FOOT & ANKLE INTERNATIONAL

DOI: 10.3113/FAI.2012.0632

# Evidence-Based Indications for Distraction Ankle Arthroplasty

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## ABSTRACT

***Background:*** **The purpose of this study was to review the literature to provide a comprehensive description of the Level of Evidence (LOE) available to support the operative technique of distraction ankle arthroplasty for the current generally accepted indications and make a grade of recommendation for each.** ***Methods:*** **A comprehensive review of the literature was performed (November 2010 to January 2011) using the PubMed database. The abstracts from these searches were reviewed to isolate literature that described therapeutic studies investigating the results of distraction ankle arthroplasty. All articles were reviewed and assigned a classification (I-V) of Level of Evidence. An analysis of the literature reviewed was used to assign a Grade of Recommendation for each current generally accepted indication for distraction ankle arthroplasty.** ***Results:*** **There is insufficient evidence based literature (Grade I) to support or refute the procedure for either: post-traumatic ankle arthritis, arthritis associated with ligamentous instability, primary degenerative joint disease, chondrolysis, deformity associated with arthritis, osteochondral defects and congenital ankle abnormalities.** ***Conclusion:*** **Inadequate evidence based literature exists to support or refute all currently accepted indications for distraction ankle arthroplasty and further high quality, scientific studies are needed upgrade to these recommendations.**

**Level of Evidence: Systematic Review of Level III Studies**

**Key Words: Ankle Joint; Distraction; Arthroplasty; Systematic Review; Level of Evidence; Grade of Recommendation**

## INTRODUCTION

There has been growing interest in the operative technique of distraction arthroplasty over the last two decades. It was originally described in a large series by Aldegheri and colleagues in 1994 as an alternative treatment for hip arthritis.[4] Though the exact physiology was not and is not yet fully understood, the procedure appears to have the potential for positive outcomes with less invasive surgery. Since 1994, the procedure has been adapted to the ankle joint with some small to medium scale success.

There has been a significant call for further studies to be produced that examine the efficacy and possible applications for distraction arthroplasty of the ankle.[5,8,14] The current generally accepted indications for this procedure include: post-traumatic arthritis, arthritis associated with ligamentous instability, degenerative joint disease, chondrolysis, deformity associated with arthritis, osteochondral defects and congenital ankle abnormalities.

The purpose of this paper was to review the literature to provide a comprehensive description of the Level of Evidence (LOE) available to support the operative technique of distraction ankle arthroplasty for currently generally accepted indications.

## MATERIALS AND METHODS

A comprehensive review of the literature was performed between November of 2010 and January of 2011 using the PubMed database and keywords “distraction” and “ankle” and “arthroplasty” revealing 171 articles. The current generally accepted indications for distraction arthroplasty were also separately searched in the PubMed database along with the key words “ankle” and “distraction.” These search terms included: “arthritis,” “chondrolysis,” “deformity,” “trauma,” “osteochondral” and “arthrodiastasis.” The reference list of each pertinent article was reviewed for other relevant papers. Non-English literature without English translation was excluded. The abstracts from these searches were reviewed to isolate literature that described therapeutic studies investigating the results of treatment. A total of thirty such articles were found. The same search criteria were used within the EMBASE health database revealing no other articles.

Dr. Rozbruch receives royalties for an ankle distraction frame made by SBI, which was used in some of the studies examined by the author group.

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**Table 1:** Grades of Recommendation for Summaries or Reviews of Orthopaedic Surgical Studies

| | |
|---|---|
| Level I | • High-quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals.<br>• Systematic Reviews of Level I RCTs (and study results were homogenous) |
| Level II | • Lesser quality RCT (e.g., 80% followup, no blinding, or improper randomization)<br>• Prospective comparative studies<br>• Systematic reviews of Level II studies or Level 1 studies with inconsistent results |
| Level III | • Case control studies<br>• Retrospective comparative studies<br>• Systematic reviews of Level III studies |
| Level IV | • Case series |
| Level V | • Expert opinion |

**Table 2:** Summary of Levels of Evidence for Therapeutic Studies

| Grades of Recommendation for Summaries or Reviews of Orthopaedic Surgical Studies |
|---|
| A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention. |
| B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention. |
| C: Poor quality evidence (Level IV or V with consistent findings) for or against recommending intervention. |
| I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention. |

All abstracts were reviewed and assigned a classification (I-V) of Level of Evidence (LOI) using the Journal of Bone and Joint Surgery Levels of Evidence for Primary Research Question (Table 1).[29] An analysis of the literature reviewed was used to assign a Grade of Recommendation for each current generally accepted indication for distraction ankle arthroplasty (A-B-C or I) (Table 2).[28]

**Table 3:** Summary of Grade of Recommendation For or Against the Current Generally Accepted Indications for Distraction Ankle Arthroplasty

| Procedure | | Grade of Recommendation |
|---|---|---|
| Post-traumatic Arthritis | I | For Intervention |
| Degenerative Joint Disease | I | For Intervention |
| Arthritis associated with Ligamentous Instability | I | For Intervention |
| Chondrolysis | I | For Intervention |
| Deformity Associated with Arthritis | I | For Intervention |
| Congenital Abnormality | I | For Intervention |
| Osteochondral Defects | I | For Intervention |

## RESULTS

A summary of the grade of recommendation for or against the current generally accepted indications for distraction ankle arthroplasty is presented in Table 3. Insufficient evidence based literature (Grade I) exists to support recommendation for the use of distraction ankle arthroplasty for any of its generally accepted indications. The largest majority of the papers written on distraction ankle arthroplasty (22/30) were literature reviews and expert opinions. While this Level V evidence showed interest in the topic, it was not valuable in discovering the true efficacy of the technique. Most of these papers came to the conclusion that more high quality studies are needed in this field.

### Post-traumatic arthritis

*Level of Evidence I-III*

In 1999, van Valburg and colleagues presented on 17 patients prospectively followed after being treated with distraction ankle arthroplasty.[27] Thirteen patients had arthritis secondary to a previous fracture while three had arthritis of unknown cause and one had a congenital leg-length discrepancy. Patients were followed for at least 1 year and in some cases 4 to 8 years, with pain questionnaires, range of motion evaluation and radiographic analysis. There was statistically significant improvement ($p < 0.05$) in pain and physical impairment that lasted to at least two years followup. The study unfortunately enrolled only 17 patients and only presented results found at the 2-year mark.

Marijnissen et al. produced another prospective trial in 2002 along with a small randomized control trial of 17 patients comparing distraction arthroplasty to ankle debridement.[12] In the open prospective study the authors found continued improvement in pain and functional scores between 1 and 3 years followup. This progressive improvement continued throughout the study period. Though this controlled study did not find any statistically significant differences between the two groups in terms of pain and function, members of the distraction group reported better improvement in symptoms. Three members of the control group were eventually treated with distraction arthroplasty as they failed on debridement alone. Again, both studies had small numbers and short lengths of followup, with the average between the two studies being 1 year.

van Roermund and Lefeber completed both a retrospective and a prospective trial examining the results of distraction ankle arthroplasty.[23] They described positive results in terms of physical and functional impairment as well as pain and mobility. No statistical data was presented, recruitment was small and followup was inconsistent.

Two more retrospective studies have been completed by van Valburg[27] (11 patients) and Ploegmakers[17] (27 patients) in 1995 and 2005. They demonstrated 55% and 73% positive outcomes, respectively. Both groups examined the retrospective effects of Ilizarov joint distraction on post-traumatic ankle arthritis.

*Level of Evidence IV*

Two case series have been reported by Paley et al.[16] and Tellisi et al.,[22] each demonstrating positive outcomes for the procedure of 78% (14 of 18) and 91% (21 of 23), respectively. Unfortunately, both were relatively small studies of only 22 and 25 patients. There was reasonable followup of at least 2.5 years but each of the authors came to the conclusion that while this seemed like a viable procedure, more high quality studies would have to be performed.

*Grade of recommendation*

Based on the small numbers of patients, short length of followup, and under powered statistics of these studies, distraction ankle arthroplasty for the treatment of post-traumatic ankle arthritis has a Grade I recommendation.

**Arthritis associated with ligament instability**

Though the literature was thoroughly examined, there were no papers that discussed distraction ankle arthroplasty as a treatment for arthritis associated with ligamentous instability. Furthermore, there were no individual cases that discussed this as the primary pathology later treated with distraction arthroplasty. Clinical trials are needed to discover the usefulness of this treatment option.

*Grade of recommendation*

The lack of evidence available requires that a Grade I recommendation be assigned to distraction ankle arthroplasty for use in treating arthritis associated with ligament instability.

**Primary degenerative joint disease (Osteoarthritis)**

There were no therapeutic studies that focused on primary degenerative joint disease as an indication for treatment using

**Table 4:** Level II, III, and IV Evidence to Support the Use of Distraction Ankle Arthroplasty in the Treatment of Post-traumatic Arthritis

| Author (Year) | Level of Evidence | Control Population | Diagnostic Groups Included | Length of Minimum Followup | Good and Excellent Outcome Rate | Study Type |
|---|---|---|---|---|---|---|
| van Valburg *et al* (1999) | II | None | Severe OA who were considered for arthrodesis | 2 years | 13/17 (76%) | Prospective |
| Marijnissen *et al* (2002) | II | None | Severe OA who were considered for arthrodesis | 1 year | 38/54 (70%) | Prospective |
| | | Debridement group | | 1 year | 14/17 (82%) | Small RCT |
| van Roermund *et al* (1999) | II/III | None | Post-traumatic ankle OA | 1 year | N/A | Prospective |
| | | None | | 1 year | N/A | Retrospective |
| van Valburg *et al* (1995) | III | None | Post-traumatic ankle OA | 9 months | 6/11 (55%) | Retrospective |
| Ploegmakers *et al* (2005) | III | None | Severe OA previously treated with distraction | 7 years | 16/22 (73%) | Retrospective |
| Paley *et al* (2008) | IV | None | Painful ankle arthrosis recommended for fusion | 2 years | 14/18 (78%) | Case series |
| Tellisi *et al* (2009) | IV | None | Post-traumatic ankle OA | 1 year | 21/23 (91%) | Case series |

distraction ankle arthroplasty. As mentioned before, the vast majority of the patients described in each series were noted to have post-traumatic arthritis. It is likely that each series contained patients who may have had osteoarthritis without any obvious trauma but these individuals were not separated.

*Grade of recommendation*

Without focused evidence based literature, we are unable to comment on distraction ankle arthroplasty as a treatment modality for primary degenerative joint disease and therefore must assign it a Grade I recommendation.

**Chondrolysis**

There were no Level I, II, III or IV studies which discussed distraction arthroplasty as a treatment method for chondrolysis of the ankle joint. There were two case studies of young patients which described the successful employment of the technique for this condition.

Knabe et al. described a 19-year-old female who developed chondrolysis insidiously and was treated with distraction arthroplasty.[7] After 3 years of followup, she had no symptoms in her ankle with normal range of motion and no pain.

Sabharwal and Schwechter used distraction arthroplasty to treat a 15-year-old male who developed chondrolysis after sustaining an open Gustilo grade II, displaced Salter-Harris III fracture of the distal tibia with a Salter-Harris I fracture of the distal fibula.[21] After 5 years of followup, he was working without restriction and had no complaints in his ankle.

*Grade of recommendation*

Given the paucity of high-quality data on the subject, we must assign a Grade I recommendation for the use of distraction arthroplasty as a treatment for chondrolysis.

**Deformity associated with arthritis**

In Tellisi et al., six of 23 cases underwent a simultaneous supramalleolar osteotomy.[22] These are the only reports of deformity associated with arthritis as an indication for distraction ankle arthroplasty and therefore it must be assigned a Grade I recommendation for its use.

**Congenital abnormality**

No Level I, II, III, or IV studies have been produced that discuss the treatment of congenital ankle abnormality by use of distraction arthrosplasty.

Adiela et al. described a single case of a 9-year-old female who had foot and ankle contracture previously treated by traditional bone-setters.[1] She was treated with soft tissue release and slow gradual external fixation and distraction to correct the contracture. After completion of the treatment she was able to weight-bear on a plantigrade foot.

*Grade of recommendation*

We have assigned it a Grade I recommendation.

**Osteochondral defects**

A final indication for the use of distraction arthroplasty in the ankle may be for the treatment of osteochondral defects. Unfortunately, only two papers exist which discuss this option. Belzjack and colleagues described a 53-year-old man who presented with ankle pain which proved to be an osteochondral lesion of the talar dome.[2] He was treated with autograft and simultaneous ankle arthrodiastasis which led to successful resolution of the lesion.

Rodriguez et al. had the only Level IV evidence with a case series describing the treatment of osteochondral lesions of the talus with cryopreserved talar allograft and ankle distraction.[19] At the end of 24 months of followup, all six patients reported an improvement in symptoms and none had major complications. The authors felt more investigation was needed to explore this treatment.

*Grade of recommendation*

Due to the nature and volume of the literature available we must assign a Grade I to the level of evidence for distraction arthroplasty as a treatment for osteochondral defects.

## DISCUSSION

There has been a significant amount of interest in the use of distraction arthroplasty as an alternative to arthrodesis and joint replacement for the treatment of ankle problems. This joint preserving procedure may provide an operative alternative to fusion or replacement and its use may not burn bridges for future interventions. Over the last two decades there has been a significant body of work produced in the Netherlands exploring the possible benefits of the procedure.[11,12,17,23–27] Unfortunately these have been smaller trials, often retrospective, that have focused mainly on post-traumatic ankle arthritis. To date, no level I randomized, controlled trials have been completed, no published papers have ever utilized a control population against which the results of distraction arthroplasty intervention can actually be compared, and no body of work has shown the benefit of distraction arthroplasty for other pathologies in the ankle. Given the large number of expert reviews which have come out recently, however, there seems to be hope for this as a viable alternative to the more standard arthrodesis and joint replacements. Unfortunately, as of yet there needs to be more investigation to discover the procedures true worth.

There were weaknesses in our paper. Even though a thorough review of the literature was performed there was a significant paucity of scientific papers. The large bulk of the studies available were Level IV and V data and the higher quality research was on a smaller, often under-powered scale. This led directly to our conclusion that more scientific endeavors were needed to assess the efficacy of distraction ankle arthroplasty. A second weakness was our inability to include data that did not have an English translation. Though only a few studies were identified, there does appear

a body of literature in this category. Finally, we did not discriminate papers based on surgical technique, postoperative management, length of followup, patient satisfaction or clinical results which varied significantly between papers. We included all papers that described using distraction arthroplasty in the treatment of ankle pathology. Further studies will be needed to discern the efficacy of the actual distraction arthroplasty procedure itself once its use has been defined.

## CONCLUSION

A comprehensive review of the literature has provided predominantly Level V evidence with far fewer Level II, III, and IV trials for the generally accepted indications for distraction ankle arthroplasty. There was no level I evidence. The evidence available has created a grade I recommendation for the use of the procedure in all of its generally accepted indications. More high quality, scientific studies are needed to discover the true value of distraction ankle arthroplasty.

## REFERENCES


1. **Adiela, VU; Ekere, AU; Yellowe, BE; et al:** Slow, gradual external fixator distraction in acquired ankle and foot contracture. Niger J Med. **15**:432–6, 2006.
2. **Belczyk, R; Stapleton, JJ; Zgonis, T; et al:** A case report of a simultaneous local osteochondral autografting and ankle arthrodiastasis for the treatment of a talar dome defect. Clin Pod Med Surg. **26**:335–42, 2009. http://dx.doi.org/10.1016/j.cpm.2009.01.002
3. **Buckwalter, JA:** Joint distraction for osteoarthritis. Lancet. **347**: 279–80, 1996. http://dx.doi.org/10.1016/S0140-6736(96)90463-8
4. **Chiodo, CP; McGarvey, W:** Joint distraction for the treatment of ankle osteoarthritis. Foot Ankle Clin. **9**:541–53, 2004. http://dx.doi.org/10.1016/j.fcl.2004.05.007
5. **Glazebrook M.** End-stage ankle arthritis: magnitude of the problem and solutions. Inst Course Lect. **59**:359–65.
6. **Inda, DJ; Blyakher, A; Rozbruch, SR; et al:** Distraction Arthroplasty of the Ankle Using the Ilizarov Frame. Tech Foot Ankle Surg. 2:249–253, 2003. http://dx.doi.org/10.1097/00132587-200312000-00005
7. **Kanbe, K; Hasegawa, A; Takagishi, K; et al:** Arthroscopic findings of the joint distraction for the patient with chondrolysis of the ankle. Diag Thera Endo.**4**:101–5, 1997. http://dx.doi.org/10.1155/DTE.4.101
8. **Kluesner, AJ; Wukich, DK:** Ankle arthrodiastasis. Clin Pod Med Surg. **26**:227–44, 2009. http://dx.doi.org/10.1016/j.cpm.2008.12.006
9. **Lafeber, FP; Intema, F; van Roermund, PM; et al:** Unloading joints to treat osteoarthritis, including joint distraction. Curr Opin Rheum. 18:519–525, 2006. http://dx.doi.org/10.1097/01.bor.0000240366.54960.a1
10. **Lamm, BM; Gourdine-Shaw, M:** MRI evaluation of ankle distraction: a preliminary report. Clin Pod Med Surg. **26**:185–91, 2009. http://dx.doi.org/10.1016/j.cpm.2008.12.007
11. **Marijnissen, AC; van Roermund, PM; van Melkebeek, J; et al:** Clinical benefit of joint distraction in the treatment of ankle osteoarthritis. Foot Ankle Clin. **8**:335–46, 2003. http://dx.doi.org/10.1016/S1083-7515(03)00044-5
12. **Marijnissen, AC; van Roermund, PM; van Melkebeek, J; et al:** Clinical benefit of joint distraction in the treatment of severe osteoarthritis of the ankle: proof of concept in an open prospective study and in a randomized controlled study. Arth Rheum. **46**:2893–902, 2002. http://dx.doi.org/10.1002/art.10612
13. **Martin, RL; Stewart, GW; Conti, SF:** Posttraumatic ankle arthritis: an update on conservative and surgical management. J Ortho Sports Phys Ther. **37**:253–9, 2007.
14. **Morse, KR; Flemister, AS; Baumhauer, JF; et al:** Distraction arthroplasty. Foot Ankle Clin. **12**:29–39, 2007. http://dx.doi.org/10.1016/j.fcl.2006.11.003
15. **Paley, D; Lamm, BM:** Ankle joint distraction. Foot Ankle Clin. **10**:685–98, 2005. http://dx.doi.org/10.1016/j.fcl.2005.06.010
16. **Paley, D; Lamm, BM; Purohit, RM; et al:** Distraction arthroplasty of the ankle–how far can you stretch the indications? Foot Ankle Clin. **13**:471–84, 2008. http://dx.doi.org/10.1016/j.fcl.2008.05.001
17. **Ploegmakers, JJ; van Roermund, PM; van Melkebeek, J; et al:** Prolonged clinical benefit from joint distraction in the treatment of ankle osteoarthritis. Osteo Cart. **13**:582–8, 2005. http://dx.doi.org/10.1016/j.joca.2005.03.002
18. **Rockett, MS; Ng, A; Guimet, M:** Posttraumatic ankle arthrosis. Clin Pod Med Surg. **18**:515–35, 2001.
19. **Rodriguez, EG; Hall, JP; Smith, RL; et al:** Treatment of osteochondral lesions of the talus with cryopreserved talar allograft and ankle distraction with external fixation. Surg Tech Int. **15**:282–8, 2006.
20. **Rozbruch, SR:** Posttraumatic reconstruction of the ankle using the Ilizarov method. Hosp Spec Surg J. **1**:68–88, 2005.
21. **Sabharwal, S; Schwechter, EM:** Five-year followup of ankle joint distraction for post-traumatic chondrolysis in an adolescent: a case report. Foot Ankle Int. **28**:942–8, 2007. http://dx.doi.org/10.3113/FAI.2007.0942
22. **Tellisi, N; Fragomen, AT; Rozbruch, SR; et al:** Joint preservation of the osteoarthritic ankle using distraction arthroplasty. Foot Ankle Int. **30**:318–25, 2009. http://dx.doi.org/10.3113/FAI.2009.0318
23. **van Roermund, PM; Lafeber, FP:** Joint distraction as treatment for ankle osteoarthritis. Inst Course Lect. **48**:249–54, 1999.
24. **van Roermund, PM; Marijnissen, AC; Lafeber, FP:** Joint distraction as an alternative for the treatment of osteoarthritis. Foot Ankle Clin. **7**:515–27, 2002. http://dx.doi.org/10.1016/S1083-7515(02)00027-X
25. **van Roermund, PM; van Valburg, AA; Duivemann, E; et al:** Function of stiff joints may be restored by Ilizarov joint distraction. Clin Ortho Relat Res. **348**:220–7, 1998. http://dx.doi.org/10.1097/00003086-199803000-00033
26. **van Valburg, AA; van Roermund, PM; Lammens, J; et al:** Can Ilizarov joint distraction delay the need for an arthrodesis of the ankle? A preliminary report. J Bone Joint Surg Br. **77**:720–5, 1995.
27. **van Valburg, AA; van Roermund, PM; Marijnissen, AC; et al.:** Joint distraction in treatment of osteoarthritis: a two-year follow-up of the ankle. Osteo Cart. **7**:474–9, 1999. http://dx.doi.org/10.1053/joca.1998.0242
28. **Wright, JG; Einhorn, TA; Heckman, JD:** Grades of recommendation. J Bone Joint Surg Am. **87**:1909–10, 2005. http://dx.doi.org/10.2106/JBJS.8709.edit
29. **Wright, JG; Swiontkowski, MF; Heckman, JD:** Introducing levels of evidence to the journal. J Bone Joint Surg Am. **85**:1–3, 2003.
30. **Younger, AS; Morrison, J; MacKenzie, WG:** Biomechanics of external fixation and limb lengthening. Foot Ankle Clin. **9**:433–48, 2004. http://dx.doi.org/10.1016/j.fcl.2004.05.015
31. **Zgonis, T; Roukis, TS; Polyzois, V:** Alternatives to ankle implant arthroplasty for posttraumatic ankle arthrosis. Clin Pod Med Surg. **23**:745–58, 2006. http://dx.doi.org/10.1016/j.cpm.2006.07.001
32. **Zgonis, T; Stapleton, JJ; Roukis, TS:** Use of Circular External Fixation for Combined Subtalar Joint Fusion and Ankle Distraction. Clin Pod Med Surg. 25:745–53, 2008. http://dx.doi.org/10.1016/j.cpm.2008.05.012