1	TITLE: A comparison of two designs of postoperative shoe for
2	hallux valgus surgery: A biomechanical study in cadaveric
3	model
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TITLE: A comparison of two designs of postoperative shoe for hallux valgus surgery: A biomechanical study in a cadaveric model

44 ABSTRACT

45 **Background:**

Hallux Valgus Surgery success depends not only on the operative technique, but also
on the care of the foot during the postoperative period. Orthopedic shoes have been
developed to decrease the weight load on the first ray, an excess of which might lead
to a loss of fixation or pseudoarthrosis.

50 The goal of this study was to determine how the load distribution changed as the forced 51 applied to the foot increased, with and without an orthopedic shoe. Also, we compared 52 to different shoe models.

53 Methods:

Pressure sensors were placed under the first metatarsal head and the heel of twenty specimens of fresh cadaveric adult feet. Two orthopedic shoes were chosen, a double padded (MS) and a reverse camber shoe (RCS). 10 kg loads were progressively applied, up to 60 kg. We first compared three instances: no shoe, MS and RCS. A secondary analysis comparing barefoot versus shoes was performed. A mean comparison was performed (ANOVA / T-student).

60 **Results:**

61 The mean pressure of the heed and the first metatarsal showed that there were 62 significant differences between groups (P < .005). The secondary analysis (no shoe vs

63	orthopedic shoes) showed that the pressure without shoe was significantly higher than
64	with any orthopedic shoe ($P < .005$). There were no statistically significant differences
65	between models of shoes ($P = .402$).
66	Conclusion:
67	After a surgical procedure for hallux valgus fixation, postoperative shoes should be
68	indicated to decrease the pressure on the first metatarsal head and heel in order to avoid
69	an overload of the postoperative area.
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71	Level of evidence
72	Cadaveric study. Level V.
73	
74	KEY WORDS
75	Hallux valgus; Orthopedic shoe; Postoperative; Forefoot relief; Plantar pressure
76	distribution
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84 INTRODUCTION

Several operative methods exist for the treatment of a symptomatic hallux valgus, most of them based on the osteotomy of the first metatarsal bone, which can be open or percutaneous. The amount of force applied to certain areas of the foot after hallux valgus surgery might determine the success or failure of the surgery. For that reason, during the immediate postoperative weeks most surgeons prefer their patients not to or partial weightbear. [1]

With the intention of reducing the pressure in specific points, orthopedic postoperative
shoes are indicated. The goal of these shoes should be to decrease the force applied on
the first metatarsal while, at the same time, allow the patient to walk with relative ease.
Failure to do so may lead to a loss of fixation of the osteotomy, and to malunion or
non-union of the osteotomy. [2]

96 There are many different options regarding postoperative shoes, and the literature 97 available on these devices is limited. Most of the studies available compare different 98 kinds of postoperative shoes by studying the plantar pressure distribution using load 99 sensors on healthy young subjects. [2-7] Other authors analyze patient satisfaction and 100 compliance on patients who underwent forefoot surgery for hallux valgus deformities. 101 [8-10]

102 There is no clear evidence about which postoperative shoe is more effective in 103 decreasing the load on the foot. We chose two designs of postoperative shoe, which are 104 the most used by foot surgeons in our environment, in order to compare them.

105 The goal of this study was, firstly, to determine whether these shoes would decrease 106 the pressure on the first metatarsal head compared to a bare foot. Secondly, to

determine which of these shoes would be more effective. And lastly, how the loaddistribution changed depending on the force applied to the foot.

109 MATERIAL AND METHODS

An experimental model was designed for analysis of loads in two different points of the foot. First metatarsal head and heel were considered the most clinically relevant points and were selected for this analysis. The study was conducted in the experimental anatomy laboratory at Girona University between May and July 2016.

114 Specimens

Twenty adult fresh-frozen cadaveric feet were used in this research. Specimens were obtained from a body donation program of the university following the legal procedures and ethical framework governing the body donation in Spain. The study was conducted in the experimental anatomy laboratory.

Each specimen consisted of a whole foot and the distal third of tibia and fibula.
Specimens with macroscopically visible scars, prior traumatic history or evidence of
osteo-degenerative diseases were excluded. Age of specimens ranged from 62 to 84
years. Before starting the biomechanical tests, feet were thawed at room temperature.

123 Orthopedic Shoes

Two designs of shoes were used, both from Darco (Darco International, Inc, Huntigton,
West Virginia, USA). The first one was a double padded postoperative shoe, Darco
MedSurg shoeTM (MS), and the second one was a reverse camber shoe, Darco
OrthoWedgeTM (RCS) (Figure 1).

128 Measurements and instrumentation

A torque-based force bench was designed, which allowed a stable attachment of the tibia. With the ankle in neutral position, vertical force could be applied which was measured by a dynamometer (Mecmesin BFG 1000N, Mecmesin Ltd, Slinford, UK) (Figure 2).

Barographic data were obtained using the I-ScanTM cable system. 400-1500 K-Scan Sensors (Tekscan Inc, South Boston, USA) were placed under the heel and the first metatarsal (Figure 3). Each sensor was equipped with 62.0 sensels/cm². The data were collected by cable and analyzed by I-ScanTM Pressure Mapping System.

Measurements were performed on each foot representing three instances: no shoe, MS
and RCS (Figure 4). The load on the foot would be increased in 10 kg intervals, up to
60 kg. Readings on both the heel and the first metatarsal sensors were taken. Unit of
measurement was Newtons (N).

141 Statistical Analysis

142 The data were analyzed using SPSS software (SPSS IBM \mathbb{R} , Chicago, USA). The data 143 from both the heel and the first metatarsal were analyzed separately. Statistical 144 significance was set at P < .05.

Two different analysis were stablished. First one, a comparison between 3 different
groups (no shoe, MS and RCS). Three-groups ANOVA was chosen as statistical test.
The second analysis compared no shoe versus orthopedic shoe, regardless of the design.
Mean of loads and standard variation were calculated using one-tailed T-student.

149 Ethical Statement

150 Regarding the specimens, ethical aspects were covered according the declaration of

151 Helsinki. All specimens were anonymized, and the research project was approved by

the Doctoral commission of the University.

153 The authors state there are no conflicts of interest. There were no funding sources.

154 **RESULTS**

Heel Pressures

156 The mean pressure of the heel was: no shoe 34.982 N, MS 19.260 N, and RCS 14.537

157 N. The ANOVA analysis showed that there were differences between groups (P <

158 .005).

159 The secondary analysis (no shoe vs orthopedic shoes) showed that the pressure on the 160 heel without shoe was significantly higher than with any orthopedic shoe (P < .005).

After applying a progressive load increase, no statistical differences were found with small loads (10 and 20 kg), while from 30 kg load the heed pressure decreased significantly with any orthopedic shoe (Table 1 and Figure 5).

164 Metatarsal pressure

165 The mean pressure on the first metatarsal was: no shoe 8.824 N, MS 2.622 N, and RCS 166 3.185 N. The ANOVA analysis showed that there were significant differences between 167 groups (P < .005).

Again, comparing bare foot and orthopedic shoe, the T-student showed that the pressure on the first metatarsal decreased significantly using any orthopedic shoe compared to no shoe. 171 The analysis of progressive loads showed that the differences were no significant in 10

kg and 20 kg load. However, from 30 kg onward the pressure was significantly higher

- in the barefoot group (Table 2 and Figure 6).
- There were no differences between models of orthopedic shoes, either MS or RCS (P= .402) for any of the different loads (Table 3 and Figure 7).

176 **DISCUSSION**

Hallux valgus (HV) is the most common pathological condition on the first
metatarsophalangeal joint. [6,11] For its correction many different surgical techniques
have been described, from soft tissue procedures to osteotomies of the first metatarsal.
[2]

During the postoperative period, surgeons might allow full weightbearing with a postoperative shoe. [10] Depending on the stability of the osteotomy and the bone quality, some authors might choose to allow partial weightbearing [12] and even not weightbearing at all. [11] Although no clear evidence on the subject is available, it is clear that an excess of load on the osteotomy may lead to a loss of reduction and malunion or non-union. [2]

Under normal circumstances, during barefoot standing, the forefoot carries 28% of the weightbearing load. [6,14] During the third rocker of a normal gait, the flexor hallucis longus and brevis muscles exert about 52% and 36% of body weight, respectively, and the peroneus longus muscle more than 58% of the body weight. [13] This produces an axial load on the first metatarsal head, resulting to about 119% of the body weight, making the first ray the most heavily loaded structure of the forefoot. [13-15]

Because the flexible sole of an ordinary shoe increases the total area of foot contactduring the stance phase, several different models of orthopedic shoes have been

described to reduce the load on the first ray, as well as, on other specific areas of the foot. [3,16] Therefore, the objective of postoperative shoes is to provide a weight relief on the forefoot, allowing bony healing and diminishing the risk of loss of reduction.

Our study focused on plantar pressure distribution in bare foot and with two differently designed forefoot relief shoes. Both shoes are used frequently as a postoperative shoe in our environment, and there is no clear evidence about which one of them is more effective in decreasing the load on the first metatarsal, so the decision seems to be relying on the surgeon's personal choice.

The goal of our research was to study how the weight would be distributed in each circumstance (no shoe, MS and RCS), and if those differences would change as the load on the foot increased.

Several studies have described the use of pressure-sensitive pads in measuring the loads applied to the foot, mostly on healthy young individuals who were asked to walk with or without postoperative shoes, thus having little control on how much force was the foot receiving on each step. [2-7] Working in a cadaveric lab allowed us to apply a precise and known amount of force on each foot, therefore registering the change in distribution as the weight increased.

In our study, no differences were found between wearing a shoe or being bare foot under 30 kg load. This stablishes a threshold load, under which it would not be worth using an orthopedic shoe (i.e. non weightbearing or bearing less than 30 kg). If, however, after foot surgery partial or total weightbearing is allowed, it would be advisable to use an orthopedic shoe. As a limitation of our study, the biomechanical model we used did not allow to reproduce normal gait on the cadaveric specimen, and only axial forces were considered.

220 Several studies have compared different kinds of orthopedic shoes and have found various results. Trnka et al. compared three postoperative shoes on healthy subjects and 221 found that the lowest average peak pressure under the first metatarsal was achieved 222 223 with a reverse camber shoe, followed by the soft-soled postoperative shoe. [11] Schuh also found that the reverse camber shoe achieved the lowest peak pressure under the 224 first metatarsal, but had high forces acting on the medial forefoot, however. [2] In their 225 226 study a soft-soled postoperative shoe had the best results in both the forefoot and the hallux regions. 227

Other than providing weight relief on the forefoot, postoperative shoes should also allow the patient to walk with certain comfort. Patel et al. compared a reverse camber shoe versus a transitional rigidity shoe on patients who underwent hallux valgus surgery, and although the patients reported a similar shoe satisfaction, there was a higher incidence of back pain and non-compliance on the reverse camber shoe group. [9]

In our study, although differences were found between the two shoe groups (MS and RCS) favoring the MS model, these differences were not statistically relevant. This could be due to that the difference between both shoe groups is small, and a larger sample is needed. The small number of subjects might have been a limitation in this regard.

If, according to Patel et al. article, there might be a worse compliance with reversecamber shoe, it might make a transitional rigidity shoe preferable. [9]

241 Further research on the subject is necessary

242 CONCLUSIONS

Postoperative shoes significantly decrease the load on both the heel and the first metatarsal head when loading the foot with 30 or more kg. After a surgical procedure for hallux valgus fixation, when weightbearing is allowed, postoperative shoes should be indicated to decrease the pressure on the first metatarsal head in order to avoid an overload of the postoperative area.

No statistically relevant differences were found between the two types of shoe westudied.

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FIGURES

- Figure 1. Postoperative shoes used in the study. A: Double padded postoperative shoe, Darco MedSurg shoe [™] (MS); B: Reverse camber shoe, Darco OrthoWedge [™] (RCS).
- Figure 2. Specimen attached to torque-based force bench. A: Lateral view; B: Frontal view. The vertical force applied can be measured with a dynamometer.
- Figure 3. Placement of the sensors under the heel and the head of the first metatarsal in a specimen.
- Figure 4. Specimen with the postoperative shoe attached to torque-based force bench. It is possible to observe the placement of the sensors for data collection between the sole of the foot and the shoe.
- Figure 5. Results for heel pressure.
- Figure 6. Results for metatarsal pressure.
- Figure 7. Metatarsal Pressure. Comparison between the two orthopedic shoe designs

Weight load (kg)	No shoe	MS	RCS	Р
Mean	34.982	19.260	14.537	< .005
10	12.286	7.120	5.812	.155
20	21.649	12.212	10.101	.066
30	32.392	17.014	14.110	< .005
40	40.737	22.846	16.232	< .005
50	47.219	26.006	18.379	< .005
60	56.694	30.364	22.584	< .005

Table 1. Results for Heel Pressure (N)

Abbreviations: MS, double padded shoe; RCS, reverse chamber shoe.

Weight load (kg)	No shoe	MS	RCS	Р
Mean	8.824	2.622	3.185	< .005
10	3.465	0.906	1.400	.077
20	5.063	1.295	1.936	.057
30	7.518	1.795	2.722	.041
40	9.942	2.540	3.370	.006
50	12.986	4.164	4.106	.002
60	13.973	5.032	5.578	.004

Table 2. Results for Metatarsal Pressure (N)

Abbreviations: MS, double padded shoe; RCS, reverse chamber shoe.

Weight load (kg)	MS	RCS	Р
Mean			.402
10	0.906	1.400	.509
20	1.295	1.936	.536
30	1.795	2.722	.484
40	2.540	3.370	.591
50	4.164	4.106	.978
60	5.032	5.578	.978
40 50 60	2.540 4.164 5.032	3.370 4.106 5.578	.591 .978 .978

Table 3. Metatarsal Pressure. Comparison between MS and RCS shoes.

Abbreviations: MS, double padded shoe; RCS, reverse chamber shoe.





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