Prolonged clinical benefit from joint distraction in the treatment of ankle osteoarthritis

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Summary

Objective: Osteoarthritis (OA) is a degenerative disabling joint disease affecting more than 10% of the adult population. No validated disease-modifying treatment is available. Joint distraction is a relatively new approach to the treatment of severe ankle OA. Short-term (3 years) clinical benefit has been proven, but long-term effects remain to be evaluated.

Methods: Patients with severe OA of the tibio-talar joint, who had been treated with Ilizarov joint distraction more than 7 years previously, were included. Pre-treatment data were obtained by retrospective analysis using questionnaires and patients’ charts. Post-treatment assessments were undertaken using the same questionnaires and by physical examination. Three approaches were used and results were compared: the van Valburg score, the Ankle Osteoarthritis Scale (AOS), and a patient satisfaction questionnaire. Retrospectively and prospectively obtained data were available from eight patients for comparison.

Results: Twenty-five out of 27 patients with severe ankle OA treated with Ilizarov joint distraction could be traced. Appropriate retrospective data could not be obtained from three patients. Six out of the 22 patients (27%) were failures. In 16 patients (73%), significant improvement in all clinical parameters was observed using each of the three approaches. Good correlations were found between the results of the three methods of assessment and retrospectively obtained pre-treatment values were very similar to the prospective data.

Conclusions: In 73% of the patients, significant clinical benefit from joint distraction of severe OA ankles was maintained for at least 7 years. There is, however, a need for further research to try and predict which patients will not respond to this unconventional form of major surgical intervention.

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Key words: Osteoarthritis, Treatment, Joint distraction, Long-term effects.

Introduction

Osteoarthritis (OA) is a slowly progressive degenerative joint disease with multiple aetiologies, but similar biological, morphological, and clinical outcome1,2. The pathology of OA reflects damage to articular cartilage and subchondral bone and secondary inflammation of the joint may occur3. These pathological changes result in symptoms of pain, stiffness, loss of mobility, and disability. There are numerous risk factors for the development of OA in different individuals4. Often OA is divided into primary and secondary types. It remains uncertain, however, whether apparently primary OA is actually secondary to an unknown preceding incident or just the result of multiple predisposing risk factors. Although OA mainly develops in the ageing population, young adults with joint injuries are also at risk for OA4.

Successful disease-modifying therapy for OA is presently lacking. In a late stage of the disease, joint fusion (arthrodesis) or joint replacement (endoprosthesis) is frequently the treatment of choice. Arthrodesis is effective in relieving pain, but this is at the expense of loss of joint motion and consequent overloading of adjacent or contralateral joints5. Especially in young patients with post-traumatic OA, this may lead to problems in later years. Joint replacement is used mainly for the hip and knee joints. Results of these joint replacements are good. However, implants have a limited life span and results of revision surgery are frequently disappointing. Particularly in light of an ageing population, it is therefore relevant to try to delay joint replacement or joint fusion for as long as possible. Procedures that relieve pain, improve function, and slow progression or even reverse degeneration in OA by facilitating repair should have great advantages, especially in young patients.

Joint distraction, using an Ilizarov external fixator, is a relatively new approach in the treatment of OA6–10. This surgical technique is based on the hypothesis that osteoarthritic cartilage has some reparative activity when the damaged cartilage is mechanically unloaded, preventing further wear and tear while the pressure changes in...
synovial fluid, essential for the nutrition of the cartilage, are maintained. A period of 3-months joint distraction using an external Ilizarov frame results in transient peri-articular osteopenia because load is partially transferred through the frame instead of the bone. Because subchondral sclerosis does not return after treatment, this effect on bone may have a beneficial influence on OA. In the treatment of severe post-traumatic ankle OA joint distraction has been demonstrated to have beneficial effects in the short and mid term, on average up to 3 years. To assess the clinical outcome of joint distraction after a long period of time, we assessed patients with severe ankle OA who had been treated with joint distraction at least 7 years previously. In a retrospective analysis three different questionnaires were used to evaluate pain, function, clinical status, and mobility.

**Patients and methods**

**Patients**

All patients who underwent Ilizarov joint distraction as a treatment for severe ankle OA at the OLV Middelares Hospital Deurne, Antwerp Belgium, at the University Hospital Leuven Belgium, or at the University Medical Center Utrecht, The Netherlands, more than 7 years previously, were included. In each institute a single surgeon had performed the operations.

**Operative Technique**

Although there were minor differences in treatment between patients, the same general procedure was followed for all patients. Under general anaesthesia, two Kirschner-wires (1.8 mm in diameter) were drilled through soft tissue and tibia, approximately 5 cm below the tibio-femoral joint and 5 cm above the tibio-talar joint. The wires were tensioned (1.3 kN) and fixed to Ilizarov rings around the leg, which were connected by screw-threaded rods to stabilize the leg. Two Kirschner-wires with olives were drilled through the calcaneus. They were tensioned (1.3 kN) and fixed to a half ring around the heel. Two pins were then drilled through the metatarsals and tibia. Distraction was carried out over a distance of 5 mm (0.5 mm twice daily for 5 days), starting the day after application of the apparatus. Full weight bearing was allowed within a few days after surgery. Generally, all patients used crutches to walk with partial weight bearing on the affected ankle shortly after leaving hospital. During the subsequent weeks, the walking distance, the frequency, and amount of loading gradually increased. During this treatment, weight-bearing radiographs of the tibio-talar joint showed an enlarged joint space. It was therefore concluded that there was no mechanical contact between cartilage surfaces during the period of distraction. Care was taken to preserve distraction during the entire distraction period and this was confirmed by several radiographs. After 12 to 22 weeks, on average at 15 ± 3 weeks after initiation of treatment, the external fixation apparatus was removed under general anaesthesia.

**Assessment of Disease Parameters**

The pre-treatment status of patients was evaluated retrospectively using three different questionnaires and by survey of the patients’ charts. Post-treatment status (at least 7 years after treatment) was evaluated using the same questionnaires and by physical examination. The first questionnaire used in the present study was the one described by van Valburg et al., slightly modified by Marinissen et al. This score was used because no validated scores were available at the time joint distraction was started for the treatment of ankle OA. Pain was scored by use of a box-scale, with a maximum score of 10. Function was scored using 10 questions with a total maximum score of 30. Patients were asked to complete the questionnaire relating to their status before treatment and their present status after treatment. Joint mobility was measured by the range of motion at the ankle and expressed as a percentage of the maximum range of motion of the contralateral ankle. Pre-operative data for joint mobility were obtained from patients’ charts. Clinical status was assessed using four questions, concerning crepitus, swelling, pain with movement and localisation of pressure pain, with a maximum score of 8. Pre-operative data on these parameters were obtained from patients’ charts. The four parameters of the van Valburg score were expressed as a percentage of the maximum score. For mobility this was related to the range of motion in the contralateral ankle. Data from individual patients as well as means (± S.E.M.) for all patients are shown.

The second questionnaire used in the present study was a translated version of a validated score for ankle OA, the Ankle Osteoarthritis Scale (AOS) used for measuring OA specific symptoms, i.e., pain and disability related to the ankle. All patients were asked to complete the AOS for their status before treatment and for their present status after treatment. Scoring of the AOS and its two subscales is measured on a 100-mm visual analogue scale. "No pain" and "no difficulty/disability" are indicated on the left side of the line and designated zero. “Worst pain imaginable” and “very difficult/unable” were at the right side of the line and designated 100 mm. In cases where “not applicable” was reported, responses have been excluded in order to calculate normalized total scores. The results of the AOS were expressed as a percentage of the maximum score. This was 900 mm for pain and 900 mm for disability (nine questions each). Data from individual patients as well as means (± S.E.M.) for all patients are shown.

To evaluate patients’ satisfaction at the time of assessment compared to their pre-operative condition, a third questionnaire, the patient satisfaction score was developed. The score was not validated but results were compared with the other two scores. The score is based on the van Valburg score and consists of 10 questions for function and a box-scale for pain. Patients were asked to indicate to what degree each item had changed at the time of evaluation when compared to their pre-operative condition using a five-point scale (0–4) [deterioration; no improvement; minimal improvement; improvement; clear improvement] with a maximum score of 40 for function (10 questions) and a maximum score of 4 for pain. The data of the patient satisfaction score are expressed as the number of patients in each of the five categories (from deterioration to clear improvement) for each parameter.

**Evaluations**

The clinical effect of joint distraction was evaluated using three different approaches: the van Valburg score, the AOS and the satisfaction score. In addition, the different questionnaires used to evaluate the same disease parameters were compared with each other to see whether
a correlation exists [van Valburg box-scale for pain vs AOS pain questionnaire and vs the satisfaction pain score; van Valburg functional ability questionnaire vs AOS disability questionnaire and vs the satisfaction function score]. Although all patients were evaluated in the same way using retrospective assessments of their pre-treatment status, pre-operative assessment data were available in eight out of the 16 patients from the study of Marijnissen et al.\textsuperscript{7} This enabled us to compare retrospectively obtained data with data obtained before treatment in these eight patients.

STATISTICAL ANALYSIS

The Wilcoxon signed rank test for paired data was used to compare status parameters before and after treatment and to compare retrospectively obtained and prospectively obtained pre-treatment data. Spearman correlation was used for comparison of outcome of different questionnaires. \(P\) values less than 0.05 were considered statistically significant.

Results

PATIENTS

Twenty-seven patients with unilateral post-traumatic OA of the tibio-talar joint, severe enough to be considered for arthrodesis, had been treated more than 7 years previously with Ilizarov joint distraction. Twenty-five out of these 27 patients could be traced. These patients were treated between April 1987 and July 1995; 15 at the OLV Middelares Hospital Deurne, Antwerp Belgium, four at the University Hospital Leuven Belgium and six at the University Medical Center Utrecht, The Netherlands. Three patients did not complete the questionnaires in an appropriate way for evaluation.

Thus, 22 out of the 27 patients treated were available for evaluation in the present study. The mean age of these patients at time of surgery was 37 ± 11 years, including eight females and 14 males. The causes of OA were fracture or subluxation of the ankle joint, congenital deformities, or deformity after polio-myelitis. In one patient the cause of OA was not known. Deformity and muscle weakness in the two patients with congenital deformities and polio were not that severe that these patients were different from the patients with post-traumatic arthritis. The mean interval between the probable disease-related trauma and joint distraction was 6.6 ± 5.6 years (see Table I). All patients had severe OA related symptoms (pain, functional impairment, and limited joint mobility) in the tibio-talar joint before treatment and showed radiographic signs of OA. All were being considered for arthrodesis.

At the time of evaluation six out of the 22 patients (27\%) were judged to be treatment failures. Five patients underwent an arthrodesis, three within the first year after treatment and two 4 years after treatment. One patient suffered from an incomplete Sudeck's atrophy, but it was not clear whether this was related to the treatment. Pre-treatment characteristics of the patients who subsequently underwent arthrodesis were not different from the other patients. The mean age of the patients who underwent arthrodesis was 33 ± 3.5 years (\(P > 0.31\)). The cause of OA in each of these five patients was fracture of the ankle joint, and the mean interval between the probable disease-related trauma and joint distraction was 7.2 ± 5.2 years (\(P > 0.69\)). The reason for failure was persisting pain in all cases.

The remaining 16 patients were evaluated retrospectively using the different questionnaires. At the time of evaluation of these 16 patients the mean time following treatment was 10 ± 2.5 years, range 7–15 years.

Table I

Demographic data of the 22 evaluated patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years) at time of surgery</td>
<td>37 ± 11 (range 19–55)</td>
</tr>
<tr>
<td>Sex</td>
<td>8 females (36%); 14 males (64%)</td>
</tr>
<tr>
<td>Cause of OA</td>
<td>Fracture or subluxation of the ankle joint (n = 19)</td>
</tr>
<tr>
<td></td>
<td>Congenital deformation (n = 1)</td>
</tr>
<tr>
<td></td>
<td>Deformation after polio-myelitis (n = 1)</td>
</tr>
<tr>
<td></td>
<td>Not known (n = 1)</td>
</tr>
<tr>
<td>Mean interval (years) between</td>
<td>6.6 ± 5.6</td>
</tr>
<tr>
<td>probable disease-related trauma and</td>
<td></td>
</tr>
<tr>
<td>joint distraction</td>
<td></td>
</tr>
<tr>
<td>Time of evaluation after surgery (years)</td>
<td>10 ± 2.5</td>
</tr>
</tbody>
</table>

CLINICAL EVALUATION

Individual values as well as means of pain, function, clinical status and mobility for all 16 patients using the van Valburg questionnaire are shown in Fig. 1. Compared to the situation before joint distraction, pain was diminished in all these patients. Mean pain score before treatment was 78 ± 3\% and decreased on average to 30 ± 5\% (\(P < 0.0001\)) of the maximum score after treatment. Functional ability increased in all patients, except one. This patient showed a function of 60\% of the maximum score before treatment and showed no change in function after treatment. Pre-treatment functional ability was on average 20 ± 4\% and increased post-treatment to 73 ± 6\% (\(P < 0.001\)) of the maximum score. Clinical status improved in 13 patients. One of the 16 patients showed a 100\% "clinical condition" before treatment and remained at 100\% when evaluated after treatment. One patient had a 33\% decrease in their clinical status, and in one patient physical examination before treatment was not recorded adequately in the chart. On average, clinical status before treatment was 21 ± 7\% and increased to a post-treatment value of 77 ± 6\% (\(P < 0.001\)).

Ankle mobility was measured in degrees and expressed as a percentage of the range of motion of the contralateral control ankle. Before treatment all osteoarthritic ankles showed a decreased range of motion compared to the contralateral control ankles, on average 52 ± 7\% of the maximum mobility. After treatment, mobility increased in six of the 16 patients. The average increase was 101 ± 38\%. Mobility decreased in six patients by 16.9 ± 6\%, and remained unchanged in one patient. In three patients no pre-operative data were available from the patients' charts. On average the range of motion of the ankle joint increased by 34 ± 23\%, but this was not statistically significant (\(P > 0.39\)).

ANKLE OSTEOARTHRITIS SCORE

Results of the AOS score with respect to pain and disability are shown in Fig. 2. Similar to the results obtained using the van Valburg questionnaire joint
Distraction resulted in a decrease in pain and a decrease in disability (increase in function). Compared to the situation before treatment, pain measured by the AOS scale diminished in 14 out of 16 patients after treatment. Two patients showed an increase in pain. One of these patients could only answer one out of the 9 questions in the questionnaire relating to the situation before treatment, making the result unreliable. Nevertheless, the mean AOS pain score before treatment was 67 ± 6% and decreased to a mean score of 25 ± 6% (P < 0.002) after treatment.

Disability measured by the AOS scale decreased after treatment in 14 out of the 16 patients. In two patients the disability score increased, and one of these patients also showed an increase in pain. Mean AOS disability score before treatment was 74 ± 5% and decreased to a mean score of 32 ± 7% after treatment (P < 0.001). On average, the total score before treatment was 69 ± 4% and

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**Fig. 1.** Clinical results of joint distraction, more than 7 years after treatment. Individual (lines) and average scores (bars) for pain, function, clinical condition, and mobility are given before and after treatment. Broken lines indicate the patients with congenital deformity and polio. For detailed description of the scores see van Valburg et al. and Marijnissen et al. Data are presented as a percentage of the maximum score being: 10 points for pain, 30 points for function and 8 points for clinical condition. Joint mobility (range of motion) is presented as a percentage of mobility of the contralateral ankle.

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**Fig. 2.** Clinical results of joint distraction evaluated using the Ankle Osteoarthritis Score. Individual (lines) and average scores (bars) for pain, disability and the total AOS score are given before and after treatment. Broken lines indicate the patients with congenital deformity and polio. Data are presented as a percentage of the maximum score being: 900 mm for pain, and 900 mm for disability (nine questions each).
decreased to a mean score of $29 \pm 6\%$ after treatment ($P < 0.001$).

**PATIENT SATISFACTION SCORE**

The patient satisfaction score evaluated subjective change in function and pain after treatment. Results of the patient satisfaction score are shown in Table II. On average 12 of the 16 patients recorded an improvement in function compared with the situation before surgery and 13 out of the 16 patients recorded improvement in pain.

**COMPARISON OF THE DIFFERENT SCORING SYSTEMS FOR PAIN AND FUNCTION**

For comparison of the three scoring systems the percentage change in values after treatment compared to the values before treatment for the van Valburg and the AOS score and the absolute values of the satisfaction score were compared. This comparison was only performed for pain and functional ability, since these two parameters are found in all three scoring systems. With respect to pain as well as function a good, statistically significant correlation was found between all different scoring systems. The changes in pain after treatment found using the van Valburg score correlated very well with those found using the AOS pain score ($R = 0.568; P < 0.03$) and with the patient's assessment using the patient satisfaction score ($R = -0.674; P < 0.004$). In addition, the changes found using the AOS score correlated very well with the results of the patient satisfaction score ($R = -0.814; P < 0.0001$).

Also with respect to functional ability good correlations were found between the different scores. The changes in function after treatment found using the van Valburg score correlated very well with the changes found using the AOS function score ($R = -0.714; P < 0.004$) and with the results of the patient satisfaction score ($R = 0.746; P < 0.002$). Also when results of the AOS function score were compared to the patient's satisfaction score a statistically significant correlation was found ($R = -0.870; P < 0.0001$).

**COMPARISON OF RETROSPECTIVELY AND PROSPECTIVELY OBTAINED PRE-TREATMENT VALUES**

For eight out of 16 patients prospectively obtained pre-treatment data were available from the prospective study of Marijnissen et al.\textsuperscript{7} To analyse whether retrospectively obtained data are similar to prospectively obtained data with respect to pain and function these data were compared with data obtained retrospectively from the same patients (Fig. 3). There was no statistical significant difference between prospectively obtained pre-treatment data (mean score of $71.7 \pm 5.0$) and the data obtained more than 7 years later retrospectively ($81.7 \pm 3.3$) for pain ($P > 0.07$). Data for functional ability obtained prospectively were slightly better (mean score of $37.5 \pm 6.7$) than the data obtained retrospectively on the basis of memory (mean score of $26.5 \pm 7.3$; $P < 0.02$).

**Discussion**

From the present study it can be concluded that joint distraction for severe ankle OA has long-term benefit. Clinical benefit was experienced by 73% of the patients and sustained on average for 10 years. Together with the results described in a larger group studied prospectively\textsuperscript{7} it can be concluded that joint distraction is very effective in the treatment of severe ankle OA.

Unfortunately three patients had to have an arthodesis after 1 year because no clinical benefit was achieved. It is, however, now known that beneficial effects are sometimes not achieved before the end of the first year after treatment. One can speculate that the first year is probably needed for full recovery from surgery. Two patients had an arthodesis in the fourth year after treatment and have to be considered failures. The reason was persisting pain. One patient developed an incomplete Sudecks' atrophy. Although a serious event, it is possible that Sudecks' atrophy would also have occurred if in this patient joint fusion had been undertaken. Overall, including the Sudecks' atrophy there was a 27% failure rate. However, one must also consider that in the worst case scenario the two patients that could not be traced and the three patients unable to complete the questionnaires adequately, could potentially also have been failures. Although the available results do not corroborate such a scenario, the success rate would then be reduced to 60%.

None of the patients showed symptoms of adverse effects in other joints. This might be due to the fact that mobility of the ankle persisted and on average even slightly improved after treatment, with consequent reduction of overloading of adjacent joints. The slight increase in

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**Table II**

Patient satisfaction score

<table>
<thead>
<tr>
<th>Worsened</th>
<th>Similar</th>
<th>Minimally improved</th>
<th>Improved</th>
<th>Noticeably improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Pain</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

Numbers refer to number of patients who replied with the respective answer to each item of the van Valburg questionnaire\textsuperscript{10} slightly modified by Marijnissen et al.\textsuperscript{7} when comparing the situation after joint distraction with that before treatment at time of evaluation (mean follow-up = 10 \pm 2.5 years). One patient was not able to answer each specific question with respect to function, resulting in a total number of 15 for this part of the questionnaire.

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**Fig. 3.** Comparison of retrospectively obtained data with prospectively obtained data with respect to pain and function. Average scores for pain and function are given for eight patients from whom retrospective as well as prospective data were available. The lines indicate data from individual patients.
mobility is comparable to the increase reported after the ankle arthroplasty, where mobility improved by 15% 17. The maintenance or slight increase in mobility might be seen as a significant advantage over an arthrodesis. Fusion of the ankle joint is associated with symptoms and stress in the adjacent joints 5. The adverse effects of arthrodesis include infection, non-union, and premature deterioration of other joints in the foot as a result of increased movement in sub-talar, inter-tarsal and mid-tarsal joints. This suggests that joint fusion should be delayed as long as possible.

Total ankle prostheses are an alternative approach. Although total ankle replacement arthroplasties have not been as promising as other weight-bearing prostheses, recent studies of new generation ankle prostheses do show beneficial effects 13-15. Koford and Sorensen 16 estimated a cumulative survival rate for ankle arthroplasty after 14 years of 70%, very similar to our results. However, prostheses will not last forever and in time will need to be revised.

The underlying basis for the clinical benefit obtained with joint distraction remains speculative. Probably there is a combination of several mechanisms that together lead to the observed clinical benefit. When osteoarthritic cartilage is exposed to intermittent fluid pressure in vitro, beneficial changes in cartilage turnover have been demonstrated 17. In vivo, application of intermittent fluid pressure in the absence of mechanical load on cartilage has been performed using joint distraction in animal models of OA 18-20. This resulted in beneficial changes in cartilage turnover after joint distraction 21,22. Most important, in patients with severe ankle OA who are treated with joint distraction, radiographic subchondral sclerosis diminished while joint space width increased, the latter suggesting cartilage repair 7. However, the observed clinical benefits might not be dependent on cartilage repair alone. For example, the increase in joint space width might be associated with the formation of fibrous tissue with a consequent change of load transfer in the joint and a decrease in pain. Stretching of the nerve endings during treatment, or diminished synovial inflammation, as has been demonstrated in vitro following intermittent fluid pressure 17 may also relieve pain. In addition persisting changes in the subchondral bone 7 may contribute to the clinical benefit.

Unfortunately, because of limited availability of pre-treatment radiographs it was not possible to evaluate structural changes in the joint with respect to joint space width and subchondral sclerosis. Moreover, where pre-operative radiographs were available, they were not appropriately standardized for evaluation.

At the start of our prospective study on joint distraction a scoring system for OA of the ankle joint was lacking. The van Valburg score was developed for evaluation of clinical effects of joint distraction in the treatment of OA 10. Subsequently Domsic and Saltzman 11 described the AOS in 2001. In the present study we have compared the van Valburg scoring system with the more recently developed AOS scoring system. In addition, we have used a non-validated satisfaction score. Very good correlations were found between the different scoring systems for pain and functional ability. At the individual level, however, a discrepancy was found between the AOS scoring system and the van Valburg score. Two patients showed an increase in pain and an increase in disability when evaluated by the AOS score, while pain decreased and function increased when evaluated by the van Valburg score. One of these patients also had involvement of other joints and had difficulties in distinguishing between symptoms originating from the ankle and from other joints. In general, the scoring system used by van Valburg 10, which has also been used in the prospective study 7, is a reliable scoring system. It was interesting that 15 of the 16 evaluated patients spontaneously declared that they would undergo the operation again.

In 50% of the evaluated patients pre-treatment data obtained retrospectively were compared to pre-treatment data obtained prospectively to analyse recall bias. Compared to data obtained prospectively, pain was scored higher retrospectively, but this difference was not statistically significant. In the case of function, the score obtained retrospectively was statistically significantly lower when compared to the data obtained prospectively. However, the difference is negligible in comparison to the change in function achieved by joint distraction. Overall, the retrospectively obtained data can be considered reliable.

In general, we may conclude that joint distraction for the treatment of severe ankle OA is followed by significant clinical benefit for a significant period of time. In cases where treatment failed arthrodesis could be undertaken. In young patients with ankle OA, conventional treatment with arthrodesis or joint replacement arthroplasty is associated with limited long-term benefits. The prolonged benefit of joint distraction in cases of ankle OA could be used to justify studies on joint distraction in the treatment of OA of other joints such as knee and hip. If similar results could be obtained for the treatment of these joints it would also have a greater social and economic impact. Nevertheless, the failure rate is 27% and further research is required to try and predict those that will not respond to this complex unconventional treatment.

References


