          | 40           | 85          | Good           |
| 5   | 9            | 3          | 34           | 74          | Good           |
| 6   | 7            | 0          | 51           | 92          | Excellent      |
| 7   | 7            | 2          | 58           | 88          | Good           |
| 8   | 8            | 5          | 24           | 0           | Poor           |
| 9   | 7            | 0          | 63           | 98          | Excellent      |
| 10  | 8            | 3          | 37           | 81          | Good           |
|     | Mean test    | 7.9        | 2            | 41          | 76 P < 0.001*  |

* 20% Exc / 70% Good / 10% Poor

COMPLICATIONS

There were large numbers of complications among the patients included in this study. As already stated, the complications were divided into two types (minor and major), depending on their severity and the need for interventions.

Among the minor complications, there were two patients with dermolysis and dehiscence of the operative wound, who responded well to treatment with a series of dressings. Another patient presented superficial infection of the surgical wound that was treated by means of local cleansing alone. Two patients were diagnosed as presenting transoperative malleolar fractures (one in the lateral malleolus and the other in the medial malleolus), and these were treated with load suppression alone, for four weeks.

Among the major complications, there were two patients with necrosis of the edges of the operative wound, with exposure of tendons and part of the prosthesis. These patients were treated by means of grafts: one patient with a skin-free graft (fourth postoperative week) and the other patient with the myocutaneous graft from the vascularized brachial triceps (third postoperative week) (Figure 4).

results (10%). Despite the large number of radiological findings potentially indicative of unsatisfactory or unfavorable evolution, the clinical and functional observations pointed in exactly the opposite direction.
Figure 3 – Patient #5: Radiographs in anteroposterior and lateral views of the right ankle at three different times: initial, one year after the operation and four years after the operation. The deepening of the tibial and talar components can be clearly seen, especially in terms of the positioning of the fixation screws of the tibial component. Nevertheless, there was no angulation of loss of functional pattern, and the patient progressed without complaints.

Figure 4 – Patient #2: Shortly after the operation, this patient presented signs of ischemia on the edges of the surgical wound that evolved to necrosis. In the fourth postoperative week, this patient underwent pedunculated grafting (brachial triceps). Here, the clinical appearance after one year of evolution is shown.
One patient presented rupture of the long extensor tendon of the hallux, which was repaired in the eighth postoperative week.

One patient presented joint locking because of the presence of a bone fragment resulting from cutting the talus, which had inadvertently been abandoned in the posterior portion of the tibiotarsal joint. This problem was corrected by means of simple resection of the free bone fragment, through posterolateral miniarthrotomy.

The most severe complication was in patient #8, who presented difficult-to-control rheumatoid arthritis, and consisted of extensive vasculitis that affected the entire lower limb. The attempts to save the limb were in vain and, at the end of the eighth postoperative week, a salvage measure consisting of transtibial amputation of the left leg was performed.

Table 5 summarizes the complications found among our sample.

Table 5 – Complications and the treatments used

| No. | Complication                  | Treatment          |
|-----|------------------------------|--------------------|
| 1   | Dehiscence of suture         | Skin-free graft    |
|     | Fracture of medial malleolus | Load suppression for 4 weeks |
| 2   | Necrosis of wound edges      | Pedunculated triceps graft |
| 3   | Fracture of lateral malleolus| Load suppression for 4 weeks |
| 4   | Dehiscence of suture         | Dressings          |
|     | ELH rupture                  | Tenorrhaphy        |
| 5   | Superficial infection        | Surgical drainage  |
| 6   | None                         | None               |
| 7   | Necrosis of wound edges      | Dressings          |
| 8   | Vasculitis of lower limb     | Transtibial amputation (PTB) |
| 9   | None                         | None               |
| 10  | Free bone fragment           | Resection          |
|     | 80% with minor and major complications |

DISCUSSION

Stimulated by successes achieved with arthroplasty on large load-bearing joints of the lower limbs (knees and hips), many researchers have sought the ideal formula for achieving similar results in relation to the ankle joint(1).

As an additional stimulus, along with the present-day trends towards preserved activity levels and quality of life, unequivocal observations have appeared regarding the complications associated with ankle arthrodesis(1) and the functional superiority of arthroplasty, compared with fusion, over the long term(11-13).

Recent advances in understanding the biomechanics and physiology of the human ankle, along with the accumulated experience from successive failures in the designs of prostheses in the past, have led to the development of unconstrained three-component prostheses that are stable under inversion and eversion, and have freedom to perform axial rotation and flexion-extension.

The HINTEGRA prosthesis, created by Beat Hintermann (Basel, Switzerland), Greta Dereymaeker (Pallenberg, Belgium), Ramon Viladot (Barcelona, Spain) and Patrice Diebold (Maxeville, France), has anatomically designed components that practically cover the anatomical surfaces. This prosthesis is supported on the most resistant zones of the tibia and talus (subchondral bone and cortical ring), thus requiring minimal bone resection. Thus, it very effectively reproduces normal ankle function (Figure 5).

However, its implantation is full of technical details and delicate steps, from which difficult-to-correct errors or serious complications may arise.

There is a large volume of literature referring to complications relating to ankle arthroplasty, independent of the prosthesis model chosen. High incidence of problems has been demonstrated in the initial cases of each series(5,7,14,15). Based on comparative analysis between different authors’ reports, it has been established that the average learning curve is around 50 cases(14-20).

Malleolar fractures and minor problems with the soft-tissue envelope of the ankle tend to diminish in frequency
as surgeons and their teams become familiarized with the pace of the technique and the intraoperative tension reduces. Among our sample, the incidence of such complications was close to that of other authors but, unfortunately, because of the number of cases, we have not yet experienced the natural reduction in the complication rate\(^{(20)}\).

The major complications exhibit a similar pattern and also tend to become less frequent as the case series progresses. Among our sample, both of the patients who presented complications of greater severity (vascularized graft and severe vasculitis that necessitated transtibial amputation) presented rheumatoid arthritis with aggressive evolution, which alerted us to establish extreme care rules for treating such cases.

Having a multidisciplinary team with the skills to support and resolve cases with the most frequent complications is essential for all services that intend to start performing total ankle arthroplasty.

Both the minor and the major complications were concentrated in the immediate postoperative period. This finding coincides with other authors’ experiences: the first postoperative year has been seen to present the highest concentration of significant occurrences\(^{(14,16,19,20)}\). Thereafter, patients’ evolution is very uneventful and a stable and long-lasting functional pattern becomes established. Among our sample, this state continued for four years.

Curiously, once the most turbulent period had passed by, during which we dealt with the abovementioned complication and worked on rehabilitating and reintegrating the patients, the clinical and radiological assessments improved and the efficacy of the treatment method crystallized.

Our numbers attest to this assertion. The low intensity of pain complaints, the functional joint mobility and the maintenance of the alignment and stability of the segment operated ensured a very adequate quality of life for these patients, including the possibility of undertaking light, non-impacting exercise (Figure 6). Even in the case in which deepening of the prosthetic components was observed, the alignment and mobility pattern were maintained, and for this reason, this patient considered that the result was good, at the assessment four years after the operation.

We did not observe any cases of failure of the intermediate component, or of loosening or failure of the prosthesis as a whole. There was no need to exchange or remove any component up to the time of our final observations.

In subjective discussions with our patients about the procedure that was performed, we received comments expressing enthusiasm, satisfaction and gratitude for the treatment received and the results achieved, even among those who suffered major complications.

By presenting our small case series, we hope to be contributing towards providing hope and encouragement for patients with severe arthrosis of the ankle. We also hope to stimulate and provide information for our specialist colleagues who, like us, have the ever-present aim of progress, seeking new solutions for old problems. This study also provides technical support for the Brazilian authorities, which have not yet given the go-ahead for the procedure of total ankle arthroplasty within our setting.

CONCLUSIONS

Based on our observations, we can conclude that despite the technical difficulties and long learning curve of total ankle arthroplasty performed using the HINTEGRA prosthesis, this is an adequate procedure that provides good functional results over a medium term of observation of four years.

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![Figure 6 – Patient #4: range of motion of the right ankle, affected by post-infection arthrosis, compared with the normal side at the final evaluation, four years after the operation](image-url)
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