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Treatment outcome at 1 year did not differ between use of cast or walker in the first 3 weeks after an acute Achilles tendon rupture. A registry study of 1304 patients from the Danish Achilles tendon database☆

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ABSTRACT

Background: The best choice of orthosis in the treatment of acute Achilles tendon rupture is still under debate.
Objective: To investigate if choice of orthosis in the first 3 weeks of treatment affected patient reported outcome (Achilles tendon Total Rupture Score (ATRS)), tendon elongation (Achilles Tendon Resting Angle (ATRA) and Heel Rise Height (HRH)) and re-rupture.
Methods: Registry study in the Danish Achilles tendon Database. Patients treated with cast and patients treated with walker in the first 3 weeks of treatment were compared using a linear mixed-effects model adjusted for potential confounders.
Results: 1304 patients were included in the study. No clinically relevant difference was found: Adjusted mean difference (using walker the whole period as reference)(95% CI) ATRS after 1 year = 0.1(−3.0; 4.1), ATRS after 6 months = 2.0(−4.5; 5.8), ATRS after 2 years = 3.0(−0.7; 7.0), HRH difference = 0.6(−6.6; 8.2), ATRA difference = 0.03°(−1.5; 1.6), re-rupture(odds ratio) = 0.812(0.4; 1.61).
Conclusion: Patients treated with cast the first 3 weeks after acute Achilles tendon rupture did not have better treatment outcome than patients treated with walker.

1. Introduction

Acute Achilles tendon rupture (ATR) is a frequent injury (31–35 per 100.000 per year) mainly seen in active adults in their fourth and fifth decade of life [1–3]. A large proportion of the patients suffer from permanent functional deficits and unsatisfactory symptoms [3–5]. The choice of treatment regime might influence the treatment outcome and has therefore been extensively studied in the past decades. No consensus has been established and the regimes differ widely between departments [3,6,7]. Some of the components that differ are choice of operative or non-operative treatment, time in orthosis, initiation of ankle motion and initiation of weight bearing [3,8–12]. Additionally, the type of orthosis has been a topic of increased interest in recent years and it is an ongoing discussion if patients should be treated with cast or a removable walker boot [13]. Many hospitals treat patients with an equinus cast during the first 2–3 weeks after rupture (from here on phrased as 3 weeks), followed by a walker with wedges potentially allowing for controlled mobilisation of the ankle joint for the remaining period [3,6]. This choice of treatment is based on the hypothesis that a cast places the ankle in a more stable equinus position compared to a walker, and thus limits the risk of lengthening and re-rupture of the tendon [14].

☆ Level of evidence: III

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The objective of this study was to investigate how choice of orthosis in the first 3 weeks of treatment after ATR affected patient reported outcome (Achilles tendon Total Rupture Score (ATRS)), indirect measurements of Achilles tendon elongation (Achilles tendon Resting Angle (ATRA), Heel-rise Height (HRH) and incidence of re-rupture 12 months after injury. The two types of orthoses investigated were cast or walker during the first 3 weeks of treatment.

The primary hypothesis was that patients treated with cast the first 3 weeks had a minimum of 10 points higher ATRS at 1-year follow-up compared to patients treated with walker. Secondary hypotheses were that patients treated with cast during the first 3 weeks of treatment had minimum 2.3 degrees lower relative ATRA (less elongation), minimum 10% points higher HRH difference (less elongation), and minimum a 25% reduced risk of having a re-rupture at 1-year follow-up compared with patients treated with walker.

2. Material and methods

The study was performed as a registry study in the Danish Achilles Tendon Database (DADB). Data extraction was performed in August 2021.

2.1. The Danish Achilles tendon database (DADB)

DADB was established in April 2012 with the purpose of quality assurance and epidemiological research. Data is collected at five time points during the rehabilitation course: 1) First patient contact (baseline), 2) 6 months after rupture (until 2018 this was listed as 3–4 months after rupture), 3) 1 year after rupture, 4) 2 years after rupture, 5) if a complication occurs (e.g., re-rupture). The questionnaires collect data such as civil registration number, age, sex, comorbidities, prodromal symptoms, pre-injury level, treatment regime, ATRS, complications, etc. Ten orthopedic departments in Denmark currently register patients with ATR in DADB. The treatment and rehabilitation regime varies between the departments [3].

A study investigating the data in DADB registered in 2016, showed a high validity for the investigated baseline parameters and an overall completeness of 77% (155/201) [15].

2.2. Study population

Patients registered in DADB from August 2015 to June 2020 at the ten hospitals registering in DADB were eligible for inclusion. Exclusion criteria were: previous rupture of the same or contralateral Achilles tendon, missing baseline data on variables included in the analyses and chronic rupture (defined as treatment start more than 14 days after rupture [3]).

2.2.1. Sample size

The sample size calculation was based on data from all patients registered in DADB the 30th of December 2020. The standard deviation (SD) for ATRS at 1-year follow-up was 25.8. The mean ATRS at 1-year follow-up was 57. We considered a 10-points difference in ATRS to be clinically relevant. Power was set at 0.8 and the alpha value was set at 0.05. Based on these values the minimum number of patients to be recruited was 208 (104 in each group).

2.3. Patient groups

The patients included in the study were divided into two groups according to choice of orthosis during the first 2 or 3 weeks after ATR (listed as the first 3 weeks in this article). One group included patients treated with an equinus plaster cast for the first 3 weeks followed by a rigid walker boot with wedges the remaining period. The second group included patients treated with a rigid walker boot with wedges for the whole period. Both groups had wedges removed from the walker over time, slowly reducing the angle of the equinus to 90°.

2.4. Primary outcome

The primary outcome was the difference between the two groups in ATRS as an absolute value 1 year after the injury occurred. ATRS is a patient reported outcome measure developed to evaluate severity of symptoms after an ATR. Patients are asked 10 questions describing their limitations on a scale from 0 to 10, where 0 indicates major limitations and 10 indicates no limitations. The maximum score is 100 points, which corresponds to no limitations or symptoms from the Achilles tendon [16,17]. A study from 2013 showed a strong validity and a good reliability for this type of patient reported outcome [17]. A clinically relevant difference in ATRS is considered to be 10 points [16].

2.5. Secondary outcome

The secondary outcomes of the study were ATRS difference at 6-months and 2-years follow-up, re-rupture at 1-year follow-up, Achilles Tendon Resting Angle (ATRA) difference at 1-year follow-up and Heel-rise height (HRH) difference at 1-year follow-up.

ATRA is an indirect measurement of Achilles tendon length [4]. The patient is positioned prone with the knee flexed 90 degrees and the ankles relaxed. The angle of the ankle is measured by placing the center of a goniometer over the distal part of the lateral malleolus and the two ends of the goniometer pointing towards the center of the head of the 5th metatarsal and the fibular head. The angle is measured bilaterally, and the difference between the legs defines the ATRA [4]. The measurement has shown excellent reliability [18,19] and acceptable construct validity [20].

HRH is a measure of maximum heel lift and an indirect measurement of Achilles tendon length [21]. The test is performed standing on one leg on a 10-degree inclined box, lifting the heel as high as possible from the box. The test is repeated on both legs, starting with the uninjured. The distance from the calcaneus to the box is measured, and the relative difference between the legs is calculated $(HRH_{injured}/HRH_{uninjured})^*$ 100%. An HRH close to 100% suggests a good treatment result on the injured leg. The test has shown excellent validity and good reliability [21,22].

2.6. Confounding variables

Confounding variables were: Sex (men/women). Comorbidities (diabetes, hypertension and rheumatic disease) or treatment with corticosteroids within the last 6 months. Age divided into 3 groups (< 35 years/35–65 years/ > 65 years) based on potential association between the outcomes and the patient's age. Treatment (operative/non-operative). Time from injury to treatment (< 5days/5 days or more), initiation of treatment was defined as the day the patient had an orthosis applied in the emergency room/doctor's office. Treatment regime including time in orthosis (less than 7 weeks/ 7–8 weeks/ more than 8 weeks), initiation of ankle motion (at week 1 and 2/ at week 3/ at week 4 or later) and initiation of weight bearing (week 1/ at week 2 and 3/ at week 4 or later). ATRS at baseline, registered by the patient assessing their symptoms a week before the injury.

2.7. Statistics

Descriptive baseline data were reported for patients treated with walker and with cast and walker.

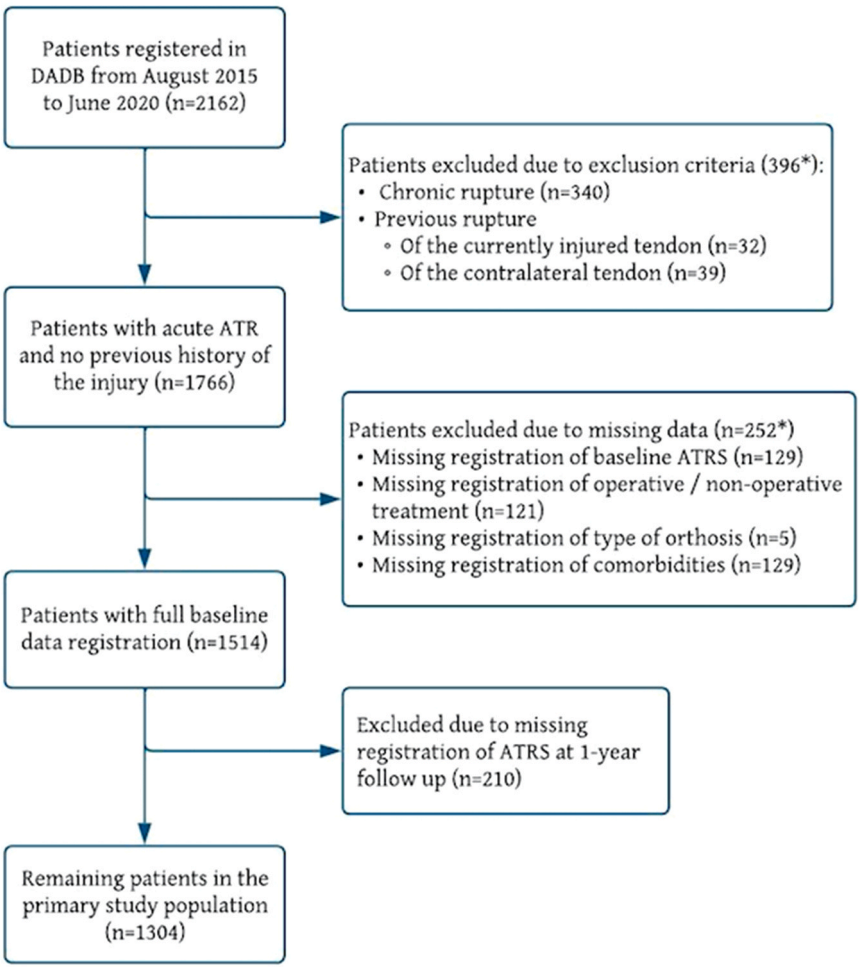

Fig. 1. Flow chart of the primary population. * A patient can be listed with several exclusion criteria and thus count more than once in the given box in the flowchart. However, a patient cannot appear in two different boxes in the chart.

2.7.1. Primary analysis

The primary analysis was performed using a linear mixed-effect model with ATRS at 1-year follow-up as outcome. The fixed effects in the model were choice of orthosis and the confounding variables (sex, age group, baseline ATRS (prior to rupture), comorbidities, corticosteroids use, treatment and rehabilitation regime, and time from injury to treatment start). The random effect was the treating hospital.

2.7.2. Secondary analyses

Four of the secondary analyses were performed with the same linear mixed-effects models as used in the primary analysis. The analyses were performed as four different analyses, with the outcome set as ATRS at 6-months follow-up, ATRS at 2-year follow-up, difference in ATRA after 1 year and HRH difference after 1 year, respectively.

Re-rupture was a dichotomous outcome and was analyzed with a logistic mixed-effects model. The outcome was re-rupture at 1-year follow-up and the fixed and random effects were the same as in the analyses mentioned above.

2.7.3. Sensitivity analysis

A sensitivity analysis was made dividing the population into operatively and non-operatively treated patients. The difference between the use of cast the first 3 weeks and walker the first 3 weeks were investigated using the same linear mixed-effect model as in the primary analysis.

Statistical analyses were performed using R 4.1.0 (R Foundation for statistical computing, Vienna, Austria), with the level of statistical significance set at $p < 0.05$.

3. Results

There were 2162 patients registered with an Achilles tendon rupture in DADB from August 1st, 2015 to June 30th, 2020. According to criteria 858 were excluded leaving 1304 patients for the primary study population (Fig. 1).

The study populations for the secondary analyses were based on the primary study population excluding patients with missing data on the relevant outcome of the analysis.

Of the 1304 patients in the population, 764 were treated with a walker during the whole orthosis-period, and 540 were treated with a cast for the first 3 weeks followed by a walker. In the walker group 81 patients were treated operatively and 683 were treated non-operatively. In the cast group 132 were treated operatively and 408 non-operatively. Descriptive baseline characteristics of the two groups are listed in Table 1. The ATRS at baseline was similar for the patients treated with walker and the patients treated with cast. The rate of comorbidities was also similar for both groups. However, the patients treated with walker were slightly older and more likely to be treated non-operatively. Moreover, the rehabilitation regime varied between the groups, as most of the patients treated with walker were allowed to do ankle motion and ankle support at week 1.

Table 1
Descriptive baseline characteristics.

	Walker n (%)		Cast n (%)		Overall n (%)	
Number of patients	764		540		1304	
Hospital						
Aalborg	347	(45)	11	(2)	358	(27)
Farsø	5	(1)	0	(0)	5	(0)
Hjørring	63	(8)	0	(0)	63	(5)
Hvidovre	20	(3)	260	(48)	280	(21)
Kolding	39	(5)	43	(8)	82	(6)
Køge	34	(4)	133	(25)	167	(13)
Nykøbing F	64	(8)	1	(0)	65	(5)
Slagelse	71	(9)	2	(0)	73	(6)
Thisted	51	(7)	1	(0)	52	(4)
Viborg	70	(9)	89	(16)	159	(12)
Sex						
Male	605	(79)	435	(81)	1040	(80)
Female	159	(21)	105	(19)	264	(20)
Age						
< 35 years	100	(13)	67	(12)	167	(13)
35–65 years	507	(66)	391	(72)	898	(69)
> 65 years	157	(21)	82	(15)	239	(18)
Rehabilitation regime						
Initiation of ankle motion						
At week 1–2	620	(81)	169	(31)	789	(61)
At week 3	104	(14)	263	(49)	367	(28)
At week 4 or later	40	(5)	108	(20)	148	(11)
Weightbearing allowed						
At week 1	199	(26)	0	(0)	199	(15)
At week 2–3	531	(70)	485	(90)	1016	(78)
At week 3 or later	34	(4)	55	(10)	89	(7)
Time in orthosis						
Less than 7 weeks	26	(3)	56	(10)	82	(6)
7–8 weeks	498	(65)	242	(45)	740	(57)
More than 8 weeks	240	(31)	242	(45)	482	(37)
Treatment						
Surgery	81	(11)	132	(24)	213	(16)
No surgery	683	(89)	408	(76)	1091	(84)
Time from rupture to treatment						
Less than 5 days	720	(94)	511	(95)	1231	(94)
More than 5 days	44	(6)	29	(5)	73	(6)
Baseline ATRS, mean (median) [IQR]	90	(100) [91–100]	91	(100) [95–100]	90 (100) [93–100]	
Comorbidities and medicine						
Diabetes						
Yes	29	(4)	17	(3)	46	(4)
No	735	(96)	523	(97)	1258	(96)
Hypertension						
Yes	130	(17)	82	(15)	212	(16)
No	634	(83)	458	(85)	1092	(84)
Rheumatic disease						
Yes	24	(3)	19	(4)	43	(3)
No	740	(97)	521	(96)	1261	(97)
Corticosteroids						
Yes	25	(3)	22	(4)	47	(4)
No	739	(97)	518	(96)	1257	(96)

The primary analysis did not show any statistically significant difference in ATRS at 1-year follow-up between the patients treated with walker and the patients treated with cast for the first 3 weeks. The secondary analyses showed no statistically significant differences between the groups either (Table 2).

The sensitivity analysis did not show any clinically relevant nor statistically significant difference between the use of cast the first 3 weeks and walker the first 3 weeks when the patients were divided into operative and non-operative treatment (Table 3).

Of 1510 patients with fully registered baseline data 210 patients were lost to follow-up after 1 year. An analysis showed that the dropout patients from the cast group were younger and had less comorbidities compared to the dropout patients from the walker group (Appendix 1).

4. Discussion

This study found no difference in ATRS 1 year after ATR between patients treated with cast or walker the first 3 weeks of treatment. Additionally, no differences were found in the secondary outcomes investigating tendon elongation by indirect measurements and re-rupture rate. Therefore, the hypotheses of the study were rejected.

The present findings corresponds to the results from Costa et al., who 9 months after ATR, found no statistically significant difference between cast or walker for non-operatively treated patients the first 8 weeks of treatment [13]. Costa found a statistically significant between-group difference in ATRS at 8 weeks in favor of the walker group. However, Hansen et al. have shown that the full ATRS questionnaire should be used with caution until 6 months after rupture [23]. This is because most of the questions in the ATRS are irrelevant at a time point where the patient is not allowed normal walking and definitely cannot jump and run. In the current study, no clinically relevant difference was found at 6 months nor at 2 years follow-up. In summary, this suggests that treating with cast for the first 3 weeks of treatment does not improve ATRS and therefore does not prevent physical limitations after injury.

As mentioned in the introduction, it has been hypothesized that cast reduces the elongation of the ruptured tendon compared to walker. This was supported by a study showing that walker produced significantly less ankle equinus compared to that of an equinus cast [24]. The result from the present study contrast this finding by showing no clinically relevant differences in elongation measured with the indirect length measures HRH and ATRA. This finding indicates that choice of orthosis during the first weeks does not influence lengthening of the tendon.

For re-rupture the adjusted analysis showed a non-significant odds ratio of 0.8 in favor of the cast group. Costa et al. did not find a statistically significant difference in re-rupture risk between the groups either [13].

The patients in the study had different rehabilitation regimes. This included operative/non-operative treatment, time in orthosis, initiation of weight-bearing, and initiation of ankle motion. The patients in the walker group had a rehabilitation regime that was different from the cast group. This was most likely because of varying rehabilitation regimes across hospitals but also because of the functional properties of a walker. The walker was removable, enabling early ankle motion, and it also allowed weight bearing. Sceptics have been concerned about early tendon loading [25], and it has been suggested that early weightbearing might lead to tendon elongation and increase the risk of re-rupture [26,27]. The healing phase after rupture has been found to lasts for at least a year with increased metabolic activity in the tendon [28], and emerging evidence suggests that less aggressive rehabilitation with delayed motion and weights-bearing might be beneficial [29]. In contrast, larger randomized trials have not been able to detect these differences. Early weight bearing mobilization is claimed to be safe and to enhance the early healing response of ATR, and also improve ankle range of motion [30,31]. In addition to this, Barfod et al. reported no difference in ATRS between an early weightbearing group and a non-weight bearing group but found a significantly better health related quality of life in the weight bearing group. These findings suggest that being able to mobilize while in treatment has a positive impact on the patient [12]. Early ankle motion has not been shown to affect treatment outcome in larger trials [13,32,33], and can therefore be considered safe for the patient.

Table 2
Primary and secondary analyses.

	Number of patients	Mean	Unadjusted mean difference (95% CI)[a]	*p* value	Adjusted mean difference (95% CI) without treatment regime[b]	*p* value	Adjusted mean difference (95% CI)[c]	*p* value
Primary outcome								
ATRS after 1 year								
Walker the whole period	764	54.8	Reference		Ref		Reference	
Cast the first 3 weeks	540	56.7	1.9 (−0.9; 4.6)	0.18	0.7 (−2.6; 4.2)	0.70	0.1 (−3.0; 4.1)	0.95
Secondary outcomes								
ATRS after 6 months								
Walker the whole period	700	50.3	Reference		Ref		Reference	
Cast the first 3 weeks	471	51.0	0.7 (−1.8; 3.2)	0.6	3.6 (−0.14; 7.5)	0.06	2.0 (−4.5; 5.8)	0.35
ATRS after 2 years								
Walker the whole period	550	62.2	Reference		Ref		Reference	
Cast the first 3 weeks	371	65.5	3.4 (0.2; 6.6)	0.04	2.6 (−1.0; 6.5)	0.20	3.0 (−0.7; 7.0)	0.18
Heel rise height difference								
Walker the whole period	446	70.1	Reference		Ref		Reference	
Cast the first 3 weeks	269	74.8	4.8 (0.8; 8.7)	0.02	-0.4 (−6.5; 6.0)	0.90	0.6 (−6.6; 8.2)	0.88
ATRA difference								
Walker the whole period	459	5.7°	Reference		Ref		Reference	
Cast the first 3 weeks	274	5.5°	-0.2° (−1.1; 0.7)	0.65	0.4 (−0.9; 1.7)	0.44	0.0° (−1.5; 1.6)	0.97
Rerupture (odds ratio)								
Walker the whole period	764		Reference		Ref		Reference	
Cast the first 3 weeks	540		1.1 (0.6; 1.8)	0.78	0.9 (0.5; 1.5)	0.70	0.8 (0.4; 1.61)	0.55

Legend: The most left column shows the result of an unadjusted (aLinear model). The middle column (b) shows the result of a linear mixed-effects model adjusted for age, gender, operative/non-operative treatment, baseline ATRS, time in orthosis, comorbidities and time from injury to treatment start. The random effect was hospital. The most right column (c) shows the result of the same linear mixed-effects model with an additional adjustment for rehabilitation regime (ankle motion and ankle support). The random effect was hospital. Controlling for treatment regime did not change the result of the study.

Applying and removing a walker and its wedges is quicker and easier than a cast and it can be done outside of a hospital. The patient needs to be adequately instructed to do so. Moreover, treatment with walker has been shown to be more cost-effective in some countries [13] and can be expected to be so in similar countries as well. Wearing a cast for the first weeks of treatment takes more effort and resources to apply and remove in the hospital. Moreover, it is non-removable at home, which might be uncomfortable for the patient. Plaster cast might put the patient at risk for unnoticed complications such as pressure wounds and deep vein thrombosis (DVT) [34,35], but it is not known if a removable orthosis reduces this risk. Because no between-group difference in treatment outcome was found, the above-mentioned arguments can be used to advocate for treating patients with walker as preferred choice of orthosis after an ATR.

The study was limited by the registry study setup not being able to control for all potential confounders. The analyses were adjusted for age, gender, comorbidities, time from rupture to treatment and treatment regime, but other confounders that were not taken into account might have influenced the findings (smoking, alcohol consumption, BMI, intake of other medicines).

In an attempt to study the isolated effect of cast vs walker, the primary analysis was adjusted for treatment regime (weightbearing and ankle motion). This could have drained the power from the analyses because the treatment regime was part of the treatment that we were studying the effect of. In Table 2 the column marked with [b] illustrates the analyses without adjustments for treatment regime, compared to the analyses with adjustments. The results showed no statistically significant between-group difference, indicating that weightbearing and ankle motion does not have any significant effect on the outcomes. The walker used in the rehabilitation regime was a fixed angle boot with wedges. Until 2018 the wedges had a flat plateau by the heel, giving the calcaneus a more comfortable ankle support. This led to a neutral position of the calcaneus which did not relieve the stress on the ruptured tendon. Wedges with a continuous slant raises the heel and relieves the stress on the tendon [36]. In 2018 the wedges were in most hospitals changed to a shape with no plateau. This change in equipment might have altered results for the patients treated before 2018. The heterogeneity of the treatment regimens of the patients was another limitation of the study. Though the analyses were controlled for these variables a sensitivity analysis (Table 3)

Table 3
Sensitivity analysis.

	Number of patients	Mean	Unadjusted mean difference (95% CI) (a)	p value	Adjusted mean difference without treatment regime (95% CI) (b)	p value	Adjusted mean difference (95% CI) (c)	p value
ATRS after 1 year								
Operatively treated patients								
Walker the whole period	81	57.4	Reference		Reference		Reference	
Cast the first 3 weeks	132	58.5	1.1 (−5.6; 7.9)	0.75	0.8 (−5.9; 7.9)	0.83	5.0 (−4.7; 14.7)	0.33
Non-operatively treated patients								
Walker the whole period	683	54.8	Reference		Reference		Reference	
Cast the first 3 weeks	408	56.5	1.7 (−1.5; 5.0)	0.30	1.6 (−1.7; 4.9)	0.34	0.3 (−3.9; 4.6)	0.87

Legend: The most left column (a) shows the result of an unadjusted linear model.
The middle column (b) shows the result of a linear mixed-effects model adjusted for age, gender, baseline ATRS, time in orthosis, comorbidities and time from injury to treatment start. The random effect was hospital. The most right column (c) shows the result of the same linear mixed-effects model with an additional adjustment for rehabilitation regime (ankle motion, ankle support, immobilisation time). The random effect was hospital.

was performed to investigate the effects of operative and non-operative treatment. The analysis showed no difference between the two choices of orthosis when the patients were divided into operative and non-operative treatment. There were also some variabilities in the treatment regimes. Some patients were 2 weeks and some 3 weeks in cast, also the shape and number of wedges was not controlled for. Lastly, the loss to follow-up was a limitation to the study. The difference between the dropout populations could potentially increase the risk of selection bias. The analyses were adjusted for all these factors, which should minimize the risk of influence (Appendix 1).

A strength of the study was the high amount of data registered in the database, making the results more reliable than studies with a smaller population. In contrast to many of the previously mentioned studies, this study had a broad variety of patients, including patients regardless of age and comorbidities. This adds knowledge about how choice of orthosis affects average treatment outcomes in a general population with ATR but might mask actual differences in subgroups of patients. It is possible that subgroups of patients would benefit from treatment with cast and other sub groups from a removable walker boot. The pragmatic, large cohort in the present study limits investigation of more individualized treatment approaches.

5. Conclusion

Patients treated with cast the first 2–3 weeks after acute Achilles tendon rupture did not have better treatment outcome than patients treated with walker. Both cast and walker boot can therefore be considered safe treatment options during the first 2–3 weeks of treating patients after ATR. When choosing between these two orthoses, departments may take into account other factors than the primary and secondary outcomes, e.g. cost and convenience.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.fas.2022.09.004.

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