Effectiveness of the Lapidus plate system in foot surgery: A PRISMA compliant systematic review

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Abstract
Lapidus arthrodesis is an established standard procedure to correct various foot surgery problems and hallux limitus, hypermobility of the first ray, hallux abductus valgus, and symptomatic lesser metatarsal. After decades, many fixation methods in the orthopaedic surgery industry have been developed for decreasing complications and improving this technique. The aim of this PRISMA compliant systematic review is to analyse the effectiveness of several Lapidus plate systems in foot surgery. We have carried out the first systematic review of the relevant published literature so as to systematically evaluate the scientific knowledge available now on this association, assigning predefined eligibility criteria. Fourteen studies were selected which had an overall of 738 cases. The first tarsal metatarsal joint and hallux valgus were treated by the application of different types of Lapidus plate system. The optimal level of the fixation in these procedures is related with the type and system insertion place of the plate with or without screw in each specific foot disease. There is an insufficient number of studies about the effectiveness of the different types of Lapidus plate system in foot surgery, and there is a need to increase outcomes knowledge on the level of the fixation, sort of the system, and insert place in foot surgery.

KEYWORDS
arthrodesis, bone-implant interface, foot, hallux

Key Messages
- We have evaluated the effectiveness of several lapidus plate systems in foot surgery
- Insufficient effectiveness of types of Lapidus plate system for treatment foot surgery
- The increase of outcomes knowledge of Lapidus plate system in foot surgery plays a key to control foot health
1 | INTRODUCTION

Lapidus arthrodesis may be considered as a first-line intervention is an established procedure of choice commonly to correct various foot surgery problems as well as hallux limitus, hallux valgus, hallux varus, hindfoot deformity, hypermobility of the first ray, metatarsal adductus, and symptomatic lesser metatarsal, \(^1^,\ 5\) because this surgical technique can re-establish the biomechanical characteristics of the first ray alignment in three planes motion. \(^6\)

After decades, these foot problems are known as an essential public health condition, related with the increase of this high prevalence, influence negative in the quality of life and the increase of orthopaedic foot surgery that is related to pain at the low back, hip, knee and osteoarthritis in the first ray joint, balance disturbance and danger of falls. \(^7^,\ 11\)

In this way, many fixation methods in the orthopaedic surgery industry have been developed to increase effectiveness and decrease worrisome complications such as malunion, nonunion, and metatarsal shortening to improve this technique's outcomes. \(^12\)

Thus, many modifications in the Lapidus procedure have been performed maybe to the technical problems related to the fixation and the surgical procedure methods, in order to improve the findings and to decrease complications during all this time. \(^6\)

Several research studies showed rates up to 25% \(^12\) related to conditions in orthopaedic foot surgery mistake concerns associated with: (a) inadequate internal fixation, (b) low joint preparation, (c) wound postoperative care, (d) large incision with aesthetically may not be nice to the patient, (e) stress on surrounding joints, (f) nonweight bearing long period and (g) inadequate patient selection (smokers, nutritional status, bone quality). \(^5^,\ 13^,\ 14\)

To date, there have not found investigations analysing the concerns to improve these several and fundamental problems related to the Lapidus arthrodesis procedure is unclear.

Our hypothesis that is few the clinical trials and studies about the effectiveness of the various Lapidus plate system in foot surgery.

This PRISMA compliant systematic review aims to analyse the effectiveness of several Lapidus plate systems in foot surgery.

2 | MATERIALS AND METHODS

2.1 | Design

This PRISMA compliant systematic review was recorded in the International Prospective Register of Systematic Reviews on health sciences associated topics, \(^15\) file number CRD42021237437.

2.2 | Search strategy

An electronic search was carried out in the MEDLINE and Web of Science using keywords and controlled vocabulary terms (i.e., medical subheading [MeSH] terms). Keywords include Lapidus plate system terms (arthrod esis, bone-implant interface, hallux, foot) and treatment-related terms (Lapidus plate system, Lapidus procedure, first metatarsocuneiform arthrodesis, foot surgery). Our search protocol strategy realised can be revised in the Supplementary info.

Besides, this review period was set during the last 10 years, and all research available in these two databases until February 2021 was included. We considered manuscripts reporting completed randomised clinical trials and controlled clinical trials published in international peer-reviewed papers. All references included in these papers published in Spanish or English were revised and restringing the evaluate and these languages.

Besides, special attention was used on the electronic search in two databases, to be assured to include all relevant research, even though at the risk of identified irrelevant information that would afterward have to be removed.

2.3 | Inclusion and exclusion criteria

We applied the selection of these inclusion and exclusion criteria to determine which investigations were incorporated in the systematic review related to used different types of Lapidus plate system. The selection of variables included were: (a) randomised clinical trials and controlled clinical trials of the last 10 years, (b) cases of patients or fresh-frozen human cadavers, (c) various foot problems, (d) type intervention on foot, (e) different plate system, (f) selection of the system insertion place, (g) outcomes measures, (h) time of follow-up, (i) efficacy level of the fixation, and (j) studies written in Spanish or English.

Disregarded criteria included were: (a) observational studies with sawbones anatomical models or finite element method, (b) letters, commentaries, expert opinions, editorials, and other non-original studies, and (c) research published in other languages different from Spanish or English. \(^15\)
| #  | Cases | Foot problem | Intervention | Type of the system | System insertion place | Outcomes measures | Follow up | Level of the fixation |
|----|-------|--------------|--------------|-------------------|-------------------------|-------------------|----------|-----------------------|
| Garas et al (2018) | 10 | First tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Total compression plate system with or without a 3.5-mm locking Screw (OrthoPro, Salt Lake City, Utah) | Medially first tarsometatarsal | Tekscan FlexiForce A201 Variable Resistance Sensors - Fluoroscopy | 12 h | Optimal (3.5-mm locking screw) |
| | | | | | - Medially plate with a planar interfragmentary screw | - Medially plate with a planar interfragmentary screw | None | Medium (without a 3.5-mm locking screw) |
| Cotom & Baker (2017) | 16 | First tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Low-profile system locking Lapidus plate (Arthrex, Naples, Florida) with a 4.5-mm cannulated screw - Plantarly applied locking plate (Arthrex, Naples, Florida) with a 4.0-mm compression screw | Plantar approach with intraplate lag screw placement | 8871 Servo Hydraulic Materials Testing System (Instron, Canton, Massachusetts) | None | Optimal (medially plate) |
| | | | | | - Medially plate with a plantar interfragmentary screw | - Medially plate with a plantar interfragmentary screw | None | Medium (plantarly plate) |
| Gutteck et al (2018) | 126 | Hallux Valgus | Osteosynthesis of the first tarsal metatarsal joint | Darco, Wright Medical® (Germany GmbH) | Plantar plate osteosynthesis | Digital measuring system PACS - Emed1-x400 sensor plate (Novel GmbH, Munich) | 12 mo | Optimal (plantarly plate) |
| Cotom et al (2013) | 10 | First tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Arthrex® LPS Lapidus plate (Arthrex, Naples, Florida) with a 4.5-mm cannulated PIFS | Medial side of the locking plate with an intraplate compression screw - Medial side of the locking plate with a plantar interfragmentary screw 4.5-mm cannulated | 8871 Servo Hydraulic Materials Testing System (Instron, Canton, Massachusetts) - OriginPro, version 8, software (OriginLab, Northhampton, Massachusetts) | None | Optimal (interfragmentary screw) |
| | | | | | - Medial side of the locking plate with a plantar interfragmentary screw 4.5-mm cannulated | - OriginPro, version 8, software (OriginLab, Northhampton, Massachusetts) | None | Medium (intraplate compression screw) |
| Menke et al (2011) | 21 | Hallux abducto valgus Metatarsus primus varus, Metatarsocuneiform arthrodeses | Interfragmental lag screw and a Darco locking H-plate | Medial to slightly plantar-medial Metatarsocuneiform | Radiographs | 16.76 mo | Sufficient |
| Garas et al (2018) | 10 | First tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Total Compression Plate System with or without a 3.5-mm locking Screw (OrthoPro, Salt Lake City, Utah) | Medially first tarsometatarsal | Tekscan FlexiForce A201 Variable Resistance Sensors - Fluoroscopy | 12 h | Optimal (3.5-mm locking screw) |
| | | | | | - Medially first tarsometatarsal | - Medially first tarsometatarsal | None | Medium (without a 3.5-mm locking screw) |

(Continues)
| Cases | Foot problem | Intervention | Type of the system | System insertion place | Outcomes measures | Follow up | Level of the fixation |
|-------|--------------|--------------|--------------------|------------------------|-------------------|----------|-----------------------|
| Cotom & Baker (2017) | 16 | first tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Low-profile system locking Lapidus plate (Arthrex, Naples, Florida) with an 4.5-mm cannulated screw | Medially plate with a planar interfragmentary screw | -Optimal (medially plate) |
| | | | | Plantarly applied locking plate (Arthrex, Naples, Florida), with a 4.0-mm compression screw | Plantarly applied plate with intraplate lag screw placement | | |
| | | | | -8871 Servo Hydraulic Materials Testing System (Instron, Canton, Massachusetts) | | |
| | | | | None | | |
| | | | | -Optimal (medially plate) | | |
| | | | | -Medium (plantarly plate) | | |
| Gutteck et al (2018) | 126 | Hallux Valgus | Osteosynthesis of the first tarsal metatarsal joint | Darco, Wright Medical® (Germany GmbH) | Plantar plate osteosynthesis | 12 mo | Optimal (plantarly plate) |
| | | | | | Digital measuring system PACS - Emed1-x400 sensor plate (Novel GmbH, Munich) | | |
| Cotom et al (2013) | 10 | first tarsal metatarsal joint | Arthrodesis of the first tarsal metatarsal joint | Arthrex® LPS Lapidus plate (Arthrex, Naples, Florida) with a 4.5-mm cannulated PIFS | Medial side of the locking plate with an intraplate compression screw | None | -Optimal (interfragmentary screw) |
| | | | | Medical side of the locking plate with a planter interfragmentary screw 4.5-mm cannulated | -8871 Servo Hydraulic Materials Testing System (Instron, Canton, Massachusetts) - OriginPro, version 8, software (OriginLab, Northhampton, Massachusetts) | | |
| | | | | | | | -Medium (intraplate compression screw) |
| Menke et al (2011) | 21 | Hallux abducto valgus Metatarsus primus varus, Metatarsocuneiform instability | Metatarsocuneiform arthrodeses | Interfragmental lag screw and a Darco locking H-plate | Medial to slightly plantar-medial Metatarsocuneiform | Radiographs | Sufficient |
| | | | | | | | 16.76 mo | |
Synthesis of information and management of search results

Two expert reviewers checked the search results in this Lapidus plate system in foot surgery (D.L.L. and J.B.L.) and if there were doubts about something, any research regarding the inclusion and exclusion criteria, this was clear up by accord us of all authors. All references added were manually evaluated, and those articles that might be incorporated were also reviewed and obtained.

**FIGURE 1** Flowchart of the included studies describing Lapidus plate system in foot surgery

**FIGURE 2** Risk of bias graph in the studies included. (1) Green (low risk), (2) white (unclear risk) and (3) red (high risk)
We recuperated the self-same information related to all articles resulting from the PRISMA declaration, using a standardised rule associated only with a present Table 1 with common fields for every paper. We showed information from every single research in an evidence table with qualitative information, and a global conclusion has been realised. The risk of bias assessment in the systematic review was analysed using the tool Review Manager (RevMan) of The Cochrane Library, v.5.3. It has not been possible to perform a meta-analysis because of the principal heterogeneity of the incorporated studies.

3 | RESULTS

3.1 | Summary of the investigations included

Figure 1 shows up the flowchart of the information published in the articles related to the Lapidus plate system in foot surgery retrieved.

Complete 14 research studies fulfilled all the inclusion criteria. Most of the records evaluated were articles on randomised clinical trials and controlled clinical trials. The major part of the papers corresponded to measurements of cases of patients, with eight and fresh-frozen human cadavers, with six studies in each and all information is shown in Table 1.

Finally, the risk of bias was analysed in 14 research studies. Only two studies recorded a low risk in random sequence generation. All studies showed an unclear risk of bias in terms of: (a) allocation concealment, (b) blinding of participants and personnel, (c) blinding of outcome assessment, (d) selective reporting, and (e) other bias. The incomplete outcome data were the low bias in these studies. All information are shown in Figures 2 and 3.

4 | DISCUSSION

To the best of our knowledge, this is a novel systematic review. The first focused on relevant published literature that exclusively evaluates the scientific knowledge available on the effectiveness of Lapidus plate systems in foot surgery.

We have found that Lapidus arthrodesis is a standard procedure of choice to correct the first tarsal metatarsal joint and hallux valgus associated with instability. This is a principal technique for arthrodesis of the first tarsal metatarsal joint. This surgical technique can re-establish the first ray alignments biomechanical characteristics in three planes of motion.6

Due to the ostensible heterogeneity evaluated among cases and interventions performed, relationated to the system insertion place, outcomes measures, and follow-up in the available studies with different types system plate used, the investigations recognised that the investigations included various types of the system of fixation.

Indeed, it was detected that the investigations showed the most level of fixation in this procedure with compression plate system with screws, this manner if help to the immediate weight-bearing, with good clinical and radiographic results in the most of the cases.16-24
The majority of these studies showed the optimal system insertion place of the Lapidus plate system in foot surgery is plantarly or dorsomedial applied plate combined with the plate system with screws in this procedure seems to provide an excellent option to increase control and avoid the elevation in the first metatarsal joint.

It is necessary for Lapidus plate system selection to consider availability, cost, structural integrity to identify the fixation construct. For that, it must be analysed and contrasted the biomechanical functionality, the size plate system for the patient’s to obtain in the foot surgery the more adequate fixation system in each case.

This systematic review highlights some limitations of the low available evidence, consequence to the heterogeneous methods related to these studies, which did not offer the opportunity to carry out a meta-analysis. Furthermore, some investigations included cases of patients while others fresh-frozen human cadavers and differences in the measures of the main characteristics of the included studies.

Finally, the present systematic review gives helpful information to foot and ankle surgery researchers and clinicians regarding the Lapidus plate system’s effectiveness. Furthermore, it shows the importance of continuous investigation on this procedure to improve the surgical outcome and the patients’ quality of life.

5 | CONCLUSIONS

There is an insufficient number of studies about the effectiveness of the different type of Lapidus plate system in foot surgery. There is a need to increase outcomes knowledge on the fixation level, type of the system, insert place in foot surgery.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

Daniel López-López: Conceptualization; data curation; formal analysis; investigation; methodology; supervision; writing—original draft; writing—review and editing.

Ricardo Larrainzar-Garjo: Conceptualization; investigation; methodology; supervision; writing—original draft; writing—review and editing.

Daniel Larrainzar-Garijo: Conceptualization; data curation; formal analysis; investigation; methodology; supervision; writing—original draft; writing—review and editing.

Javier Bayod López: Conceptualization; data curation; formal analysis; investigation; methodology; supervision; writing—original draft; writing—review and editing.

DATA AVAILABILITY STATEMENT

The dataset supporting the conclusions of this article is available in the daniellopez@udc.es in the Research, Health and Podiatry Group. Department of Health Sciences. Faculty of Nursing and Podiatry. Universidade da Coruña, Ferrol, Spain.

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