Medial Gastrocnemius Muscle Architecture in Children with Idiopathic Toe Walking and The Effect of Serial Casting

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Abstract

Background

Idiopathic toe walking (ITW) is persistent toe walking after the age of two years, following the exclusion of any neurological or orthopaedic abnormalities or neuropsychiatric diagnoses. It is not currently known whether the triceps-surae muscle structure of children with ITW is different to that of typically developing children (TDC). Current treatment is aimed at maintaining or increasing ankle dorsiflexion (DF) range and retraining the walking pattern. A period of serial casting is commonly used to achieve this goal. There is little evidence on the effect the casting has on triceps-surae muscle structure and how this relates to any change in ankle DF range of motion (ROM), achieved with serial casting.

Objective

The objective was firstly to examine differences in ankle ROM and medial gastrocnemius muscle architecture between children with a diagnosis of ITW and TDC. Secondly, to investigate changes in medial gastrocnemius muscle architecture and ankle ROM following serial casting for the treatment of ITW, and finally to assess the relationship between changes that occurred in these elements.

Study Design

A two group, pre- and post-intervention study, with comparisons within and across limbs of ITW and TDC groups was undertaken. Sixteen participants with a diagnosis of ITW underwent assessment pre and one-week post a six-week intervention of serial casting. Seventeen age and gender matched TDC control participants underwent the same assessment protocol on two occasions, seven weeks apart.

Method

Resting ankle position and maximal ankle DF ROM were measured by goniometry at each assessment point. Medial gastrocnemius muscle-tendon length, tendon length, fascicle length, pennation angle, and muscle thickness were measured with 2D B-mode ultrasound at three joint angles (40° plantarflexion or resting, neutral, maximal DF), at each assessment point. MATLAB and ImageJ software were utilised for post-scanning

analysis. Statistical analysis involved a two-factor ANOVA and Pearson correlation coefficients (alpha level 0.05).

Results

Prior to casting, ankle ROM was significantly decreased ($p < 0.05$) at rest (mean 13.1° difference, Cohen's d = -2.4) and at maximal DF (mean 14.7° difference, Cohen's d = -3.3) in the ITW group, compared to the control group. Between group differences in medial gastrocnemius muscle-tendon length, fascicle length and pennation angle were not clinically significant. The muscle belly to tendon ratio was not significantly different between groups. Muscle thickness was significantly increased ($p < 0.05$) in the ITW group compared to the control group at all joint angles (mean difference: 0.13cm at 40° plantarflexion, 0.21cm at neutral, 0.18cm at maximal DF).

Following serial casting in the ITW group, ankle ROM significantly increased ($p < 0.05$, mean difference 13.9° at rest, 14.6° at maximal DF). Increases in muscle-tendon length were not clinically significant. Muscle thickness significantly decreased ($p < 0.05$, mean difference: 0.10cm at 40° plantarflexion, 0.19cm at neutral, 0.12cm at maximal DF). There was no significant difference in ankle ROM or muscle architecture variables between ITW and TDC at follow-up. There was no significant correlation between changes in ankle ROM and changes in medial gastrocnemius muscle architecture in the ITW group following serial casting.

Conclusion

The findings of this study demonstrate that although children with ITW have significantly decreased ankle DF ROM, overall, their medial gastrocnemius muscle architecture is not wholly different to that of TDC. The exception to this was a finding of increased muscle thickness, which is suggestive of a change in triceps-surae function, with the plantarflexor muscles being active for a greater portion of the gait cycle with toe-walking.

The findings following serial casting are reassuring for clinicians who are utilising this treatment modality for ITW, as they suggest that muscle architecture and ankle ROM are improved to a normal range. The lack of correlation between ROM and muscle architecture changes may reflect the relatively small changes which occurred in muscle architecture and the contribution of other tissues to ROM.

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Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

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Signature	Date

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Abbreviations

Abbreviation	Meaning
2D	two dimensional
3D	three dimensional
AFO	ankle-foot-orthoses
ANOVA	analysis of variance
COVID-19	coronavirus disease 2019
CP	cerebral palsy
DF	dorsiflexion
FL	fascicle length
ICC	intraclass correlation coefficient
ITW	idiopathic toe walking
MG	medial gastrocnemius
ML	muscle belly length
M_{Th}	muscle thickness
MTJ	muscle-tendon junction
MTL	muscle-tendon length
NCRS	national child rehabilitation service
PA	pennation angle
PF	plantarflexion
ROM	range of motion
TDC	typically developing children
TL	tendon length
US	ultrasound

Chapter 1 Introduction

1.1 Statement of the problem

Idiopathic toe walking was first described in the literature by Hall et al. (1967) as "congenital short tendo calcaneus". Subsequently, the term idiopathic toe walking (ITW) became commonly used to describe a gait condition of persistent or habitual toe walking, with restricted ankle dorsiflexion range of motion (Hicks et al., 1988; Kalen et al., 1986). Toe-walking refers to lack of a heel-strike or predominant forefoot weight bearing during gait (Pomarino et al., 2017). It is considered part of normal development up to the age of two years (Babb & Carlson, 2008; Katz, 1984). ITW is a diagnosis of exclusion, ruling out cerebral palsy, neuromuscular disorders and other neurological or developmental conditions that may cause persistent toe-walking (Babb & Carlson, 2008; Oetgen & Peden, 2012; Stott et al., 2004).

The prevalence of ITW in New Zealand in unknown, but it has been reported as between 1-12% internationally (Bernhard et al., 2006; Bernhard et al., 2005; Engelbert et al., 2011; Engstrom & Tedroff, 2012). Within this population, 30 to 42% are reported to have a family history of toe walking (Bartoletta et al., 2021; Engstrom & Tedroff, 2012; Fox et al., 2006; Pomarino et al., 2016; Sobel et al., 1997; Stricker & Angulo, 1998). Studies have found a higher prevalence of boys (55% to 68%) than girls with ITW (Bartoletta et al., 2021; Bernhard et al., 2005; Eastwood et al., 2000; Engstrom & Tedroff, 2012; Fox et al., 2006; Pomarino et al., 2016; Sobel et al., 1997; Stricker & Angulo, 1998).

In respect to impairments associated with the condition, reduced ankle dorsiflexion (DF) range of motion (ROM) or contracture of the triceps surae muscle-tendon complex in children with ITW has been reported to varying degrees (Engelbert et al., 2011; Engström & Tedroff, 2018; Hall et al., 1967). Perceived functional issues attributed to this gait disturbance include poor balance, abnormal shoe wear, and foot pain (Davies et al., 2018; Fox et al., 2006; Lindsay et al., 2022). Although there are varied reports of functional deficits in the literature, few studies have quantified these deficits. In one long-term ITW follow-up study (Davies et al., 2018), patient reported functional outcome measures (questionnaires) did not show any reduction in health-

related quality of life or physical function compared to the general population. Further questioning identified forty percent of participants reported activity limitations across both treated (with casting and ankle foot orthoses, ± botulinum toxin-A) and non-treated groups. These were varied and included ankle sprains, foot pain, lower limb muscle tightness and difficulties with functional activities such as stairs, squatting or walking on hills. Similarly, a recent retrospective study (Lindsay et al., 2022) reported significant differences in a patient-reported outcome measure, for domains of mobility and peer relationships. Yet, pain interference scores were not significantly different from a healthy cohort. An association between decreased ankle DF ROM and ankle injuries in children aged 2-17 years has been reported (Tabrizi et al., 2000). In the adult literature, there is some evidence for gastrocnemius contracture contributing to foot and ankle problems such as foot pain, plantar fasciitis, metatarsalgia, posterior tibialis tendinopathy, and Achilles tendinosis (Amis, 2014; DiGiovanni et al., 2002; Hill, 1995; Patel & DiGiovanni, 2011). Such associations provided limited indirect evidence that restricted ankle DF ROM related to ITW may be associated with foot and ankle problems, although no studies have directly examined long-term outcomes into later adulthood in the ITW population.

The management of ITW is focussed on restoration of ankle ROM and normalisation of the gait pattern. Treatment includes serial casting, physiotherapy (stretching and/or strengthening exercises), botulinum toxin-A injections, orthoses, and surgical lengthening of the gastrocnemius or soleus muscles or the Achilles tendon (Sala, 2022; van Kuijk et al., 2014). Literature (Caserta et al., 2019) on the effectiveness of these treatments is variable, and as such, it is not clear what the most effective form of treatment might be. The current study is focussed on serial casting because this is traditionally a first line treatment used within paediatric orthopaedics in Auckland. Whilst it is relatively non-invasive compared to surgery, it does have a significant time commitment and cost associated with its use. Serial casting involves applying a cast to hold the ankle in a position to stretch the triceps surae complex with the aim of increasing ankle DF ROM, as well as placing the ankle in an optimal position to achieve a heel-toe gait pattern. The cast is applied sequentially for up to six weeks, with changes every 1-2 weeks (Brouwer et al., 2000; Stott et al., 2004; Thielemann et al., 2019).

The quality of research evidence on the effectiveness of serial casting is variable. Serial casting appears to provide a short-term (0-6 months) improvement in ankle DF ROM (Brouwer et al., 2000; Engström et al., 2013; Griffin et al., 1977; Katz, 1984; Thielemann et al., 2019). Studies with medium term follow-up (1-3 years) demonstrate variable preservation of DF ROM compared to immediately post-casting (Katz, 1984; Stricker & Angulo, 1998). Furthermore, several retrospective studies suggest that the long-term effect (5-15 years) of serial casting may be negligible (Davies et al., 2018; Hirsch & Wagner, 2004; Stott et al., 2004).

The current study seeks to examine potential mechanisms for improvements in ROM. To date, there has been just speculation concerning the structures responsible for the observed increases in DF ROM at the ankle joint after casting for ITW, with both contractile and non-contractile elements of the muscles being suggested (Brouwer et al., 2000). Studies involving animals being put in casts with muscles immobilised in a lengthened position provide some evidence that contractile elements, such as muscle length or fibre length, can be increased (Herbert & Balnave, 1993; Spector et al., 1982; Williams, 1978). However, while these studies involving animals provide insight into possible mechanisms, there is not a clear picture of changes in tendon versus contractile elements of the muscles following casting in humans. Several studies have used ultrasound to examine medial gastrocnemius (MG) muscle architecture following prolonged stretch in the cerebral palsy paediatric population. Cerebral palsy (CP) is a condition where there is limited ankle DF ROM in some children and stretching, ankle-foot-orthoses, or serial casting are used as management options. Similarly to the aforementioned animal studies, there are conflicting findings in the CP literature with some studies showing significant increases in fascicle length (Zhao et al., 2011) or muscle-tendon length (Peeters et al., 2020), while other studies show no significant changes (Hösl et al., 2015; Martín Lorenzo, Rocon, et al., 2017) or significant decreases in fascicle length (Hösl et al., 2015) or tendon length (Zhao et al., 2011). Other studies using ultrasound to measure MG muscle architecture in humans have been cross-sectional in design. For instance, it has been shown that fascicle lengths increase and pennation angles decrease with increasing ankle DF in typically developing children (Legerlotz et al., 2010; Shortland et al., 2002).

1.2 Significance of the problem

Overall, based on the literature, there is limited and inconsistent evidence concerning the effects of serial casting on muscle architecture in ITW or other clinical conditions involving children. An examination of differences in ankle DF ROM and MG muscle architecture across ITW and typically developing children is an important first step in increasing our knowledge in this area. Thereafter, an appreciation of changes that occur in muscle architecture due to serial casting may provide some evidence to re-evaluate its effects. If we demonstrate that a particular muscle or tendon element changes in the current study, it may enable us to propose more targeted treatments for further in-depth assessment with the aim of improving the function of these children.

1.3 Purpose of the study

The purpose of the study is as follows:

1. To measure differences in the architectural properties (muscle length, tendon length, fascicle length, pennation angle, thickness) of the medial gastrocnemius muscle and range of motion (resting and maximal dorsiflexion) at the ankle joint across idiopathic toe walking and typically developing children.
2. To investigate whether six weeks of serial casting leads to changes in ankle resting or maximal dorsiflexion range of motion and architectural properties of the medial gastrocnemius muscle in idiopathic toe walking participants.
3. To assess the relationship between changes in ankle resting or maximal dorsiflexion range of motion and selected architectural changes of the medial gastrocnemius muscle after serial casting.

Chapter 2 Literature Review

2.1 Introduction

This chapter examines the relevant literature. It begins by outlining the search strategies used for the key aspects of the literature review. A brief overview of the natural history of ITW, and the development of DF limitations is given, followed by a discussion of triceps surae anatomy and function during gait. A review of the effect of serial casting treatment, firstly on ankle DF ROM, and secondly on MG muscle architecture, is then undertaken. Thereafter, literature on the use of two-dimensional (2D) ultrasound (US) to measure MG muscle architecture is examined. Finally, the chapter concludes with a summary and rationale for the thesis.

2.2 Search Strategy

2.2.1 Introduction

There were several aspects of interest in the review of the literature. The first was that of serial casting as a treatment for ITW and the effect of this treatment on ankle DF ROM and MG muscle structure. Due to the limited literature examining the effect of serial casting on muscle structure in this group, a further search was undertaken to include paediatric, adult and animal literature. The second key literature search was focussed on the use of 2D-US to assess MG muscle architecture.

2.2.2 Search strategy for serial casting

A literature search on serial casting as a treatment for ITW was undertaken in July 2021 and updated in May 2023. The search strategy was formulated with the Population, Intervention, Comparison and Outcome (PICO) structure. The electronic databases searched were Medline (via EBSCO), CINAHL Complete (via EBSCO), Cochrane Library (via OVID), Scopus, Sport Discus (via EBSCO) and PEDro. The search was limited to published studies with participants aged 2-18 years old and published in English. Search terms were used in combination to identify potential literature (Table 2.1). Article titles and abstracts were reviewed to determine eligibility. Reference lists of included articles were searched manually to identify further relevant literature.

Table 2.1

Terms used in serial casting literature search

Toe Walking	Serial Casting	Exclusion terms
Idiopathic toe walk*	Serial cast*	Club foot
Toe walk*	Cast*	Clubfoot
Equinus*	Plaster*	Talipes
Tip toe*		Rupture
Habitual toe walk*		Diabet*

Note. *truncation

Studies were included if they met the following criteria:

- diagnosis of ITW
- participants aged 2-18 years
- articles that assessed the effect of serial casting on toe walking
- articles that used either of the following outcome measures:
    - change in ankle DF ROM
    - change in MG muscle architecture; fascicle length, pennation angle, thickness, muscle-tendon length

Studies were excluded for the following reasons:

- not published in English
- the presence of a neurologic, psychiatric, or orthopaedic cause for toe walking

The above literature search identified that there were no published studies on the effect of serial casting on MG muscle architecture in ITW. Thus, a general search in a range of clinical populations was undertaken within the same databases. An initial search of the literature on immobilisation effects on MG muscle architecture was performed, and from this point, an extensive list of search terms was devised (Table 2.2).

Table 2.2

Terms used in serial casting effect on medial gastrocnemius literature search

Serial Casting	Muscle Architecture	Medial Gastrocnemius
Cast*	"muscle architecture"	"medial gastroc*"
Immobil*	"fascicle length"	Gastroc*
Splint*	"pennation angle"	Calf
	"muscle thickness"	"lower limb"
	"tendon length"	"lower leg"
	"muscle belly"	"tendo achilles"
	"muscle fibre"	"achilles tendon"
	"muscle fiber"	"hind limb"
	Sarcomere*	"fore limb"

Note. *truncation

2.2.3 Search strategy for 2D ultrasound to assess MG muscle architecture

A literature search on the use of 2D-US as a method to assess MG muscle architecture was undertaken in June 2022 and updated in January 2023. The search terms used are outlined in Table 2.3. Using the above-mentioned databases, article titles and abstracts were reviewed to determine relevance and further pertinent studies were identified from the examination of reference lists.

Table 2.3

Terms used in 2D ultrasound literature search

Ultrasound	Muscle Architecture	Medial Gastrocnemius
Ultrasound	architecture	"medial gastroc*"
	"fascicle length"	Gastroc*
	"pennation angle"	Calf
	"muscle thickness"	"lower limb"
	"tendon length"	"lower leg"
	"muscle belly"	"tendo achilles"
	"muscle morphol*"	"achilles tendon"

Note. *truncation

The search was limited to human studies published in English, with a focus on children aged 0-18 years. Related adult and cadaver studies were included if they provided evidence of reliability or validity of the use of 2D-US for assessment of MG muscle architecture. Studies that used three-dimensional (3D) US were also included if they

provided evidence of normative values for MG muscle architecture elements in typically developing children.

2.3 Idiopathic Toe Walking

ITW was first described by Hall et al. (1967) as congenital short tendo calcaneus. They reported on twenty patients who presented with a toe-walking gait and were found to have ankle DF limitations and short Achilles tendons. Subsequent papers have described ITW as including both those with ankle DF limitations and those who habitually toe walk whilst still having adequate DF ROM. This section will examine the natural history of toe walking and its relationship to the development of DF limitations. This establishes the context for treatment aimed at improvement in ankle DF ROM and resolution of toe walking.

2.3.1 Natural history

There are differing opinions regarding whether ITW resolves over time without intervention. Eastwood et al. (2000) found that in a group of 49 untreated ITW participants, at 2-12 year follow-up, 88% continued to toe walk. Of those treated with serial casting (n = 41) 78% continued to toe walk and of those who underwent surgical lengthening (n = 46) 63% continued to toe walk. In contrast, Engström and Tedroff (2018) reported on a larger group of 1401 Swedish children who they followed from 5 to 10 years of age. Based on parental reports, they found that prior to 5 years of age, 4.5% of the group toe-walked; at 5.5 years 1.9% had persistent toe-walking, at 8 years 1.1% continued to toe-walk, and at final follow-up (10 years of age) this had reduced to 0.6%. Between 5.5 and 10 years of age, five of the 26 children with toe-walking underwent surgical lengthening, which accounted for 8% of the original toe-walking group, with 79% resolving spontaneously.

2.3.2 Development of dorsiflexion limitations

Ankle dorsiflexion limitations, sometimes termed plantarflexion contractures depending on the literature, are associated with ITW. It is thought they may develop over time with persistent toe-walking. Hall et al. (1967) first described observing a shorter Achilles tendon and longer muscle belly during surgery in a group of 20 toe-walkers undergoing Achilles tendon lengthening. A recent pilot study by Harkness-

Armstrong et al. (2021b) analysed a group of five children with ITW, mean age 8 years, with ankle DF limitations ranging from 30°PF to no limitation. Similar to Hall et al. (1967) they found that at a common ankle angle (15°PF), the ITW group had reduced tendon length (37% of total muscle-tendon unit length), when compared to their typically developing peers (47% of total muscle-tendon unit length, n = 14, mean age 10 years). This preliminary data suggested that the underlying ankle DF limitation may be primarily due to shortening of the Achilles tendon. Sobel et al. (1997) reported on a group of 60 toe-walkers aged 1-15 years. They found that with increasing age, ankle DF ROM decreased: mean of 13°DF at 2 years of age, 8°DF at 3 years of age, and no DF (0°) at ages four, five, and 6-15 years. Within this cohort, there was a subgroup (46%) of "equinus toe walkers" with fixed ankle DF limitations (< 0° ankle DF). Compared to those with ankle DF > 0°, this group was less able to walk heel-toe on request (68% compared to 95% of those with ankle DF > 0°) and had more difficulty standing with feet flat on the floor (71% compared to 96%).

2.4 Anatomy and Function of the Triceps Surae Complex

The triceps surae complex includes the soleus and the gastrocnemius, which consists of a medial and lateral head. As a group, they function to plantarflex the ankle joint and stabilise the foot and ankle during gait (Dalmau-Pastor et al., 2014; Moore & Dalley, 1999). The plantaris is also part of this muscle complex, however it is thought to have a minor contribution (Dalmau-Pastor et al., 2014; Moore & Dalley, 1999).

2.4.1 Anatomy and architecture

The medial head of gastrocnemius originates on the posterior surface of the medial femoral condyle and superior to this on the popliteal aspect of the femur, whilst the lateral head originates at the lateral aspect of the lateral femoral condyle (Cohen, 2009; Dalmau-Pastor et al., 2014). The two muscle bellies extended distally to form an aponeurosis which becomes the Achilles tendon, with the medial head being wider and thicker and continuing further distally than the lateral (Dalmau-Pastor et al., 2014; Moore & Dalley, 1999). Together, the two heads have a bi-pennate arrangement of fibres, crossing the knee and ankle joints, thus acting to flex the knee and plantarflex the ankle joint (Cohen, 2009; Dalmau-Pastor et al., 2014; Moore & Dalley, 1999).

The soleus sits anterior (deep) to the gastrocnemius muscle in the posterior compartment of the lower leg (Moore & Dalley, 1999). Its fibres originate from the posterior aspect of the fibula and tibia and the interosseus membrane (Cohen, 2009). The soleus aponeurosis extends distally to join the Achilles tendon below the level of gastrocnemius, with the former having a 3 to 11cm tendinous component and the latter having a longer 11 to 26cm tendon (Abdulmassih et al., 2013). Soleus is a multipennate muscle, with an anterior bipennate aspect and a posterior unipennate aspect (Cohen, 2009). The soleus crosses the ankle joint and thus acts with gastrocnemius to plantarflex the ankle (Cohen, 2009; Moore & Dalley, 1999).

The Achilles (calcaneal) tendon is the largest and strongest tendon in the body, comprising the insertions from both the gastrocnemius and soleus (Dalmau-Pastor et al., 2014). The tendon is wide at its origin, at its narrowest point at the level of the ankle joint, and then widens and flattens to insert onto the posterior aspect of the calcaneus (Cohen, 2009; Dalmau-Pastor et al., 2014). The fibres of the tendon rotate variably (Edama et al., 2015; Szaro et al., 2009), with a cadaver study by van Gils et al. (1996) finding a range of 11° to 65° torsion. This torsion provides improved distribution of stress and thus greater tensile strength (Handsfield et al., 2020; Shim et al., 2018).

2.4.2 Triceps surae role in gait

Although the current work is not measuring gait changes as a result of serial casting, the inherent name of the condition (ITW) warrants some review of the role of the triceps surae during gait and of how this is altered with toe walking. During normal gait, the plantarflexor muscles are inactive from initial contact to midstance (0-10% of the gait cycle) whilst the muscle-tendon unit is shortening, as the dorsiflexors act eccentrically to lower the foot to the floor (Cohen, 2009). The plantarflexor muscles then work in a primarily isometric manner during the single support phase (10-50% of the gait cycle) while the Achilles tendon is lengthening, storing elastic energy, as ankle DF increases from 0 to 10°DF. During pre-swing (50-60% of the gait cycle) the plantarflexors work concentrically whilst the Achilles tendon also shortens rapidly to move the ankle into approximately 20°PF at toe-off. Finally, during swing phase (60-100% of the gait cycle) the ankle moves back to a neutral position as both the muscle bellies and Achilles tendon lengthen passively (Cohen, 2009; Kalsi et al., 2016; Lichtwark & Wilson, 2006).

Several studies have sought to investigate the impact of toe-walking on triceps surae muscle function during gait. Based on an analysis of kinematic and kinetic data in able-bodied subjects, Kerrigan et al. (2000) proposed that toe-walking may require less plantarflexor muscle power and hence may provide an advantage in neuromuscular conditions with underlying muscle weakness. In contrast, Perry et al. (2003) analysed kinematic, kinetic, and additionally electromyographic data to ascertain soleus and gastrocnemius activity in able-bodied participants during toe-walking, compared with heel-toe walking. These authors found that overall greater soleus and gastrocnemius activity was required to maintain a toe-walking pattern, as the muscles were active through a larger percentage of the gait cycle to generate greater power output. A more recent study (Harkness-Armstrong et al., 2021a) examined kinematic data and isometric maximum voluntary contractions in ITW (n = 5). Unsurprisingly, they observed that the ITW group was in significantly more ankle PF between 0-6% (after initial contact) and 43-100% (mid stance to toe-off) of stance phase. Furthermore, the ITW group generated a greater plantarflexor moment between 0-39% of stance (initial contact to mid stance) and between 80-93% of stance (terminal stance to pre-swing) generated a smaller plantarflexor moment, when compared with a typically developing control group (n = 14). The maximal voluntary contraction peak moment-angle was found to be in significantly more PF of 16°PF in the ITW group compared to 1°DF in the control group. Such findings may suggest a shift in the length-tension relationship. Overall, these findings give us some insight into how triceps surae muscle activity may be altered in ITW. However, the impact of this upon triceps surae muscle architecture is unclear.

2.5 Serial Casting

2.5.1 Introduction

Tachdjian (1972) first proposed serial casting followed by gait re-education and stretching exercises as a conservative treatment method for ITW, where DF limitation is present. They described a casting regime of 4 - 6 weeks, with cast changes at 2-weekly intervals, gradually stretching the ankle into further DF. Subsequent studies (Brouwer et al., 2000; Pistilli et al., 2014; Stott et al., 2004; Thielemann et al., 2019) have used a variety of protocols, typically involving application of below-knee walking casts, with the ankle set at the end range of DF. Casts are changed at intervals (1-3

weeks) with the aim to increase the amount of DF of the ankle at each change. Care is taken to position the subtalar joint in a neutral position and to align the forefoot to the hindfoot so that the primary motion is DF at the talocrural joint (Brouwer et al., 2000; Thielemann et al., 2019). Furthermore, casts are positioned such that the child walks with a heel-toe gait pattern whilst in them, to retrain the gait pattern. Once a satisfactory degree of ankle DF is achieved (10-20°DF with the knee extended), the serial casting is ceased (Stott et al., 2004; Thielemann et al., 2019). This is usually followed by physiotherapy provision of plantarflexor stretching, strengthening and gait re-education exercises to maintain the change in DF ROM (Bartoletta et al., 2021; Engström et al., 2013; Fox et al., 2006; Griffin et al., 1977).

Traditionally, research evidence on the effects of serial casting primarily focuses on change in ankle DF ROM and the restoration of a heel-toe gait pattern. The following section will first review the literature on the effect of serial casting on ankle DF ROM in ITW. Secondly, it will consider the effect of serial casting on MG muscle architecture. As there is no literature on this subject within the ITW population, this review will encompass populations other than ITW and consider the effect of other modalities of prolonged stretch.

2.5.2 Effect on ankle dorsiflexion range of motion

An examination was undertaken of papers that had assessed changes in ankle DF ROM with serial casting in the ITW population. This involved the ROBINS-I critical appraisal tool for assessing risk of bias in non-randomised interventional studies (Sterne et al., 2016). This tool assesses studies for risk of bias in the following seven domains: confounding, selection of study participants, classification of interventions, deviation from intended interventions, missing data, measurement of outcomes and selection of the reported result (Appendix C; ROBINS-I assessment tool). Each domain is given a judgement on the risk of bias: low, moderate, serious, critical, or no information (therefore unable to score). Following this step, an overall judgement is given, based on the range of judgements across the seven domains. Table 2.4 provides a summary of results concerning the papers reviewed. As only a small number of papers met the review criteria (6), thereafter the overall literature in this section, including studies which do not have a control or comparison group, is discussed in a narrative style.

Table 2.4

Risk of bias (ROBINS-I) in included serial casting for idiopathic toe walking studies

Study (author, year)	Bartoletta 2021	Davies 2018	Engstrom 2013	Hirsch 2004	Hoffman 2022	Stott 2004
Bias due to confounding	Moderate	Moderate	Low	Serious	Serious	Serious
Bias in selection of participants	Low	Moderate	Low	Moderate	Low	Moderate
Bias in classification of intervention	Serious	Low	Low	Low	Low	Moderate
Bias due to deviations from intended interventions	NI	Low	Low	NI	Low	Low
Bias due to missing data	Low	Moderate	Low	Low	Low	Low
Bias in measurement of outcomes	Moderate	Low	Moderate	Moderate	Moderate	Moderate
Bias due to selective outcome reporting	Moderate	Low	Low	Moderate	Low	Low
Overall score	Serious	Moderate	Moderate	Serious	Serious	Serious

Overall, a small number of studies (Table 2.5) have examined the short-term (0-6 months) effects of serial casting. The quality of this research is hampered by a lack of control groups and small participant numbers in most studies. The highest quality evidence is that of a randomised controlled trial by Engström et al. (2013), which was judged to have a moderate risk of bias based on the ROBINS-I score (Table 2.4). This compared two groups of 26 participants; one received casting alone and the other botulinum toxin-A injections followed by casting. Their aim was to assess the additional benefit of botulinum toxin-A from casting alone and did not include a non-casted control group. Both groups had a significant improvement from baseline to 3 months: mean of 4°DF to 11°DF in the cast alone group and 6°DF to 11°DF in the botulinum toxin-A and cast group, with no significant difference between groups. Thus, it was concluded that there was no additional benefit from the botulinum toxin-A. Hoffman et al. (2022) randomised 35 ITW participants to receive treatment with either serial casting or carbon fibre ankle-foot-orthoses (AFO's) worn for 23 hours per day. There was no significant difference between groups, with both having a significant

improvement in ankle DF ROM from between 4-7°DF at baseline, to 26-30°DF post-intervention and 25-30°DF at 4-month follow-up. The quality of this study was limited by non-reporting of treatment duration or DF ROM required to cease the intervention, an exercise program co-intervention during treatment, and AFO use post-casting. Thus, it was judged to have a serious risk of bias with the ROBINS-I tool (Table 2.4). Other studies that have examined the short-term effects of casting predominantly have smaller cohorts of 6-10 participants, without a control group. The exception to this was a chart review study by Zapata et al. (2022) which analysed casting results of 60 ITW patients. These studies have shown significant improvements in ankle DF ROM of between 10° to 23° following 3-8 weeks of serial casting (Brouwer et al., 2000; Griffin et al., 1977; Katz, 1984; Thielemann et al., 2019; Zapata et al., 2022). Two of these studies reported statistical significance with an improvement in ankle DF ROM of 13° (Brouwer et al., 2000) and 16-18° (Zapata et al., 2022) post-casting. Statistical significance was not reported in the other studies. Whilst these short-term changes in DF ROM appear to be clinically significant, the research evidence for casting improving ankle DF ROM is quite limited.

Table 2.5

Ankle dorsiflexion range of motion (knee extended) before and after casting for ITW; short term follow-up (0-6 months)

Study	Participants		Casting Protocol		Ankle DF ROM knee extended		
	n	Mean age years (range)	Description	Duration (wk)	Pre mean (SD)	Post mean (SD)	Follow-up time
Brouwer 2000	8 ITW	7.5 (5-10)	Change 1-2 wkly	3 – 6	3.5°PF (2.6)	9.5°DF (1.4)*	Post cast removal
	8 CP	7.1 (3-12)			4.6°DF (1.7)	16.5°DF (1.4)*	
	8 ITW					11.6°DF (2.1)*	6-weeks
	8 CP					10.7°DF (1.9)*	
Hoffman 2022	18 ITW cast	4-9 (mean NR)	Change wkly	NR	6.1°DF right 5.8°DF left	25.6°DF right* 26.0°DF left*	Post cast removal
	17 ITW AFO	4-9 (mean NR)	Worn 23 hrs per day	NR	6.8°DF right 4.8°DF left	29.8°DF right* 28.8°DF left*	
	18 ITW cast					25.6°DF right* 25.0°DF left*	4 months
	17 ITW AFO					28.6°DF right* 29.6°DF left*	
Griffin 1977	6 ITW	7 (5-9)	Set at maximal DF	6 – 8	2.5°PF	20.8°DF	Post cast removal
Katz 1984	6 ITW cast 2 ITW stretch	7 (3-10)	Serial DF cutout casts NR	Mean 7 (2-16) NR	1.3°PF 1.5°DF	12.1°DF 12.5°DF	Post cast removal
		7.1 (1.7-12.9)		Mean 4.5	10.6°PF (7.7)	5.5°DF (3.8)*	Post cast removal

Study	Participants		Casting Protocol		Ankle DF ROM knee extended		
	n	Mean age years (range)	Description	Duration (wk)	Pre mean (SD)	Post mean (SD)	Follow-up time
Zapata 2022	60 ITW (analysed in 2 groups of 30).		Set at max DF, until 10°DF achieved. Change wkly	Mean 5.1	10.9°PF (10.1)	7.6°DF (3.8)*	
Engstrom 2013	26 ITW cast	9.4 (5-14.5)	Set at neutral	4	4.3°DF	10.9°DF*	3 months
	26 ITW Botox & cast				5.6°DF	11.4°DF*	
Thielemann 2019	10 ITW	10.1 (5-15)	Set at max DF, until 20°DF achieved. Change 2 wkly	4 (9/10) 6 (1/10)	3.5°PF	14.0°DF	6 months

Note. ITW = idiopathic toe walking. *n* = number. wk = week. CP = cerebral palsy. PF = plantarflexion. DF = dorsiflexion. AFO = ankle foot orthoses. NR = not reported.

* = statistically significant (p <0.05)

In respect to how long changes in DF ROM prevail, the best evidence is gained from Engström et al. (2013). At 1-year follow-up, they showed a negligible reduction in DF ROM; 10°DF compared to 11°DF at 3 months post-casting (Table 2.6). An early study by Katz (1984) demonstrated a trend of reduction in ankle DF ROM with an initial improvement from 1°PF to 12°DF (mean) post-casting, which decreased to a mean of 8°DF at 2.5 year follow-up. Similarly, a later study by Fox et al. (2006) demonstrated a modest improvement in ankle DF ROM at 14-month follow-up; from 1°DF at baseline to a mean of 6°DF. In contrast, a study by Stricker and Angulo (1998) reported that a serial casting or AFO group had no significant difference from baseline in median DF ROM at 2.5-3 year follow-up. In each of these studies, the only post-casting treatment protocol reported was “stretching”. A more recent retrospective clinical notes review (Jadhav, 2017) showed greater improvements in ankle DF ROM at 1-year follow-up with a post-casting treatment protocol of “aggressive AFO wear” for 23 hours per day initially, tapering after 4-months. Mean ankle DF ROM improved from 8°DF to 29°DF at 1-year follow-up (n = 38), although they reported those who followed the strict AFO wear regime had a greater resolution of toe walking than those who only wore AFO’s during the day. Whilst there appear to be clinically significant changes in DF ROM immediately post-casting (although not well supported by research evidence), there is even less evidence for maintenance of DF ROM over 1-3 years post casting. It is plausible that ongoing treatment, including gait re-education, muscle strengthening, and stretching, is required for the new ROM to be utilised during daily function and therefore maintained. However, thus far, this has not been clearly demonstrated in the literature.

Table 2.6

Ankle dorsiflexion range of motion (knee extended) before and after casting for ITW; medium term follow-up (1-3 years)

Study	Participants		Casting Protocol		Ankle DF ROM knee extended		
	n	Mean age years (range)	Description	Duration (wk)	Pre mean (SD)	Post mean (SD)	Follow-up time
Katz 1984	6 cast	7 (3-10)	Serial DF cutout casts	Mean 7 (2-16)	1.3°PF	7.8°DF[a]	2.5 years (mean)
	2 stretch				1.5°DF	10DF°	
Engstrom 2013	26 cast	9.4 (5-14.5)	Set at neutral	4	4.3°DF	9.8°DF*	12 months
	26 botox & cast				5.6°DF	11.1°DF*	
Fox 2006	44	6.1 (2-14)	Set at neutral, change 2 wkly	Mean 5.7 (3-10)	1.1°DF (5.08)	5.8°DF (5.6)*	14 months
Jadhav 2017	38 cast	NR	All casting followed by AFO wear	2 – 4	7.7°DF	29.0°DF	12 months
	46 botox & cast				0.0°	22.6°DF	
Stricker 1998	17 cast /AFO	4.2	Cast (n=8) or AFO's 3-8 mths (n=9)	6 – 12	5.0°DF	5.0°DF	2.7-3 years
	15 surgery	3.9			10.0°PF	10.0°DF	
	48 observation	3.2			10.0°DF	10.0°DF	

Note. ITW = idiopathic toe walking. *n* = number. wk = week. PF = plantarflexion. DF = dorsiflexion. AFO = ankle foot orthoses. NR = not reported.

* = statistically significant (p <0.05)

In the long term (greater than 5 years) it is not clear that serial casting is more effective than no treatment with regard to improvement in ankle DF ROM at skeletal maturity. Three studies (Table 2.7) which undertook long-term follow-up of adolescents and young adults (age range 14-28 years), found that there was no significant improvement in ankle DF ROM compared to baseline in those participants who were treated with serial casting as children (Davies et al., 2018; Hirsch & Wagner, 2004; Stott et al., 2004). In two of these studies, results were comparable to those of inactive treatment groups who underwent either physiotherapy (Hirsch & Wagner, 2004) or stretching (Davies et al., 2018). These studies were evaluated with the ROBINS-I tool, and had moderate (Davies et al., 2018) to serious risk of bias (Hirsch & Wagner, 2004; Stott et al., 2004) (Table 2.4).

In summary, the research demonstrates there is limited evidence of short-term improvement in ankle DF ROM immediately post-casting, and it is less certain that increases are maintained over longer time intervals.

Table 2.7

Ankle dorsiflexion range of motion (knee extended) before and after casting for ITW; long term follow-up (5-15 years)

Study	Participants		Casting Protocol		Ankle DF ROM knee extended		
	n	Mean age years (range)	Description	Duration (wk)	Pre mean (SD)	Post mean (SD)	Mean follow-up time
Stott 2004	6 cast	5.1 (3.6-7.6)	Cast change 2 weekly, aiming for 10°DF	6	9.0°DF (3)	9.0°DF (5)	10.9 years
	7 surgery (after failed casting)	10.5 (7.5-14)			7.0°PF (6)	6.0°DF (5)	10.5 years
Davies 2018	23 cast + AFO's 1 year +/-botox	7.2 (4.3- 12.2)	Cast only (n=6), cast+botox (n=17), all AFO's for 1-year post-casting. Change 2 weekly	6	2.3°DF (8)	0.2°DF (3.8)*	13.0 years
	20 stretching				3.9°DF (6.2)	0.6°DF (2.9)*	13.7 years
Hirsch 2004	5 cast +/-AFO	6.8	Set at maximal DF.	2 – 4	10.0°DF	12.5°DF	14.5 years
	6 physio	6.5			10.4°DF	11.3°DF	

Note. ITW = idiopathic toe walking. *n* = number. wk = week. PF = plantarflexion. DF = dorsiflexion. AFO = ankle foot orthoses.

* = statistically significant (p <0.05)

2.5.3 Effect on medial gastrocnemius muscle architecture

No studies have examined changes in fascicle length (FL), pennation angle (PA), muscle tendon-length (MTL) or muscle thickness (M_{Th}) in response to prolonged stretch or serial casting in ITW. Thus, a wider literature search was undertaken, assessing animal, adult, and other paediatric conditions to ascertain the potential effect of casting on the above-mentioned outcome variables.

Studies involving animals undergoing hindlimb immobilisation in cast, with the triceps surae in a lengthened position, provide some evidence for changes in muscle architecture. A universal finding is the disuse muscle atrophy caused by immobilisation which is reported as a decrease in cross-sectional area of the muscle (Spector et al., 1982) or the individual muscle fibres (Nicks et al., 1989), muscle belly circumference (Gossman et al., 1986) or muscle weight (Herbert & Balnave, 1993; Nicks et al., 1989; Spector et al., 1982). The degree of atrophy is less significant when muscles are held in the lengthened position (Gossman et al., 1986; Herbert & Balnave, 1993; Spector et al., 1982). For example, Spector et al. (1982) reported that muscle weight of the rat MG following 4 weeks of brace immobilisation was 84% in the lengthened group compared to 46% in the shortened group (reported as percentage of control weight).

There is some variation in MTL changes in animal models, with immobilisation in the lengthened position. Studies in adult animals have shown that immobilisation in a lengthened position does not cause a significant change in the length of multi-joint muscles. For instance, Spector et al. (1982) found that in the MG muscle belly of rats immobilised in a lengthened position for 4 weeks, there was no significant difference in muscle belly length (ML) compared to a control group. Similarly, Gossman et al. (1986) found that ML was unchanged in the plantaris muscle of rabbits immobilised in the lengthened position. Neither of these studies examined any change in tendon length (TL). Williams (1978) investigated changes in muscle architecture of the soleus muscle, which is not a multi-joint muscle like the gastrocnemius muscles. Young and adult mice were assessed after a 3-week period of cast immobilisation in a lengthened position. In the adult mice (n = 5) there was no difference in ML compared to a control group. In contrast, the young mice (n = 5) had a reduction in ML, with the mean ML measuring 5.3mm post immobilisation, compared to 7.0mm in the control group. As

the bone growth in the young growing mice continued as normal, it was thought that the TL was increasing over the time of lengthened immobilisation to compensate for the decrease in ML, although this was not specifically measured.

Changes in the contractile elements of the animal muscle immobilised in a lengthened position have also been examined. In an early study, Williams (1978) investigated changes in sarcomere length and number in the soleus muscle of young and adult mice after a 3-week period of immobilisation in a lengthened position. In the adult muscle, they found that sarcomere length was significantly decreased compared to the controls, but sarcomere number was increased. In the young (growing) mice, both sarcomere number and sarcomere length were decreased in the immobilised muscle compared to the control group, along with a decrease in ML, as described above. In contrast, Spector et al. (1982) found that in the soleus muscle of rats immobilised in a lengthened position for 4 weeks, there was no significant change in sarcomere length, whereas fibre length was significantly increased compared to a control group. Yet, in the same study, the MG muscle showed no significant difference in muscle fibre length or sarcomere length. This difference in findings may be because multi-joint muscles (MG) respond differently to single joint muscles (soleus) when immobilised in a lengthened position, as both the knee and ankle joints were immobilised in this study.

The degradation of muscle fibres during immobilisation is also of concern. Baker and Matsumoto (1988) investigated the change in soleus and MG myofibrils of rats immobilised for 4 weeks in a shortened position compared to a neutral ankle angle. They found that a neutral cast position led to less atrophy and degradation of the myofibrils in both the MG and the soleus. Similarly, Baewer et al. (2004) investigated the effect of hindlimb suspension unloading on the soleus muscles of rats. They reported that this caused areas of focal myofibril breakdown. However, with the addition of 10-20 minutes of daily splinting in a lengthened position, this was significantly reduced. The authors thought that this was due to both the muscle lengthening effect of the stretched position and the contractile activity of the muscles, as in a lengthened position, the rats could push against the splint, thus activating the soleus muscle.

One study in the animal literature has examined changes in non-contractile elements with immobilisation in a lengthened position. Williams et al. (1988) assessed connective tissue changes in rabbit soleus muscles that were immobilised in either a lengthened or shortened position for 7 days. They found that there was no change in connective tissue concentration in those immobilised in a lengthened position, whereas there was an increase in connective tissue amount per area of muscle in the shortened group.

While these studies involving animals provide insight into possible mechanisms, overall, the findings do not provide a clear picture of changes in contractile versus non-contractile elements of the muscle. While immobilisation causes muscle atrophy, there is no clear evidence that either MTL, fibre length or sarcomere length increases with immobilisation in a lengthened position. In fact, most studies did not show significant changes. The contribution of non-contractile elements to any change in ROM is also unclear.

Within the adult literature, previous studies have explored the effects of immobilisation post ankle fracture. One such study (Christensen et al., 2008) investigated changes in cross-sectional area of the triceps surae muscle complex and the Achilles tendon in adults (n = 12) with cast immobilisation of 6-10 weeks post unilateral malleolus fracture. They reported a mean decrease of 15% in muscle cross-sectional area compared to baseline after 7-weeks immobilisation, whereas the Achilles tendon cross-sectional area did not change significantly (measured by CT scan). Likewise, Psatha et al. (2012) found a decrease in MG cross-sectional area of 23.3% at 4 weeks (measured by MRI), within a 6-week immobilisation period post unilateral ankle fracture (adults, n = 18). This study also examined PA (by MRI) and found that the mean PA of MG was decreased in the immobilised limb to 21° compared to the control limb at 24°. These studies further support the conjecture that muscle atrophy is associated with immobilisation and suggest a reduction in PA may occur.

The literature on repeated short-term stretch in adults can provide some appreciation for changes that may occur, albeit without the effect of immobilisation. Such studies have not reported changes in muscle architecture parameters. For example, Nakamura

et al. (2012) found MG FL did not change significantly in a group of healthy adults (mean age 21 years, n = 9) following a 4-week static stretching program, despite increases in ankle DF ROM (+6.7°). This suggested that the changes came from other factors, such as connective tissue or decreased muscle stiffness. Furthermore, a systematic review of 26 studies examining the effects of stretching interventions of 3-8 weeks' duration on either ankle plantarflexors or knee flexors found no effect on FL or PA (Freitas et al., 2018). By contrast, adult studies with longer duration stretch programs have shown changes in MG muscle architecture. A study in healthy adults (mean age 21 years, n = 21) compared a 12-week muscle-directed with a nerve-directed stretching protocol (Andrade et al., 2020). They found significant increases in MG FL (+0.4cm) and decreases in triceps surae stiffness (measured with shear wave elastography) along with increases in DF ROM with the knee extended (+7.3°) in the muscle-directed group compared to a control group (n = 18). M_{Th} was unchanged. The nerve-directed group showed significant decreases in sciatic nerve stiffness (measured with shear wave elastography), along with increases in DF ROM with the hip flexed (+9.9°). This is of interest as it demonstrates other tissues (e.g., nerve or fascia) can influence ankle ROM. A study (Pradines et al., 2019) in independently mobile adults with hemiparesis caused by stroke (n = 8), compared 1-year of daily self-guided stretches, with conventional treatment alone (n = 11). The stretches included static body weight stretches of gastrocnemius and/or soleus, alternated with unaided active DF for 15 seconds at a time. Compared to the control group, ankle DF ROM with knee flexed (+4.1°), soleus FL (+1.8cm) and soleus M_{th} (+0.48cm) significantly increased. Ankle DF ROM with knee extended (+7.0°) and MG FL (+0.63cm) also increased significantly, but MG M_{Th} did not. While these adult studies provide insights into the effects of stretch on DF ROM and muscle architecture, studies in typically developing children (TDC) are lacking and thus the evidence of its effect in children comes primarily from the CP literature, which is presented next.

There is evidence from studies with paediatric CP participants on the effect of serial casting or prolonged stretch on muscle architecture variables. In a non-RCT study Martín Lorenzo, Rocon, et al. (2017) published preliminary data examining changes in FL and ML of the MG muscle, measured with 2D-US following combined botulinum toxin-A injections and 2-weeks of serial casting in five ambulant children (8 legs) with

CP. Ankle DF ROM with knee extended was not significantly different post-casting (+5°). They found that neither FL nor ML, at rest or at maximal ankle DF, were significantly different post-intervention. More recently, Peeters et al. (2020) investigated the effect of botulinum toxin-A injection (n = 17) versus 2-weeks of serial casting (n = 14) on MG ML and TL in children with CP. Post-casting there was a significant increase in ankle DF ROM with the knee extended (mean 10°). Using 3D-US, they found that at 2-weeks post-casting there was a significant increase in MTL at maximal ankle DF, from a median of 27.2cm at baseline to 28.8cm post-casting. Furthermore, ML did not change significantly, whereas increases in TL were significant, with the median TL at maximal ankle DF increasing from 13.7cm to 14.5cm. A key difference in the CP population compared to TDC is that children with CP are known to have smaller MG muscle bellies and longer Achilles tendons (Fry et al., 2004; Gao et al., 2011; Wren et al., 2010). Thus, from these two preliminary studies, there is limited evidence that serial casting may lengthen the Achilles tendon in the CP population, and that there is minimal effect on lengthening the muscle belly.

Hösl et al. (2015) compared MG MTL and FL measured by 2D-US in a group of 17 ambulant children with CP, pre and post 16 weeks of wearing an ankle-foot brace which blocked PF but allowed DF. They found that maximal ankle DF ROM increased significantly with the knee flexed (mean 6°) but not significantly with the knee extended. Despite this change in DF ROM, MTL did not change significantly. However, FL was significantly shorter at all ankle angles, with an 11% decrease in length (compared to baseline) at a matched mid-range of motion position. In addition, MG M_{Th} (which is an indirect measure of muscle size) was decreased, most prominently in the resting position (12% change), while there was no change in PA.

A number of studies have examined the effect of shorter duration stretch on triceps surae muscle architecture in children with CP. Zhao et al. (2011) used US to evaluate changes in MG and soleus muscle-tendon properties in a group of seven children with CP who underwent three sessions per week over six weeks of combined passive ankle stretching (20 minutes + 10 minutes) and active movement training (30 minutes). In contrast to Hösl et al. (2015), they found that with the ankle at a neutral position, MG FL increased significantly from a mean of 40.2 to 41.5mm and PA decreased significantly from a mean of 17° to 16° after six weeks of training. Surprisingly, Achilles

TL significantly decreased from 55.7 to 52.6mm. Although these measures were reported as statistically significant, it is uncertain whether they are clinically significant given a 1.3mm mean change in FL is equivalent to approximately 3% of the baseline FL and the change in PA was 1°. In 16 children with a diagnosis of CP, a later study (Kalkman et al., 2019) compared a 10-week program of stretching alone (control) to a combined stretching and strengthening (intervention) regime (4 sessions per week). They reported a median increase in maximal ankle DF ROM of 5° in the control group and 8° in the intervention group, which was not significantly different between groups. There was no significant change in MG ML or TL (measured with 2D-US) in either group. The only significant difference was an increase in median resting FL in the intervention group (+2.2mm) compared to the control group (-0.5mm) post intervention. As both groups undertook the same stretching regime, with the addition of the strengthening program in the intervention group, this difference may be attributed to the strength training. A limitation of this study was the lack of a true control group. However, it is interesting to note that although maximal ankle DF ROM increased, MG ML or TL did not increase, thus suggesting that other structures may be responsible for the increase in ankle DF ROM as highlighted by Andrade et al. (2020) in young adults.

Overall, these studies in the paediatric CP population do not give a clear explanation as to how changes in ankle DF ROM occur following prolonged stretching, with many of the studies reporting non-significant changes in muscle architecture parameters of MTL and variable changes in FL reported. Furthermore, it is thought that plantarflexor muscles in children with CP are stiffer than in TDC (Alhusaini et al., 2010), as the underlying brain lesion causes changes in motor control and heightened stretch reflex activity (spasticity) which may contribute to changes in the muscle properties over time. Thus, the effect of stretch in the CP population is not generalisable to the ITW population. Although the differences in MG architecture between CP and TDC have been examined, the comparative effect of stretch has not been directly investigated. There is a lack of literature on the effect of stretch on DF ROM and muscle architecture in TDC, which may be more applicable to the ITW population.

2.6 Ultrasound

Ultrasound (US) is a non-invasive tool which can be used to visualise muscle architectural properties in vivo. The US transducer emits sound waves that are transmitted through soft tissues with the echoes reflecting off the tissue interfaces to generate a 2D image (Fry et al., 2004). 2D-US is used to quantify muscle architectural properties such as FL, PA, and M_{Th}. The use of 2D-US to visualise muscle structure for clinical purposes has developed with the addition of 3D motion capture to build 3D reconstructions of muscle structure (3D-US), thus enabling measurement of muscle volume and length (Barber et al., 2009; Cronin & Lichtwark, 2013). The reasons for choosing to assess MG as a component of the triceps surae muscle group are firstly that the gastrocnemius, being more superficial than the soleus, is easier to image with US. Secondly, gastrocnemius, as a biarticular muscle, is thought to be a greater contributor to reduced ankle DF ROM than soleus (DiGiovanni et al., 2002), and MG is thought to contribute more plantarflexor force than the lateral gastrocnemius during function (Silver et al., 1985). Other authors have highlighted greater muscle stiffness in MG which may contribute to these differences in force and DF ROM. Le Sant et al. (2017) and Le Sant et al. (2019) found when mapping triceps surae muscle stiffness using ultrasound in shear wave elastography mode, that MG had the greatest stiffness when in a stretch position (ankle DF with knee extended) in both adult stroke participants and healthy adult participants. Furthermore, the distal portion of the MG muscle was consistently the stiffest part. Thus, the focus of this review was on the use of US to assess MG muscle architectural properties: FL, PA, M_{Th} and MTL.

2.6.1 Validity and reliability of medial gastrocnemius architecture measurement

Several authors have provided descriptions of the most common architectural variables measured by US (Binzoni et al., 2001; Herbert et al., 2015; Lieber & Fridén, 2000; Narici et al., 1996). MG FL is a measure of muscle fibre bundle length from the attachment on the superficial to the deep aponeurosis. PA is the angle formed between the fascicle and the force generating axis, at either the superficial or deep aponeurosis. M_{Th} is the measured distance between the superficial and deep aponeurosis, often measured at the left and right side of an US image and the values averaged.

The suitability of 2D-US to provide a valid measure of FL, PA, and M_{Th} has been explored across several studies. Two cadaver studies have evaluated the validity of 2D-US to measure FL, PA and M_{Th} in MG. Narici et al. (1996) as part of a wider study, compared 2D-US with direct measurement in one adult male cadaver (age 62 years). Although they reported good agreement between the measures, the statistical validity cannot be determined from a sample size of one. A later study (Bénard et al., 2009) compared 2D-US measurements of FL, PA, and M_{Th} with anatomical sections from the MG of four human cadavers (mean age 75 years). They found that when the US measures were taken in the true fascicle plane, there was no significant difference between the anatomical section measures and the 2D-US measures. However, they also assessed the impact of scan orientation in the presumed fascicle plane and found that when the transducer was tilted 15° compared to the true fascicle plane (in two of the cadavers), there were significant differences in FL and PA measures. M_{Th} measurement was not significantly affected by a change in tilt angle of the US transducer. Bolsterlee et al. (2016) used a simulated MG model based on magnetic resonance imaging (MRI) and diffusion tensor images of eight healthy subjects (mean age 30 years), to create virtual US images at different locations in the MG muscle belly and at various transducer orientations. Like Bénard et al. (2009), they found that increasing transducer misalignment (tilt and rotation) was related to increasing measurement error in a linear manner for FL and PA. They suggested that by keeping the US transducer perpendicular to the skin, the most accurate MG FL and PA measures could be attained. In a study population more like the current study, Cenni et al. (2018) investigated validity of 2D-US and 3D-US measures of MG FL and PA in 11 children with a diagnosis of CP and 11 TDC across a range of ankle joint angles. They found that there was a tendency for 2D-US to overestimate fascicle lengthening across the full ROM (absolute discrepancy 7-8mm) and to overestimate change in PA across the ROM, when compared to 3D-US. Overall, these studies investigating the validity of 2D-US for measurement of MG architectural parameters illustrate the potential for absolute measurement errors when US probe alignment is inaccurate. A number of strategies have been suggested to reduce the potential for probe alignment error (Bénard et al., 2009; Bolsterlee et al., 2016), with the method suggested by Bolsterlee et al. (2016), of keeping the US transducer perpendicular to the skin, being utilised in the current study.

The reliability of 2D-US measures of MG muscle architecture is also an important consideration. Two studies with adult participants investigated intra-rater reliability of 2D-US measures of MG architecture for within-session and between-session measures (May et al., 2021; McMahon et al., 2016). McMahon et al. (2016) examined intra-rater reliability in a group of 16 males with a mean age of 23 years. They captured 2D-US images of the MG muscle belly halfway between the muscle-tendon junction (MTJ) and the medial femoral condyle, with the ankle resting in a neutral (90°) position. Reliability of within-image repeat measures was excellent, with intraclass correlation coefficients (ICCs) of 0.99 – 1.00 for M_{Th}, FL, and PA. Between-image (within-session) reliability was good with ICCs ranging from 0.83 to 0.95. Between-session intra-rater reliability was also good, with ICCs of 0.89 to 0.93. More recently, May et al. (2021) investigated the same aspects of intra-rater reliability in a larger group of 87 participants aged 13-63 years. Images were obtained with the ankle at neutral (90°) and the knee flexed 20-30°. The US probe was placed at the MG mid belly, determined as one third of the distance down from the posterior knee crease to the medial malleolus of the ankle. May et al. (2021) reported within-image intra-rater reliability as excellent, with ICCs of 0.99 for FL, PA and M_{Th} of MG. Between-image ICCs were also excellent with a range from 0.94 to 0.97. Test-retest reliability varied from moderate to excellent with ICCs of 0.63 to 0.91, FL having the most reliability and PA having the least. Although the within-session reliability was shown to be excellent in these studies, the between-session variability may be such that 2D-US is not exact enough to detect change over time on an individual basis. May et al. (2021) reported minimal detectable change values of 10-12mm for FL, 5.7-6.4° for PA and 3mm for M_{Th}. These values represent approximately 20% of the group mean FL and M_{Th} and 30% of mean PA. McMahon et al. (2016) reported smallest detectable difference percentages of 11% for FL, 10% for PA and 11% for M_{Th}. Furthermore, a recent study (Ritsche et al., 2022) analysing between-session reliability of 2D-US measures of MG in a group of 36 adults (mean age 26 years), reported standard error of measurement percentages of 9% for FL, 9% for PA and 6% for M_{Th}. This also suggests that a large degree of difference is required to show a true change in muscle architecture over time.

Few studies have evaluated the reliability of 2D-US for MG measurement within paediatric populations. Legerlotz et al. (2010) investigated within-session (n = 21) and

between session (n = 4) reliability in TDC. MG 2D-US images were obtained with the knee extended and the ankle passively positioned at neutral and at maximal PF. The US probe was positioned at the MG mid belly and aligned perpendicular to the long axis of the leg. The between session measures were repeated at 4-6 weeks after the initial assessment. ICCs for within-session measures were 0.94 to 0.98 for M_{Th}, 0.85 to 0.96 for PA, and 0.87 to 0.96 for FL. The coefficient of variation (CV) within-session was 2.1 to 3.1 for M_{Th}, 4.1 to 6.0 for PA, and 4.5 to 6.3 for FL. The reliability did not change significantly in the between session comparison, with CV's of 1.9 to 4.8 for M_{Th}, 5.1 to 5.9 for PA and 2.3 to 5.9 for FL. Cenni et al. (2018) also explored within-session reliability of 2D-US measures of FL and PA, alongside 3D-US measures in a group of 11 children with a diagnosis of CP and 11 TDC. Like the previous study, the US probe was positioned longitudinally above the fascicle plane at MG mid belly. Measures were taken at maximal ankle DF, maximal PF and 50% of total ROM, with the knee flexed to 20°. ICCs for within-session measures were 0.21 to 0.96 for PA, and 0.69 to 0.92 for FL (range across three joint angles). The standard error of measurement for PA was 1.0°-1.7° or 5-10% and for FL was 2.3-3.5mm or 5-10%. These standard error of measurement values are comparable to those discussed earlier, from the adult study by Ritsche et al. (2022). Boulard et al. (2021) examined between-session reliability of 2D-US measurement of MG M_{Th} in the paretic and non-paretic limbs of 10 children with a diagnosis of CP. 2D-US images were captured at MG mid belly, in the longitudinal axis, with repeat measures one week apart. They showed acceptable levels of intra-rater between-session reliability, with ICCs of 0.75 to 0.98 (across paretic and non-paretic limbs, two joint angles, two investigators). Minimal detectable change values were 1.1-3.8mm. These ICC and minimal detectable change values are in keeping with the adult studies previously discussed.

For MG MTL, a 2D method of measurement was validated by Barber, Barrett, et al. (2011) in a group of 15 typically developing individuals (mean age 19 years) and nine individuals with CP (mean age 17 years). The US transducer is used to visualise the most superficial aspect of the medial femoral condyle (as a standard approximation for the proximal insertion of MG). The distance to the Achilles tendon insertion on the calcaneus (distal insertion) is measured with a tape measure attached to the transducer. MG TL is measured from the US transducer over the muscle-tendon

junction to the Achilles tendon insertion on the calcaneus. This method was compared to 3D-US measurement of MTL at 3 ankle angles: 30, 60, and 100% of maximal ankle DF ROM. Results showed that the limits of agreement between methods across all ankle angles was 6% for both groups. Within-session (between image) reliability testing of the US-tape method found ICCs of greater than 0.99 across both groups and ankle angles (Barber, Barrett, et al., 2011). Given these findings, this US-tape method is appropriate for the present study.

2.6.2 Medial gastrocnemius normative values and changes with growth

With changes in ankle DF ROM from PF to DF in a given individual, MG MTL, FL and M_{Th} values increase, and PA decreases (Bénard et al., 2011; Cenni et al., 2018; Harkness-Armstrong et al., 2021b; Legerlotz et al., 2010). For example, Bénard et al. (2011) reported that ML increased 13% and FL 15% with a change in ankle angle from 0° to 20°DF. From 50°PF to 20°DF, M_{Th} increased 10% and PA decreased (percentage not specified). Similarly Legerlotz et al. (2010) reported significant increases in MG M_{Th} (5%) and FL (28%) and decreases in PA (35%) from maximal PF to 0° ankle angle. Within the muscle-tendon unit, the muscle belly is the primary contributor to changes in length as the ankle moves from PF to DF, whereas change in TL is small (Bénard et al., 2011). Other tissues, such as fascia and nerves, also provide resistance to passive movement (Andrade et al., 2020; Gajdosik, 2001).

Normative values for MG architectural variables and how these change with growth in TDC, is of interest. There are a number of cross-sectional US studies which provide valuable information on typical values across different age groups. Table 2.8 provides an overview of the published values for MG FL, PA, M_{Th}, and MTL. No studies have reported any statistically significant differences between male and female muscle architectural variables (Bénard et al., 2011; Binzoni et al., 2001; Kawakami et al., 2006).

Until recently, there has been little in the literature which looks at triceps surae architectural properties in ITW. However, one recent pilot study by Harkness-Armstrong et al. (2021b), investigated MG architectural changes in a group of ITW with DF limitations (mean ROM not reported), albeit with a small number of participants (ITW = 5, TDC = 14). They reported a significant decrease in TL (mean 4cm shorter) and an increase in FL (mean 2cm longer) in the ITW group compared to the TDC group

when measured at a common ankle angle (15°PF). There were no significant differences in PA or M_{Th} when compared at a common joint moment (0 Nm).

Table 2.8

MG architectural properties in typically developing children, aged 2-15 years

Study	Sample size (male:female)	Age (years) mean (SD)	Ankle position	Mean (SD)
Fascicle Length (cm)				
Chen 2018	24 (12:12)	4.8 (2.0)	Resting	3.70 (0.48)
Wijnands 2022	19 (2:17)	5.8 (1.4)	Resting	5.25 (0.73)
Kawano 2018	27 (11:16)	6.4 (1.3)	Resting Max DF, 19.2DF	3.14 (0.32) 4.96 (0.92)
Legerlotz 2010	21 (13:8)	6.6 (2.3)	Max PF, 43PF Neutral, 0°	2.97 (0.41) 4.12 (0.62)
Shortland 2002	5 (3:2)	7.8 (2.2)	30PF Resting, 23.8PF 15PF Neutral, 0°	3.61 (0.63) 3.74 (1.01) 4.10 (1.02) 4.99 (1.44)
Bulut 2022	5 (NR)	8.1 (1.1)	Resting	2.97 (0.36)
Mohaghegi 2008	50 (20:30)	9.1 (2.3)	Resting, 25PF	4.20 (0.50)
Weide 2020 *3D-US*	14 (5:9)	9.3 (0.5)	Resting (0 Nm)	5.30 (0.20)
Malaiya 2007 *3D-US*	15 (6:9)	9.5	Resting, 18.0PF Max DF, 14.1DF	4.50 (0.70) 4.90 (0.40)
Harkness-Armstrong 2021	14 (5:9)	10.0 (2.0)	32PF 15PF	3.50 (5.0) 4.20 (0.50)
Cenni 2018	11 (7:4)	10.5 (2.6)	Max PF 50% ROM Max DF	3.13 (0.46) 4.45 (0.92) 5.43 (0.92)
Kruse 2018	12 (5:7)	11.3	Resting, 20.8PF	4.40 (0.80)
Pennation Angle (°)				
Chen 2018	24 (12:12)	4.8 (2.0)	Resting	15.4 (3.3)
Wijnands 2022	19 (2:17)	5.8 (1.4)	Resting	13.8 (2.7)
Kawano 2018	27 (11:16)	6.4 (1.3)	Resting Max DF, 19.2DF	25.9 (3.2) 15.1 (2.5)
Legerlotz 2010	21 (13:8)	6.6 (2.3)	Max PF, 43PF Neutral, 0°	21.5 (3.3) 15.7 (1.8)
Shortland 2002	5 (3:2)	7.8 (2.2)	Resting, 23.8PF 30PF 15PF Neutral, 0°	21.7 (4.6) 21.4 (3.4) 19.2 (4.2) 16.8 (2.9)
Bulut 2022	5 (NR)	8.1 (1.1)	Resting	25.3 (2.7)

Study	Sample size (male:female)	Age (years) mean (SD)	Ankle position	Mean (SD)
Wren 2010	21 (7:14)	8.8 (2.3)	Resting, 18PF	17.9 (2.5)
Weide 2020 *3D-US*	14 (5:9)	9.3 (0.5)	Resting (0 Nm)	13.5 (0.4)
Malaiya 2007 *3D-US*	15 (6:9)	9.5	Resting, 18.0PF Max DF, 14.1DF	17.0 (1.9) 15.8 (1.2)
Harkness-Armstrong 2021	14 (5:9)	10.0 (2.0)	16PF (0 Nm)	20.0 (2.0)
Cenni 2018	11 (7:4)	10.5 (2.6)	Max PF 50% ROM Max DF	24.9 (6.6) 19.7 (3.3) 17.2 (3.2)
Kruse 2018	12 (5:7)	11.3 (2.5)	Resting, 20.8PF	18.1 (2.7)
Muscle Thickness (cm)				
Chen 2018	24 (12:12)	4.8 (2.0)	Resting	0.97 (0.18)
Kawano 2018	27 (11:16)	6.4 (1.3)	Resting Max DF, 19.2DF	1.37 (0.16) 1.26 (0.14)
Legerlotz 2010	21 (13:8)	6.6 (2.3)	Max PF, 43PF Neutral, 0°	1.05 (0.14) 1.11 (0.14)
Harkness-Armstrong 2021	14 (5:9)	10.0 (2.0)	16PF (0 Nm)	1.40 (0.30)
Kruse 2018	12 (5:7)	11.3 (2.5)	Resting, 20.8PF	1.30 (0.20)
Muscle-tendon Length (cm)				
Wijnands 2022	19 (2:17)	5.8 (1.4)	Resting	ML 15.3 (2.3) TL 9.6 (2.0)
Mogi 2020	30 (NR)	9.1 (1.4)	Neutral, 0°	TL 15.2 (2.1)
Weide 2020 *3D-US*	14 (5:9)	9.3 (0.5)	Resting (0 Nm)	MTL 34.7 (1.2) ML 20.3 (0.7) TL 14.4 (0.6)
Malaiya 2007 *3D-US*	15 (6:9)	9.5	Resting, 18.0PF Max DF, 14.1DF	ML 19.1 (3.5) ML 20.4 (3.3)
Harkness-Armstrong 2021	14 (5:9)	10.0 (2.0)	32PF 15PF	ML 18.9 (2.4) TL 17.3 (2.2) MTL 37.3 (3.9) ML 19.7 (2.5) TL 17.6 (2.3)
Cenni 2018 *3D-US*	11 (7:4)	10.5 (2.6)	Max PF 50% ROM Max DF	ML 14.8 (1.8) ML 16.3 (2.4) ML 17.6 (2.4)
Mogi 2020	48 (NR)	12.8 (0.7)	Neutral, 0°	TL 18.5 (1.7)

Note. MG = medial gastrocnemius. DF = dorsiflexion. PF = plantarflexion. NR = not reported. MTL = muscle-tendon length. ML = muscle belly length. TL = tendon length.

The US literature provides some evidence for how MG muscle architecture changes with growth. Length measures (FL, MTL) appear to increase proportionally with increasing tibia length. Bénard et al. (2011) in a cross-sectional 3D-US study of 5-12-year-olds (n = 30) found that tibia length increased significantly with age ($r > 0.82$). FL and MTL also increased with age, but once normalised to tibia length, no age correlation was present. Overall yearly increases were found to be 1.0cm (6%) for ML, 0.9cm (8%) for TL and 0.2cm (5%) for FL. Similarly, a 3D-US study of adolescent males (age 10-19 years) found that height increased by 4.2cm per year and tibia length by 0.8cm (Weide et al., 2015). They noted that once length variables (TL, ML, FL) were normalised to tibia length, there was no significant correlation with age. A 2D-US study (Mogi, 2020) analysing changes in MG TL before, during and after the adolescent growth spurt (n = 120, age 6-18 years) found that there was no significant difference in ratio of TL to lower leg length (50-52%) amongst the groups, thus implying that TL increase is relative to growth in height.

Several studies have expressed MG TL and ML as a percentage of the whole muscle-tendon unit (Table 2.9). These show a range of 39-48% for TL and 51-61% for ML. The recent study by Harkness-Armstrong et al. (2021b) suggested that ITW may have shorter MG TL and longer MG ML relative to TDC. At a common ankle angle of 15°PF, they reported the TDC group had MG ML of 53% and TL of 47% compared to the ITW group who had ML of 62% and TL of 37%. However, these values in the ITW group are within the range of others reported in TDC studies listed in Table 2.9, for example values of 61% for ML and 39% for TL (Wijnands et al., 2022).

A large cross-sectional study sought to determine MG PA changes across the lifespan (0-70 years). Using 2D-US in 134 healthy participants, Binzoni et al. (2001) measured PA and M_{Th} of the MG at a neutral ankle position. Results showed that PA increased uniformly with growth from birth to the end of the adolescent growth spurt, at which point it stabilised. MG PA was linearly related to increase in M_{Th}, with formulas but not R values reported. Similarly, they showed a linear increase in M_{Th} with growth in tibia length. In another large study, Kawakami et al. (2006) measured MG PA and M_{Th} using 2D-US in a sample of 711 individuals aged 3-94 years. When M_{Th} was normalised to limb length, it was found to be significantly positively correlated to PA (r = 0.56). A 2D-US study (Radnor et al., 2020) of 126 boys, sought to examine growth changes in MG

M_{Th} and PA between pre-peak height velocity (n = 57, mean age 13 years), circa-peak height velocity (n = 32, mean age 14 years) and post-peak height velocity (n = 37, mean age 16 years). They found a significant difference in PA and M_{Th} between groups, showing both increasing with age. In contrast, a smaller 2D-US study (Legerlotz et al., 2010) of 4 to 10-year-olds (n = 21), found that while M_{Th} was correlated to leg length (r = 0.64), PA and FL were not (r = 0.26-0.32). Similarly, the previously discussed study by Bénard et al. (2011) found that MG PA did not change significantly from age 5 to 12 years (n = 30).

Overall, these findings concerned with growth will provide reference values and an indication of what variables would be better normalised (e.g., to leg length), to enable comparisons across ITW and typically developing groups.

Table 2.9

MG architectural properties in typically developing children, normalised to leg length

Study (normalised to)	Sample (male:female)	Age (years) mean (SD)	Ankle position	Mean (SD)
Normalised Fascicle Length (%)				
Shortland 2002 (fibula length)	5 (3:2)	7.8 (2.2)	Resting, 23.8PF 30PF 15PF Neutral, 0°	13.0 12.6 14.2 17.1
Wren 2010 (tibia length)	21 (7:14)	8.8 (2.3)	Resting, 18PF	12.0
Mohaghegi 2008 (lower leg length)	50 (20:30)	9.1 (2.3)	Resting, 25PF	13.0
Martin-Lorenzo 2018 (fibula length)	9 (NR)	9.2 (2.7)	Resting, 27PF Max DF, 21.7DF	13.9 19.8
Martin-Lorenzo 2017 (tibia length)	10 (7:3)	11.0 (3.4)	10PF Neutral, 0° 10DF	19.5 20.6 22.3
Normalised Muscle-tendon Length (%)				
Mogi 2020 (lower leg length)	30 (NR)	9.1 (1.4)	Neutral, 0°	TL 51.6
Martin-Lorenzo 2018 (fibula length)	9 (NR)	9.2 (2.7)	Resting, 27PF Max DF, 21.7DF	ML 64.2 TL 54.2 ML 70.0 TL 52.2
Mogi 2020 (lower leg length)	48 (NR)	12.8 (0.7)	Neutral, 0°	TL 51.9
Muscle or tendon length as a percentage of MTL (%)				
Wijnands 2022	19 (2:17)	5.8 (1.4)	Resting	ML 61 (7) TL 39 (8)
Wren 2010	21 (7:14)	8.8 (2.3)	Resting, 18PF	ML 55 (4) TL 45 (4)
Weide 2020 *3D-US*	14 (5:9)	9.3 (0.5)	Resting (0 Nm)	ML 59 TL 41
Harkness-Armstrong 2021	14 (5:9)	10.0 (2.0)	32PF 15PF	ML 51 (5) TL 48 (6) ML 53 (4) TL 47 (4)
Kruse 2018	12 (5:7)	11.3 (2.5)	Resting, 20.8PF	ML 54 (4) TL 46 (4)

Note. MG = medial gastrocnemius. DF = dorsiflexion. PF = plantarflexion. NR = not reported. MTL = muscle-tendon length. ML = muscle belly length. TL = tendon length.

2.7 Summary

ITW is persistent toe walking after the age of two years, following the exclusion of any neurological or orthopaedic abnormalities or neuropsychiatric diagnoses. It is not currently known whether the triceps surae structure of children with ITW is different from that of typically developing peers. Current treatment of ITW is aimed at maintaining or increasing ankle DF ROM and retraining the walking pattern. This is commonly achieved with a period of serial casting, despite there being only weak evidence for improvement in ankle DF ROM immediately following serial casting and limited quality evidence for any longer-term effects. Furthermore, there is a lack of evidence on the effect it has on triceps surae muscle architecture. The MG component of triceps surae has been chosen as the focus for assessment in this study as it is thought to have a greater contribution to reduced ankle DF ROM. This study firstly aims to investigate whether there are differences in resting and maximal ankle DF ROM and MG architecture across ITW and TDC. Secondly, it will examine the influence of serial casting on resting and maximal ankle DF ROM and MG architecture in the ITW group. Thirdly, in the ITW group, associations between changes in ankle joint ROM with changes in specific MG architectural variables will be examined. These aims may better inform future treatment decisions for children with ITW.

Chapter 3 Materials and Methods

3.1 Introduction

This chapter begins with descriptions of the study design, participant recruitment, and selection. Thereafter, the experimental measures and the procedures are presented. Finally, the statistical analyses are described.

3.2 Design

A two-group pre-test and post-test design was implemented. Participants with a diagnosis of ITW underwent an intervention of serial casting over a six-week period. Pre-intervention assessment occurred on the same day the serial casting commenced, and the post-intervention assessment was one week following casting completion. The control group of TDC, matched by age and gender, was assessed over a similar time period. Participants underwent assessment of ankle ROM and 2D-US generated architectural measures of the MG muscle, as described hereafter.

3.3 Participants

3.3.1 Idiopathic toe walking group

Sixteen children with a diagnosis of ITW participated. They were a convenience sample recruited from individuals referred from the Paediatric Orthopaedic Outpatient Department, Starship Children's Hospital to the National Child Rehabilitation Service (NCRS) for serial casting to treat their toe walking. Serial casting is part of standard care. An orthopaedic surgeon or advanced physiotherapy clinician discussed the treatment recommendation of serial casting with children and their parent/guardian. If the family decided to proceed with serial casting, they were placed on the waitlist at the NCRS. Once on the waitlist, the study was discussed, and the patient information sheets provided. If they agreed to participate, the researcher contacted the parent/guardian to arrange study appointments that aligned with their serial casting treatment at the NCRS. Inclusion criteria for age of participants was based on the age of children typically being referred for serial casting and being old enough to tolerate the length of the testing sessions.

Inclusion criteria:

- Aged 4-15 years old.
- Diagnosis of ITW made by paediatrician, neurologist, or orthopaedic surgeon.
- Undergoing serial casting to treat ITW.

Exclusion criteria:

- Neurological, psychiatric, or orthopaedic condition causing or contributing to the toe walking.
- Previous serial casting in the year prior to first assessment.
- Surgery or injury to the leg which would influence ankle joint ROM, muscle architecture or muscle-tendon length.

Sample size was determined based upon published research (Barber, Barrett, et al., 2011; Barber, Hastings-Ison, et al., 2011; Legerlotz et al., 2010; Malaiya et al., 2007) and a pilot study within our lab. To detect a 15 percent difference across the groups in MTL, TL, ML, M_{Th}, and FL, with the alpha level set at 0.05 and power at 0.80, a sample size of 16 participants was required.

3.3.2 Control group

A group of TDC with no known neurological, psychiatric, or orthopaedic diagnoses were age and gender matched with the ITW participants. These participants were recruited by word of mouth and advertising at the Auckland University of Technology. Parents who expressed interest in their child participating were given an information sheet before consenting to take part in the study. Control participants attended two testing sessions, seven weeks apart, at which the same testing procedures undertaken on the ITW participants were performed.

3.3.3 Intervention

ITW participants attended two testing sessions. The baseline measures were completed during the initial assessment, after which the research physiotherapist applied the first set of serial casts (see Figure 3.1). An independent physiotherapist undertook the subsequent cast changes at the NCRS. The NCRS has a credentialing process for physiotherapists to become part of the serial casting team. Casts are

changed weekly, with each change aiming to increase the amount of DF of the ankle in the cast. Routine practice is to set the ankle angle in the cast at the maximal passive DF ROM with knee extended, measured prior to each cast application. The children are able to walk in the casts and are encouraged to be as active as possible. Serial casting continued for a maximum of six weeks or until the physiotherapist independent of the study deemed that the child had achieved adequate ankle DF ROM (greater than 10° DF with the knee extended). The second testing session took place one-week after the final set of serial casts were removed.

Figure 3.1

Serial cast being applied

3.4 Experimental Procedures

3.4.1 Ethics protocol

Ethical approval was received from the Health and Disability Ethics Committee (reference number 18/STH/197, Appendix A). Written (Appendix B) and verbal explanations of the procedures were given to all participants and their parent or guardian. An opportunity for them to ask further questions was provided. Participants' personal and medical information was recorded, and a unique identification number was assigned to conceal individual results. A document of informed consent (Appendix B) was signed by the parent or guardian, and child (participant) assent was also required.

3.4.2 Demographic and anthropometric data

Standard demographic data was collected at the first assessment, including age (date of birth), gender, and ethnicity. At the start of each testing session, participant height, weight, leg length, and fibula length of the right leg were measured. The participant lay supine on the plinth, with the hips and knees in a neutral position for the leg and fibula length measures. Leg length was measured using a tape measure, from the anterior superior iliac spine to the inferior aspect of the medial malleolus. The reliability and validity of this method has been established (Beattie et al., 1990). Fibula length was measured using a tape measure, from the palpated fibula head to the lateral malleolus, as described by Fry et al. (2004).

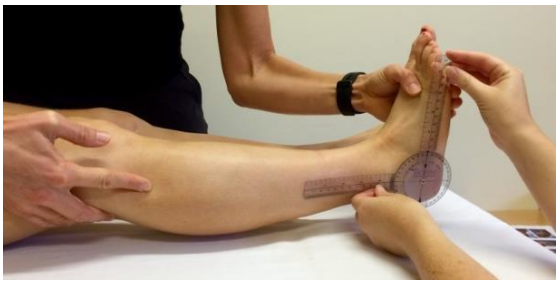
3.4.3 Ankle range of motion

Maximal ankle DF ROM and resting ankle position were measured by goniometry. The axis of the goniometer was positioned inferior to the lateral malleolus. The stationary arm of the goniometer was aligned to the fibula head so that it was parallel to the long axis of the fibula, and the moving arm was aligned parallel to the long axis of the 5th metatarsal (Kilgour et al., 2003; Lee et al., 2013). This method was chosen as it allowed relatively accurate assessment without the increased time that is required to measure ROM with the Biodex isokinetic dynamometer.

Maximal ankle DF ROM was measured with the participant in supine lying, with the hip and knee held in neutral extension (0°) by the research assistant, as described by Kilgour et al. (2003). Care was taken to ensure the subtalar joint (hindfoot) was in a neutral position before moving into maximal DF. The ankle was moved to maximal DF by the research physiotherapist, and this position was then maintained by the research assistant while the physiotherapist measured the ankle angle (see Figure 3.2). The participant was instructed to relax, to decrease any plantarflexor muscle activity during the assessment. Resting ankle position was measured with the participant in prone lying, the hip and knee in neutral extension and the foot and ankle resting off the end of the plinth. With the participant relaxed, the research physiotherapist measured the ankle angle in this resting position.

Figure 3.2

Measurement of maximal ankle dorsiflexion range of motion with knee extended



Note. Source: Starship Clinical Gait Analysis Service Physiotherapy Assessment Guidelines (p. 14), NCRS Physiotherapy Team, September 2019. Not publicly available. Reprinted with permission.

3.4.4 2D ultrasound measures

Ultrasound measures of the MG were performed using a 2D B-mode Ultrasound Machine (Aixplorer, V12, Supersonic Imagine, Aix-en-Provence, France) with a linear transducer that has a 50mm field of view (4-15 MHz, SL15-4, Supersonic Imagine, Aix-en-Provence, France).

To prepare for ultrasound data collection, the following landmarks were visualised with 2D-US, and their location marked on the skin:

- Achilles tendon insertion on the calcaneus
- Most superficial aspect of the medial femoral condyle
- MG MTJ at the most distal point
- 50% of MG muscle belly length, measured from medial femoral condyle to MTJ
- Lateral border of MG muscle belly at midpoint of muscle belly length
- Medial border of MG muscle belly at midpoint of muscle belly length
- 50% of MG muscle belly width, measured from medial to lateral border of MG

The first set of measures were assessed with the ankle in a resting position because MTL and TL could not reliably be measured at the 40°PF angle due to the Biodex footplate obstructing tape measure placement on the heel. Thereafter, the foot was positioned on the footplate of the Biodex isokinetic dynamometer utilising a technique described by Barber, Barrett, et al. (2011), so that the ankle joint could be passively maintained in the correct position (40°PF, neutral, and maximal DF), as shown in Figure 3.3a. The plinth was aligned with the footplate and the height adjusted so that the axis of rotation of the ankle joint was aligned with the axis of the Biodex lever arm.

The foot was secured to the footplate with Velcro straps around the ankle and across the forefoot.

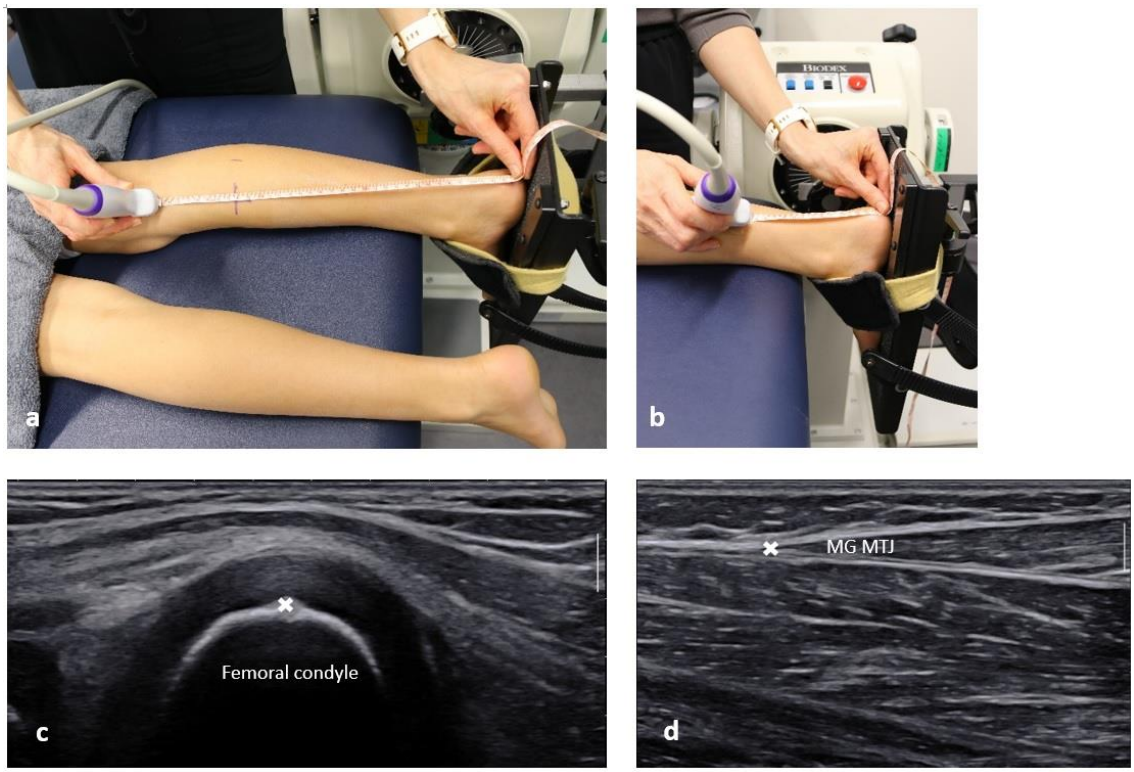
US measures were assessed at three angles: (1) with the ankle in a resting position (MTL and TL only), or with the ankle in 40°PF (FL, PA, and M_{Th} only), (2) neutral/0° (all measures) and (3) maximal DF (all measures). If the subject's maximal available passive ankle DF ROM was less than neutral (0°), then measures were not recorded at the neutral position. Three measurements of MTL and TL, FL, PA, and M_{Th} were recorded at each joint angle.

Muscle-tendon length and tendon length

With the subjects lying prone with the hip and knee in neutral extension, MG-MTL and TL were measured using the techniques described by Barber, Barrett, et al. (2011), whose work provided evidence of validity and reliability. Specifically, the Achilles tendon insertion on the calcaneus was visualised with the US and the skin marked at this point. The tape measure was attached to the US transducer at one end and the distance from the edge of the tape measure to the edge of the transducer scan plane was recorded. For MG-MTL, the most superficial aspect of the medial femoral condyle (as a standard approximation for proximal insertion), was visualised with the US transducer and the tape measure positioned over the distal insertion of the Achilles tendon on the calcaneus. The tape measure distance from the attachment on the US transducer to the calcaneus was recorded (see Figure 3.3a). For MG-TL, the most distal point of the MTJ was visualised with the US transducer and the tape measure positioned over the Achilles tendon insertion on the calcaneus. The tape measure distance from the attachment on the US transducer to the calcaneus was then recorded (see Figure 3.3b).

Figure 3.3

Ultrasound-tape measure method for measuring muscle tendon length and tendon length



Note. Measurement technique for muscle-tendon length (a) and tendon length (b). (c) and (d) show ultrasound images used for muscle tendon length (c) and tendon length (d) calculations.
MG MTJ = medial gastrocnemius muscle-tendon junction.

Fascicle length, pennation angle and thickness

Based upon the work of Legerlotz et al. (2010) which showed satisfactory reliability, MG FL, PA, and M_{Th} measures were taken from images recorded at the midpoint of the MG muscle belly, defined as 50% between the MTJ and the most superficial aspect of the medial femoral condyle, and 50% between the medial and posterior borders of the MG muscle belly. For consistency, the midpoint was marked on the skin prior to the US images being recorded. During the procedure, the transducer probe was positioned perpendicular to the long axis of the leg.

Intra-rater reliability of ultrasound measures

To determine the reliability of the ultrasonographer, a cohort of five TDC with no known neurological or orthopaedic diagnoses took part in a preliminary study on two occasions 6-8 days apart. The findings showed ICCs ranging between 0.98 (FL) and 0.99 (MTL) with 95% confidence intervals of 0.86 – 0.99 (FL) and 0.99 – 0.99 (MTL). These

values, together with results shown on Bland and Altman plots, were deemed satisfactory for commencing the main study.

3.4.5 Analyses of ultrasound data

MTL and TL measures were analysed using a custom-built MATLAB (MathWorks Inc, Natick, MA) software script. For each MTL image, the most superficial point of the medial femoral condyle was identified (see Figure 3.3c). MTL was then calculated following the method described by Barber, Barrett, et al. (2011). This utilises Pythagoras' theorem with the combined tape measurement distance and the condyle to the edge of the US image distance, in addition to the depth of the condyle. Similarly, for the TL image, the most distal point of the MTJ was identified (see Figure 3.3d) and the measure was then calculated with the same technique as described for the MTL measure. ML was calculated by subtracting TL from MTL for the purposes of this analysis, as it was not measured directly during data collection.

To improve the reliability of FL, PA, and M_{Th} measures, an ImageJ script called Simple Muscle Architecture Analysis (SMA) was utilised to measure the US images (Seynnes & Cronin, 2020). This tool pre-processes the image using spatial filters before detecting the superficial and deep aponeuroses, measuring the dominant fascicle orientation in defined regions of interest (ROI), and then calculating the parameters of FL, PA, and M_{Th}. A mean, median, or maximal value is given from a pre-specified number of ROI and the images with measurements overlayed are saved. The script settings are adjusted by the user to achieve optimal aponeuroses and fascicle detection, as described by Seynnes and Cronin (2020). Images can be analysed individually or in multiples. For our analysis, we used mean values taken from three ROI for each image. Processed images were visually inspected and for images where aponeuroses detection was erroneous, script settings were adjusted (tubeness sigma value), or the image was manually cropped by the researcher to enhance aponeurosis detection.

Muscle architecture data used in the statistical analysis was the mean of measures taken from three images. For MTL and TL, one measure was taken from each image. For FL, PA and M_{Th}, measures were taken from the mean of three ROI on each image.

3.4.6 Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 29. The alpha level was set to 0.05 for all analyses. Data was checked for normality using skewness and kurtosis values, Shapiro-Wilks test, histogram plots and the normal Q-Q plot. Descriptive statistics, boxplots, and Grubb's test were used to check for errors and outliers in the data. No outliers were observed.

An independent samples t-test was used to assess for any significant difference in demographic characteristics between the ITW and control groups. Covariate (e.g., age, gender, leg length) associations with the dependent variables were assessed and, where significant, normalisation was undertaken for subsequent group comparisons. Most notably, MTL, TL, and ML were normalised to fibula length, for the analyses.

A two-factor analysis of variance (ANOVA) was utilised for research questions 1 and 2:

1. Are there differences in the architectural properties (muscle-tendon length, tendon length, fascicle length, pennation angle, thickness) of the medial gastrocnemius muscle and range of motion at the ankle joint across idiopathic toe walking and typically developing children?
2. Does six weeks of serial casting change range of motion and architectural properties of the medial gastrocnemius muscle in idiopathic toe walking participants?

The factors were time (pre/post (*repeated measure*)) and groups (control/ITW). From this two-factor ANOVA, question 1 was analysed by comparisons across baseline measures of each group, and question 2 was analysed through assessment of interaction and main effects. Separate two-factor ANOVAs were performed for each ankle joint position. It was thought that the interpretation of a three-factor ANOVA that would have included joint position (3 levels) as an additional factor would have added notable complexity to the analysis and differences across joint angles were not a primary aim.

For question 3, Pearson correlation coefficients were calculated to determine whether there was a relationship between changes in ankle ROM and changes in selected MG muscle architecture variables (MTL, TL, ML, FL) after serial casting.

Chapter 4 Results

4.1 Introduction

This chapter is divided into three main sections. Section 4.2 outlines the demographic details of the participants. Section 4.3 addresses whether there are any differences in ankle DF ROM and MG muscle architectural properties between ITW and TDC groups. This includes reporting of changes in ankle DF ROM and MG architectural properties before and after serial casting in the ITW group. Finally, section 4.4 examines the relationship between changes in ankle DF ROM and changes in MG muscle architecture after serial casting.

4.2 Demographics

Seventeen children with ITW who were due to undergo serial casting consented to participate. One of the ITW participants completed the initial assessment, but subsequently did not complete the study due to an unrelated medical event. Therefore, their data is not included in this analysis. Of the 16 remaining ITW participants, 12 completed 6-weeks of serial casting. Of these, four participants had an interruption to their casting due to skin complications (see Table 4.1), but in total completed 6-weeks. The remaining four participants had less than 6-weeks in casts (3 to 5 weeks) as the treating physiotherapist determined that they had achieved adequate ankle DF ROM. This is standard clinical practice which had to be adhered to. The majority of ITW participants completed their follow-up assessment 1-2 weeks post cast removal, with one participant having their follow-up delayed to three weeks due to COVID-19 restrictions. Seventeen age and gender matched TDC were recruited as a control group. Fifteen of 17 control participants had their follow-up 7-weeks after their initial assessment, and two had their follow-up 8-weeks after initial assessment.

Table 4.2 presents the demographic and anthropometric data for the groups. There was no significant demographic or anthropometric difference between groups at baseline ($p > 0.05$). Both groups had a mean age of 8 years (± 1.7), ranging from 5 to 11 years. Mean height was 130.8cm (± 9.0) in the ITW group and 130.1cm (± 9.8) in the control group. Mean leg length was 68.2cm (± 5.9) in the ITW group and 67.7cm (± 6.5)

in the control group. Mean weight was 30.7kg (± 8.0) in the ITW group and 28.9kg (± 5.5) in the control group.

Table 4.1

Casting complications

Complication	Effect
1. Blisters, difficulty attending appointments	3-week break in casting
2. Casts got wet	3 days out of casts for skin to dry
3. Scabies	5 days out of casts for skin treatment
4. Pressure area from foreign body	5 days out of casts for skin to heal
Fungal infection	5 days out of casts for skin treatment
Pressure area right side only	4 days out of right cast for skin to heal

Table 4.2

Participant characteristics at baseline (mean ± 1SD)

	Idiopathic toe walkers	Typically developing
Age (years)	8.0 (1.7)	8.1 (1.7)
Gender (male:female)	9:7	10:7
Ethnicity (n (%))		
- Māori	4 (25)	0 (0)
- Pacific	0 (0)	1 (6)
- European	9 (56)	12 (71)
- MELAA	1 (6)	2 (12)
- Asian	2 (13)	2 (12)
Height (cm)	130.8 (9.0)	130.1 (9.8)
Body mass (kg)	30.7 (8.0)	28.9 (5.5)
Leg length (cm)	68.2 (5.9)	67.7 (6.5)
Fibula length (cm)	28.3 (2.5)	28.4 (2.8)

Note. For ethnicity, data are number (%). MELAA = Middle Eastern, Latin American, and African.

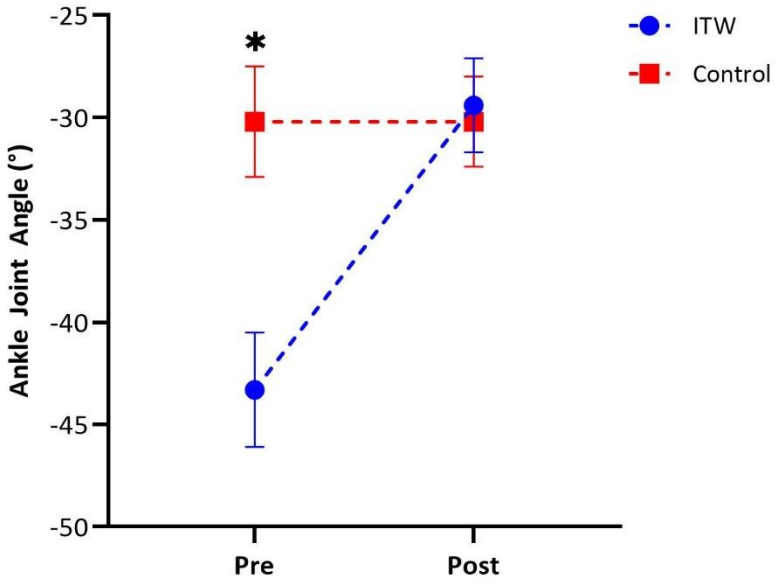
4.3 Idiopathic toe walking and typically developing group comparison

4.3.1 Ankle dorsiflexion range of motion

There was a significant group by time interaction ($p < 0.05$) for resting ankle ROM in prone lying, with a large effect size (partial eta squared: 0.81). Subsequent analysis showed that the ITW group had significantly greater ($p < 0.05$) mean resting ankle ROM (ITW: 43.3°PF, TDC: 30.2°PF) at baseline (Cohen's d = -2.4), however casting of the ITW group led to a decrease of 13.9° (SD 4.5°), and there was no significant difference across groups at follow up (ITW: 29.4°PF, TDC: 30.2°PF), as shown in Figure 4.1.

Figure 4.1

Ankle joint resting angle at baseline and follow-up



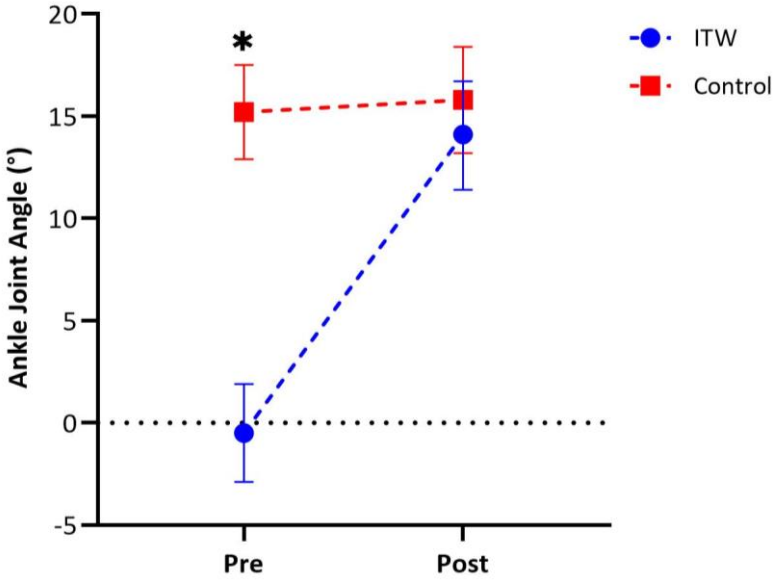
Note. Data are means and 95% confidence intervals. ITW = idiopathic toe walkers.

* = p < 0.05 across groups.

Similarly, for maximal ankle DF ROM in supine lying, there was a significant group by time interaction ($p < 0.05$), with a large effect size (partial eta squared: 0.85). Subsequent analysis of the interaction showed that the ITW group had significantly less ankle DF ROM (ITW: 0.5°PF, TDC: 15.2°DF) at baseline (Cohen's d = -3.3). However, at follow-up after casting of the ITW group, a mean increase of 14.6° (SD 4.2°) had occurred, and there was no significant difference across groups (ITW: 14.1°DF, TDC: 15.8°DF), as shown in Figure 4.2.

Figure 4.2

Ankle joint maximum dorsiflexion angle at baseline and follow-up



Note. Data are means and 95% confidence intervals. ITW = idiopathic toe walkers.

* = p < 0.05 across groups.

4.3.2 Muscle-tendon length

Muscle-tendon length

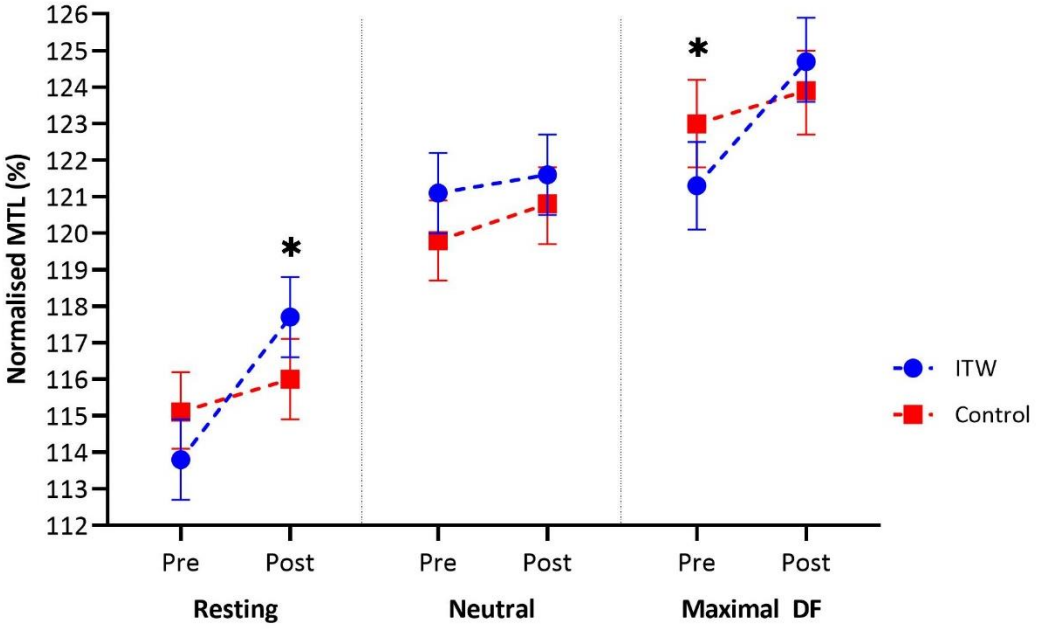
There was a significant group by time interaction ($p < 0.05$) for normalised MTL at the resting joint angle and the partial eta squared for the interaction was 0.64 (large effect size). Subsequent analysis showed there was no significant difference between group means at baseline. As shown in Figure 4.3, following casting, the ITW group had a mean increase of 3.9% (SD 1.4%) and there was a significant difference between groups ($p < 0.05$) at follow-up (Cohen's d = 0.75). Given the crossover in confidence intervals (see Figure 4.3), the mean difference and confidence interval of the difference is reported here (mean difference 1.7%, upper confidence interval 3.2%, lower confidence interval 0.09%).

At the neutral joint angle, there was no interaction effect and no significant main effect ($p > 0.05$) across groups. However, there was a main effect for time ($p < 0.05$) with a partial eta squared of 0.22 (large effect). The mean MTL increase across time was 1% (SD 1.2%) in the control group ($p < 0.05$) and 0.5% (SD 1.6%) in the ITW group ($p > 0.05$).

Regarding MTL at maximal ankle DF, there was a significant group by time interaction ($p < 0.05$) with a large effect size (partial eta squared: 0.55). Subsequent tests across groups showed there was a significant difference between group means at baseline ($p < 0.05$), with the ITW group 1.7% shorter (Cohen's d = -0.72, mean difference 1.7%, upper confidence interval 3.4%, lower confidence interval 0.02%). Following casting, the ITW group had a mean increase in MTL of 3.5% (SD 1.4%) and there was no significant difference across groups (see Figure 4.3). The mean data for MTL is presented in Appendix D. Mean data for muscle-tendon length.

Figure 4.3

Medial gastrocnemius normalised muscle tendon length at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. MTL = muscle-tendon length. DF = dorsiflexion.

* = p < 0.05 across groups.

Tendon length

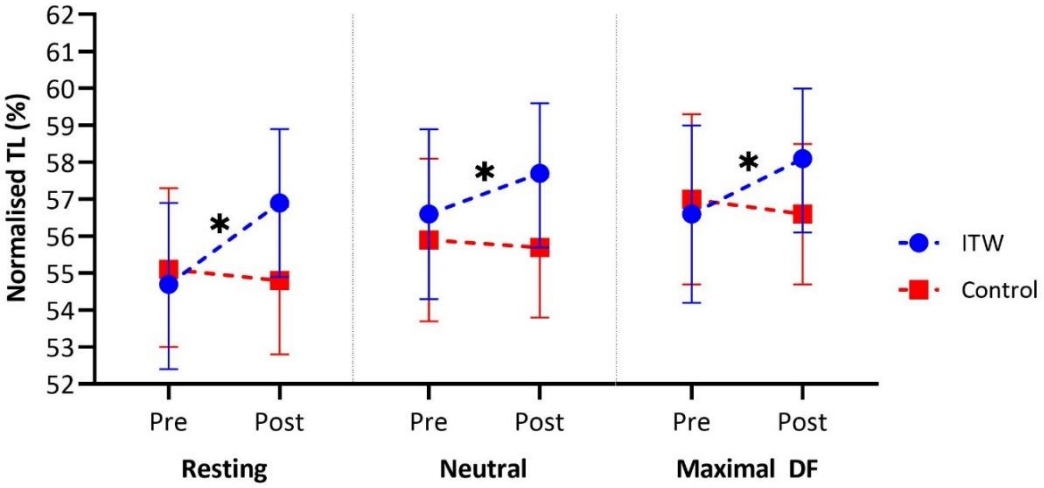
There was a significant group by time interaction ($p < 0.05$) for normalised TL at the resting joint angle, with a large effect size (partial eta squared: 0.35). Subsequent analysis showed there was no significant difference between groups at baseline or at follow-up. The ITW group significantly increased TL ($p < 0.05$); mean 2.2% (SD 1.9%) following casting (Cohen's d = -1.21), as shown in Figure 4.4.

At the neutral joint angle, there was a significant group by time interaction ($p < 0.05$) for TL, with a medium effect size (partial eta squared: 0.13). Subsequent analysis showed there was no significant difference between groups at baseline or at follow-up. However, across time, the ITW group significantly increased TL ($p < 0.05$); mean 1.1% (SD 1.9%) following casting (Cohen's d = -0.58), as shown in Figure 4.4.

Similarly, there was a significant group by time interaction effect ($p < 0.05$) for TL at the maximal DF angle, with a large effect size (partial eta squared: 0.18). Subsequent analysis showed there was no significant difference between groups at baseline or at follow-up. However, across time, the ITW group significantly increased TL ($p < 0.05$); mean 1.4% (SD 1.8%) following casting (Cohen's d = -0.80) (see Figure 4.4). The mean data for TL is presented in Appendix D. Mean data for muscle-tendon length.

Figure 4.4

Medial gastrocnemius normalised tendon length at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. TL = tendon-length. DF = dorsiflexion.

* = p < 0.05 across time points.

Muscle belly length

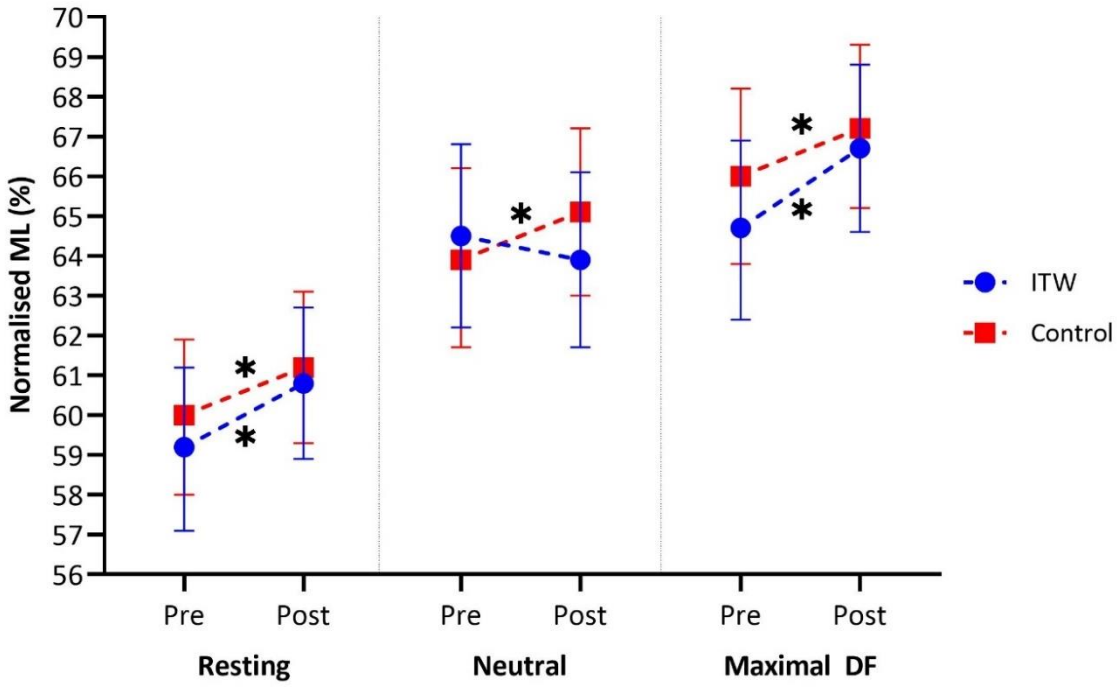
There was no significant interaction effect and no main effect for groups ($p > 0.05$) for normalised ML at the resting joint angle. However, there was a main effect of time ($p < 0.05$), with a partial eta squared of 0.40 (large effect size). From baseline to follow-up, there was a mean increase of 1.6% (SD 2.1%) in the ITW group and 1.3% (SD 1.6%) in the control group (see Figure 4.5).

At the neutral joint angle, there was a significant group by time interaction for ML ($p < 0.05$), with a large effect size (partial eta squared: 0.27). Subsequent analysis showed there was no significant difference between groups at baseline or at follow-up. However, the control group significantly increased ML (mean 1.2%, SD 1.4%) across time points ($p < 0.05$, Cohen's d = -0.83), as shown in Figure 4.5.

At the maximal DF joint angle, there was no interaction and no significant difference ($p > 0.05$) across groups for ML. However, there was a main effect of time ($p < 0.05$), with a partial eta squared of 0.39 (large effect size). From baseline to follow-up, there was a mean increase of 2.0% (SD 1.9%) in the ITW group and 1.2% (SD 2.2%) in the control group (see Figure 4.5). The mean data for ML is presented in Appendix D. Mean data for muscle-tendon length.

Figure 4.5

Medial gastrocnemius normalised muscle belly length at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. ML = muscle belly length. DF = dorsiflexion.

* = p < 0.05 across time points.

Muscle to tendon ratio

For the comparison of tendon ratio (as a percentage of MTL), there was no interaction nor a significant main effect ($p > 0.05$) for group or time at the resting joint angle or at the maximal DF joint angle.

At the neutral joint angle, a two-way analysis of variance showed a significant group by time interaction ($p < 0.05$), with a large effect size (partial eta squared: 0.22). Subsequent analysis showed there was no main effect of group. The ITW group significantly increased tendon ratio (mean 0.7%, SD 1.3%) across time points ($p < 0.05$, Cohen's d = -0.56). The mean data related to tendon ratio is presented in Appendix E. Mean data for tendon length ratio.

4.3.3 Fascicle length, pennation angle, thickness

Fascicle length

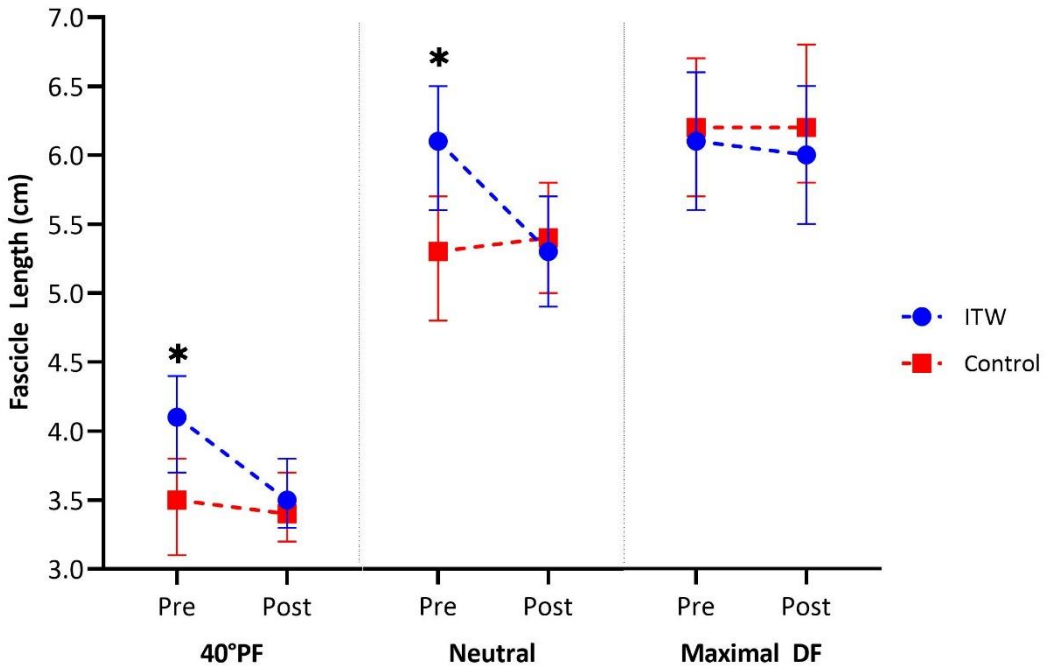
For FL, there was a significant group by time interaction ($p < 0.05$) at the 40°PF joint angle, with a large effect size (partial eta squared: 0.34). At baseline, the ITW group had significantly greater ($p < 0.05$) FL (mean 4.1cm, SD 0.9cm) when compared to the control group (mean 3.5cm, SD 0.4cm) (Cohen's d = 0.92). Serial casting led to a significant decrease in FL of 0.6cm (SD 0.5cm), and there was no significant difference between groups at follow-up (see Figure 4.6).

Similarly, at the neutral joint angle, there was a significant group by time interaction ($p < 0.05$) with a large effect size (partial eta squared: 0.44). The ITW group had significantly greater ($p < 0.05$) FL at baseline (mean 6.1cm, SD 1.1cm), when compared to the control group (mean 5.3cm, SD 0.7cm) (Cohen's d = 0.92). After casting, the ITW group had a mean decrease of 0.8cm (SD 0.7cm), and there was no significant difference ($p > 0.05$) between groups (see Figure 4.6).

At maximal ankle DF, there was no significant interaction effect ($p > 0.05$) and no significant main effect for groups or time (see Figure 4.6). The mean data for ML is presented in Appendix F. Mean data for fascicle length.

Figure 4.6

Medial gastrocnemius fascicle length at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. PF = plantarflexion. DF = dorsiflexion.

* = $p < 0.05$ across groups.

Pennation angle

Figure 4.7 shows that there was a significant group by time interaction ($p < 0.05$) for PA at the 40°PF joint angle, with a large effect size (partial eta squared: 0.16). Subsequent analysis showed there was no significant difference (p >0.05) between groups at baseline nor at follow-up. However, across time, the ITW group significantly increased PA following serial casting ($p < 0.05$); mean 1.6° (SD 1.6°), with a large effect size (Cohen's d = -1.04).

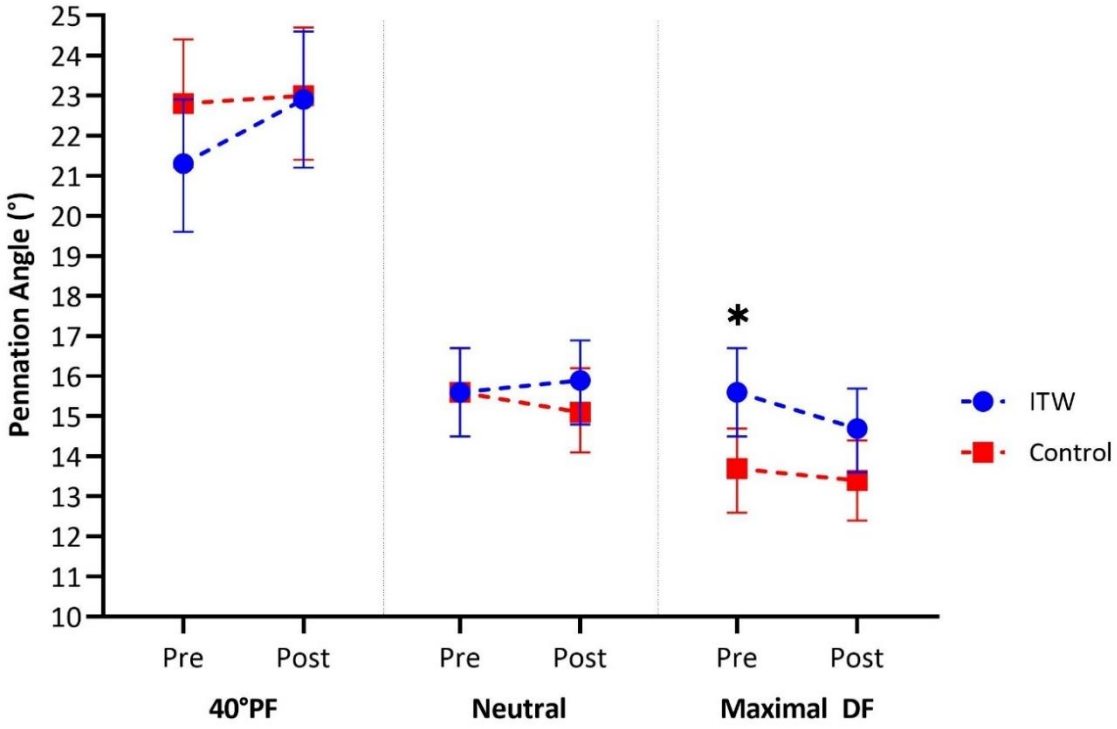
At the neutral joint angle, there was no significant interaction effect ($p > 0.05$) for PA, neither was there a significant main effect for groups or time (see Figure 4.7).

At the maximal DF angle, there was no significant interaction effect for PA ($p > 0.05$). There was a significant main effect of group, with the ITW group having significantly greater ($p < 0.05$) mean PA at baseline (ITW 15.6°: TDC 13.7°), with no significant difference between groups at follow-up. There was also a main effect of time, with a large effect size (partial eta squared: 0.20). The mean PA decrease across time was 0.9°

(SD 1.6°) in the ITW group ($p < 0.05$) and 0.2° (SD 0.8°) in the control group ($p > 0.05$) (see Figure 4.7). The mean data for PA is presented in Appendix G. Mean data for pennation angle and muscle thickness.

Figure 4.7

Medial gastrocnemius pennation angle at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. PF = plantarflexion. DF = dorsiflexion.

* = $p < 0.05$ across groups.

Muscle thickness

There was a significant group by time interaction effect ($p < 0.05$) for M_{Th} at the 40°PF joint angle, with a large effect size (partial eta squared: 0.17). Subsequent analysis showed that the ITW group had significantly greater ($p < 0.05$) mean M_{Th} at baseline (ITW 1.45cm: TDC 1.32cm). Casting of the ITW group led to a significant decrease in M_{Th} (mean 0.10cm, SD 0.15cm) and there was no significant difference across groups at follow-up (see Figure 4.8).

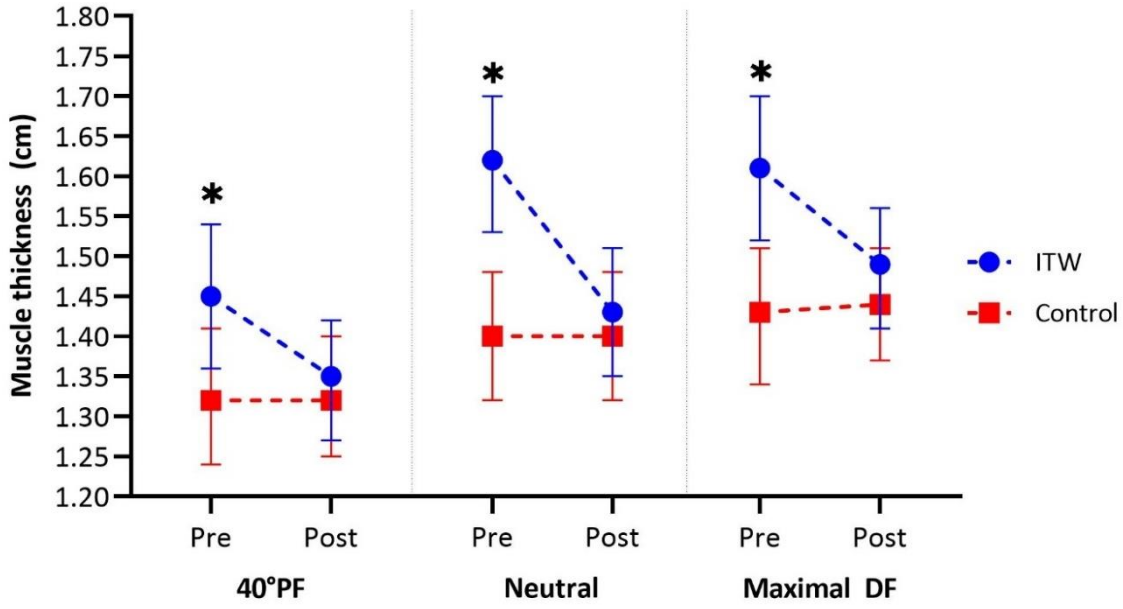
Similarly, at the neutral joint angle, there was a significant group by time interaction ($p < 0.05$) for M_{Th}, with a large effect size (partial eta squared: 0.46). The ITW group had significantly greater ($p < 0.05$) mean M_{Th} at baseline (ITW 1.61cm: TDC 1.40cm). Following casting, the ITW group significantly decreased M_{Th} (mean 0.19cm, SD

0.14cm) and there was no significant difference across groups at follow-up (see Figure 4.8).

Finally, at the maximal DF joint angle, there was a significant group by time interaction ($p < 0.05$) for M_{Th}, with a large effect size (partial eta squared: 0.38). The ITW group had significantly greater ($p < 0.05$) mean M_{Th} at baseline (ITW 1.61cm: TDC 1.43cm). Casting of the ITW group led to a significant decrease in M_{Th} (mean 0.12cm, SD 0.12cm) and there was no significant difference across groups at follow-up (see Figure 4.8). The mean data for M_{Th} is presented in Appendix G. Mean data for pennation angle and muscle thickness

Figure 4.8

Medial gastrocnemius muscle thickness at each measured joint angle, at baseline and follow-up



Note. Data are means and 95% confidence intervals.

ITW = idiopathic toe walkers. PF = plantarflexion. DF = dorsiflexion.

* = $p < 0.05$ across groups.

4.4 Relationship between change in ankle range of motion and change in muscle architecture

Pearson correlation coefficients were used to examine the association between changes (follow-up minus baseline values) in resting and maximal ankle DF ROM and changes in muscle architectural variables. With change in resting ROM as the

dependent variable, no significant correlation was found with change in normalised MTL, TL, ML, or FL at the resting joint angle (see Table 4.3). Similarly, with change in maximal ankle DF ROM as the dependent variable, no significant correlation was found with change in normalised MTL, TL, ML, or FL at the maximal ankle DF joint angle (see Table 4.3). A further correlation examined the association between change in normalised ML as the dependant variable and change in normalised FL (as a contractile element of the muscle belly). FL change did not correlate significantly with ML change at any joint angle (see Table 4.4).

Table 4.3

Pearson correlation coefficient between changes in ankle ROM and changes in medial gastrocnemius muscle architecture variables following serial casting in the ITW group

	MTL change score	**TL change score**	**ML change score**	**FL change score**
R**esting ROM change score**	0.04	-0.15	0.16	-0.35
M**aximal DF ROM change score**	0.35	-0.24	0.46	-0.09

Note. ROM = range of motion. ITW = idiopathic toe walking. MTL = muscle-tendon length. TL = tendon length. ML = muscle belly length. FL = fascicle length. DF = dorsiflexion.

Table 4.4

Pearson correlation coefficient between changes in medial gastrocnemius muscle belly length and changes in fascicle length following serial casting in the ITW group

	FL 40°PF change score	**FL neutral change score**	**FL maximal DF change score**
ML resting change score	0.20	-	-
ML neutral change score	-	0.09	-
ML maximal DF change score	-	-	0.06

Note. ROM = range of motion. ITW = idiopathic toe walking. ML = muscle belly length. FL = fascicle length. PF = plantarflexion. DF = dorsiflexion.

Chapter 5 Discussion

5.1 Introduction

Limited research has been conducted on triceps-surae muscle architecture in ITW and the effect of serial casting on this, despite it being a commonly used treatment method. The primary objectives were (1) to investigate MG muscle architecture and ankle ROM in ITW compared to TDC, (2) to analyse the effect of serial casting on MG muscle architecture and ankle ROM in ITW, and (3) to examine whether changes in ankle ROM related to serial casting, might be associated with changes in muscle architecture. The first section of this chapter discusses the participant characteristics. In the second section, the differences between the ITW and TDC groups are examined. Changes in ankle DF ROM and muscle architecture following serial casting in ITW are then addressed. The relationship between changes in ankle DF ROM and muscle architecture is also examined. Finally, the limitations, conclusions, clinical implications, and future research directions are presented.

5.2 Participants

The ITW and TDC (control) groups were similar in demographics, with no significant differences in age, gender, height, weight, leg length, or fibula length between groups. The ITW group mean age of eight years was comparable with published studies investigating the short-term effect of serial casting on passive DF ROM, with a mean age range of 7-10 years (Brouwer et al., 2000; Engström et al., 2013; Griffin et al., 1977; Katz, 1984; Thielemann et al., 2019; Zapata et al., 2022). The demographics of height, weight, leg length and fibula length (or lower leg length), were consistent with other paediatric US studies (Harkness-Armstrong et al., 2021b; Legerlotz et al., 2010; Malaiya et al., 2007; Martín Lorenzo et al., 2018; Mohagheghi et al., 2008; Weide et al., 2020) with a similar mean age (6-10 years).

5.3 Idiopathic toe walking and typically developing group comparison

5.3.1 Range of motion at baseline

At baseline, the control group had a mean of 15.2° maximal ankle DF, which is central among the range of 9-23°DF reported in other TDC studies (Kawano et al., 2018;

Malaiya et al., 2007; Martín Lorenzo, Albi Rodríguez, et al., 2017; Matthiasdottir et al., 2014; Shortland et al., 2002; Wren et al., 2010). In contrast, the maximal ankle DF of the ITW group was significantly less, with a mean of 0.5° PF. This angle was in the range of other short-term follow-up studies involving casting for ITW (range of means: 11°PF to 7°DF) (Brouwer et al., 2000; Engström et al., 2013; Griffin et al., 1977; Hoffman et al., 2022; Katz, 1984; Thielemann et al., 2019; Zapata et al., 2022). These studies either did not have a TDC control group (Brouwer et al., 2000; Engström et al., 2013; Griffin et al., 1977; Hoffman et al., 2022; Katz, 1984; Zapata et al., 2022), or did not publish the control group DF ROM (Thielemann et al., 2019).

The control group resting ankle joint position of 30.2°PF was in accordance with TDC groups in other paediatric US studies, which have reported a range of 18-44°PF (Kruse et al., 2018; Malaiya et al., 2007; Martín Lorenzo, Albi Rodríguez, et al., 2017; Matthiasdottir et al., 2014; Shortland et al., 2002; Wren et al., 2010). The resting ankle joint position was significantly more plantarflexed in the ITW group, with a mean of 43.3°PF. Other studies in the ITW population have not reported resting ankle joint position.

Our findings of reduced DF ROM in ITW are comparable with previous studies, which show a decrease in DF ROM over time with persistent toe walking (Bartoletta et al., 2021; Engelbert et al., 2011; Sobel et al., 1997). However, this finding is not consistent across the ITW literature, with other studies showing no clear progression of ankle DF limitation over time (Engström & Tedroff, 2018). It is not well quantified as to whether DF ROM decreases as a consequence of persistent toe walking, or if the DF limitation causes the toe-walking (Sobel et al., 1997).

5.3.2 Muscle-tendon length at baseline

Baseline MTL in the control group was 32.7cm (115% normalised to fibula length) at the resting joint angle, 34.0cm (120%) at neutral and 34.9cm (123%) at maximal DF. These values are comparable to the few studies which have measured MTL in TDC previously: 34.7cm at the resting joint angle (Weide et al., 2020) and 37.3cm at 15°PF (Harkness-Armstrong et al., 2021b).

There was no significant difference between the ITW and control groups' MTL at the resting or the neutral joint angles. These findings are similar to those of Harkness-

Armstrong et al. (2021b) who also found no significant difference between ITW and TDC groups at a common joint angle (15°PF). This result is logical, given MTL is mainly influenced by anthropometry (Bénard et al., 2011), which was similar between groups. At maximal DF, there was a significant difference between groups (0.6cm or 1.7%), with the ITW group having shorter MTL. No other studies have examined MTL at maximal DF in ITW as a comparison. This finding is probably explained by the large difference in maximal ankle DF ROM between groups at baseline, as discussed above (0.5°PF ITW: 15.2°DF control), as the ITW group maximal DF MTL is effectively the same as the neutral joint angle measure at baseline. However, the 2D-US technique for measuring MTL which the present study followed (Barber, Barrett, et al., 2011), reported overall 6% (1.5cm) limits of agreement with 3D-US for ML, which suggests that the degree of difference seen at maximal DF in the present study is within normal variability and is not clinically significant.

Looking at the components of the overall MTL: baseline TL in the control group was 15.7cm (55% normalised to fibula length) at the resting joint angle, 15.9cm (56%) at neutral and 16.2cm (57%) at maximal DF. These lengths are comparable to the mean TL range of 14.4cm to 17.6cm or normalised TL range of 52-54%, reported in other paediatric US studies with control groups of a similar age (Harkness-Armstrong et al., 2021b; Martín Lorenzo et al., 2018; Mogi, 2020; Weide et al., 2020). ML in the control group was 17.0cm (60% normalised to fibula length) at the resting joint angle, 18.1cm (64%) at neutral and 18.7cm (66%) at maximal DF. These lengths are comparable to the mean ML range of 14.8cm to 20.4cm or normalised ML range of 64-70%, reported in other paediatric US studies (Cenni et al., 2018; Harkness-Armstrong et al., 2021b; Malaiya et al., 2007; Martín Lorenzo et al., 2018; Weide et al., 2020).

TL alone or ML alone were not significantly different between the ITW and TDC groups at any joint angle at baseline. This finding is contrary to that of Harkness-Armstrong et al. (2021b), who found that ITW MG TL was significantly shorter and ML significantly longer than a TDC control group at a common joint angle (15°PF). They reported that TL was 37% of the total MTL in the ITW group, compared to 47% in the TDC group. In the present study, TL as a percentage of MTL was not significantly different between groups, with mean values ranging from 46% to 48% across the ROM measured. Other paediatric studies in TDC have reported a range of 39-46% for TL as a percentage of

MTL (Kruse et al., 2018; Weide et al., 2020; Wijnands et al., 2022; Wren et al., 2010). The study by Harkness-Armstrong et al. (2021b) had a small ITW sample size (N = 5) and within this number, three had fixed DF limitations of 12-30°PF; however, the group mean ROM was not reported. This would suggest that the ITW group maximal DF ROM was significantly less than the current study (0.5°PF), which may be an explanation for the difference in findings. It is possible that Achilles tendon shortening is present in some children who fit within the ITW diagnostic category, but not all. Another perspective is that there is a range of TL to ML ratio within the normal population and it does not necessarily predispose someone to toe walking. Baseline TL as a percentage of MTL ranged from 39% to 55% in the ITW group and from 41% to 55% in the control group in the present study (see Appendix E. Mean data for tendon length ratio).

Overall, the current findings suggest that there is not a clinically significant difference in TL, ML and total MTL in the MG of ITW when compared to TDC.

5.3.3 Fascicle Length at baseline

As the ankle moves from PF to DF, the muscle-tendon unit lengthens and within the muscle belly, the fascicles lengthen (Bénard et al., 2011). Fascicle lengthening is affected both by the contractile elements of the muscle fibres (stretching of actin and myosin filament cross-links within the sarcomeres) and by stretching of non-contractile elements of the connective tissue surrounding the muscle fibres, fascicles, and muscle belly (Gajdosik, 2001; Lieber, 2002). The control group FL values in the present study were 3.5cm (12% normalised to fibula length) at the 40°PF angle, 5.3cm (19%) at neutral, and 6.2cm (22%) at maximal DF. The fascicle lengths at 40°PF are comparable to the mean FL range of 3.0cm to 4.2cm or normalised FL range of 13-14%, reported in previous TDC studies (Harkness-Armstrong et al., 2021b; Legerlotz et al., 2010; Martín Lorenzo et al., 2018; Mohagheghi et al., 2008; Shortland et al., 2002). FL values at the neutral and maximal DF angles are slightly longer than those reported in previous studies of TDC aged 6-11 years: 4.1cm to 5.0cm at neutral (Cenni et al., 2018; Legerlotz et al., 2010; Shortland et al., 2002), and 4.9 to 5.4cm at maximal DF (Cenni et al., 2018; Kawano et al., 2018; Malaiya et al., 2007). Yet normalised FL is within the range of previously published TDC values: 17-21% at neutral (Martín Lorenzo, Albi Rodríguez, et al., 2017; Shortland et al., 2002) and 20-22% at maximal DF (Martín Lorenzo, Albi Rodríguez, et al., 2017; Martín Lorenzo et al., 2018).

Comparing our results across ITW and control groups, it was apparent that FL was significantly longer at the 40°PF (0.6cm or 2% normalised to fibula length) and neutral (0.8cm or 3%) ankle angles. This degree of difference is greater than the minimal detectable difference values of 0.2-0.4cm shown in paediatric US studies (Cenni et al., 2018; Legerlotz et al., 2010). Our findings are consistent but much smaller than those of Harkness-Armstrong et al. (2021b), who found significantly longer FL (2.0cm) in an ITW group at a common ankle angle (15°PF). From a physiological perspective, the increased length at these shared joint angles suggests that the ITW fascicles are at greater strain. As the ITW maximal DF ROM is decreased compared to controls, the range of motion that the fascicles operate within is shifted toward a more plantarflexed position. Furthermore, in the current study, there was no significant difference in FL between groups at the maximal DF angle, which supports the notion that the fascicles are operating in a more plantarflexed position, yet the total FL available is not different to TDC. In contrast, Harkness-Armstrong et al. (2021b) reported significantly longer FL at all joint positions, however, they had an ITW group with a greater degree of DF limitation and significantly longer ML at all joint positions.

Considering these findings, it seems that ITW FL is greater than that of TDC when compared at the same joint angle, however, the maximum FL is not different between groups.

5.3.4 Pennation Angle at baseline

PA typically decreases as FL increases during ankle movement from a plantarflexed to a dorsiflexed position (Bénard et al., 2011; Legerlotz et al., 2010). The control group PA values in the present study were 22.8° at 40°PF, 15.6° at neutral and 13.7° at maximal DF. These findings are comparable to published figures of 21-25° at angles similar to 40°PF (Bulut et al., 2022; Cenni et al., 2018; Legerlotz et al., 2010; Shortland et al., 2002), 16-17° at a neutral joint angle (Legerlotz et al., 2010; Shortland et al., 2002), and 15-17° at maximal DF (Cenni et al., 2018; Kawano et al., 2018; Malaiya et al., 2007).

Between groups, baseline PA at the 40°PF and neutral ankle angles was not significantly different, however at maximal DF the ITW group had a significantly greater PA (1.9°). Previous paediatric US studies have shown minimal detectable difference values of 1-2° or 5-10% (Cenni et al., 2018; Legerlotz et al., 2010) and

similarly adult studies have reported 9-10% (McMahon et al., 2016; Ritsche et al., 2022). The 1.9° difference in the present study is 12% of the ITW group PA (15.6°) at maximal DF. Thus, it is slightly above reported minimal detectable differences values and could be cautiously interpreted as clinically significant.

Our findings at the 40°PF and neutral ankle angles are consistent with the evidence of Harkness-Armstrong et al. (2021b) who did not find a significant difference in PA between ITW and TDC at a common joint moment (0 Nm), equivalent to 22°PF in the ITW group and 16°PF in the TDC group. This was despite the ITW group having significantly longer FL at common joint angles in both the Harkness-Armstrong et al. (2021b) study and in our study.

Although the PA at maximal DF is slightly higher in the ITW group, FL was not significantly different between groups. This might be explained by the influence of muscle hypertrophy in the ITW group. As M_{Th} is greater in the ITW group at maximal DF, PA must also be greater if FL is unchanged ($FL = M_{Th}/\sin(PA)$).

Overall, it appears that ITW PA is not significantly different from that of TDC when compared at the same joint angle. However, at the maximal DF angle it is slightly greater, which may be related to the increase in M_{Th}.

5.3.5 Muscle thickness at baseline

The baseline mean M_{Th} in the control group was 1.32cm at the 40°PF ankle angle, 1.40cm at neutral and 1.43cm at maximal DF. This is consistent with a range of 1.05cm to 1.40cm in TDC of a similar age (Harkness-Armstrong et al., 2021b; Kawano et al., 2018; Kruse et al., 2018; Legerlotz et al., 2010).

The ITW group had significantly greater M_{Th} at all joint angles compared to the TDC: 1.45cm at 40°PF (+0.13cm), 1.62cm at neutral (+0.22cm), and 1.61cm at maximal DF (+0.18cm). Published minimal detectable difference values in paediatric US studies range from 0.05cm (Legerlotz et al., 2010) to 0.11-0.38cm (Boulard et al., 2021), whilst in adult US studies they range from 0.09cm to 0.32cm (May et al., 2021; McMahon et al., 2016; Ritsche et al., 2022). There is a large degree of variation in these values, with a range of 3-28% of the mean M_{Th} value. In the present study, there was a 10-16% greater magnitude in the ITW group when compared to the control group values.

Overall, this is above the minimal detectable difference values in the majority of studies, with the exception of May et al. (2021) and Boulard et al. (2021).

The only other study (Harkness-Armstrong et al., 2021b) to examine M_{Th} in ITW, reported 1.70cm in ITW compared to 1.40cm in TDC at a common joint moment (0 Nm), which was equivalent to 22°PF in the ITW group and 16°PF in the TDC group. However, these results did not reach statistical significance, which may be due to smaller sample size (ITW, n = 5). A possible explanation for the observed increase in M_{Th} in ITW in the present study is that the increased triceps surae muscle activity during toe-walking gait (Harkness-Armstrong et al., 2021a; Perry et al., 2003), leads to muscle hypertrophy. Both concentric and eccentric strength training have been shown to produce increases in muscle hypertrophy, with muscle thickness being one way to measure this (Schoenfeld et al., 2017; Warneke et al., 2023). Perry et al. (2003) found that the gastrocnemius and soleus muscles were active through a larger percentage of the gait cycle during toe-walking and thus it could be speculated that with prolonged toe-walking there is an effect similar to strength training.

Overall, the current findings suggest that M_{Th} is greater in ITW when compared to TDC, yet the magnitude of difference is not large considering minimal detectable difference values in previous studies.

5.4 Effect of Serial Casting

5.4.1 Range of motion

Ankle DF ROM with the knee extended increased significantly post-casting from a mean of 0.5°PF to 14.1°DF. These findings are consistent with previous short term follow-up studies which show an increase in maximal ankle DF ROM between 6.6° to 23.3° after serial casting for ITW (Brouwer et al., 2000; Engström et al., 2013; Griffin et al., 1977; Hoffman et al., 2022; Katz, 1984; Thielemann et al., 2019; Zapata et al., 2022). Similarly, the resting ROM in the ITW group changed significantly from 43.3°PF pre-casting to 29.4°PF after casting. Previous studies have not examined the effect of casting on resting ankle ROM.

At follow-up, both resting ROM and maximal ankle DF ROM were not significantly different to the control group. Other studies have not compared post-casting ankle

ROM in ITW to TDC. However, as described in section 5.3.1, these parameters are within the normal range compared to other published data for TDC (Kawano et al., 2018; Malaiya et al., 2007; Martín Lorenzo, Albi Rodríguez, et al., 2017; Matthiasdottir et al., 2014; Shortland et al., 2002; Wren et al., 2010).

5.4.2 Muscle-tendon length

MTL at rest and at maximal DF significantly increased in the ITW group post casting; 1.1cm (4% normalised to fibula length) at rest and 1.0cm (4%) at maximal DF. There are no comparable studies in the ITW literature, although in the CP literature there are contrasting findings. Two studies reported no significant change in MTL following 16-weeks of wearing an ankle-foot brace with a 4° increase in DF ROM (Hösl et al., 2015) and following a 10-week stretching program with a 5° increase in DF ROM (Kalkman et al., 2019). These findings are contrary to those of Peeters et al. (2020) who reported a significant 1.6cm increase in MTL at maximal DF after two weeks of casting, with a 6° increase in DF ROM. This latter finding by Peeters et al. (2020) is surprising, as it is a larger change in MTL (6% relative to baseline value) than the present study or the previously described studies, over a much shorter time period. All these studies have smaller changes in DF ROM compared to the present study and thus one might expect smaller changes in MTL, which is evident in the non-significant changes seen in the first two studies. The clinical significance of the MTL changes seen at rest and at maximal DF is important. Barber, Barrett, et al. (2011) reported 6% (1.5cm) limits of agreement for ML alone with the US-tape measure method. The changes of 1.1cm and 1.0cm seen in our study do not meet this threshold. It is possible that the small changes at rest and at maximal DF can be attributed to the changes in ankle angle values at these measurement points between baseline and follow-up (14° change in resting and maximal DF values), as at the common joint angle (neutral) there was no difference post-casting.

Like MTL, ML at rest and at maximal DF significantly increased in the ITW group post casting; 0.5cm (2% normalised to fibula length) at rest and 0.6cm (2%) at maximal DF. These changes are not greater than the 6% (1.5cm) limits of agreement for ML reported by Barber, Barrett, et al. (2011) and thus may not be clinically significant. Considering previous literature, several adult animal studies found that ML of ankle plantarflexors did not change when immobilised in a lengthened position (Gossman et

al., 1986; Spector et al., 1982; Williams, 1978). However, one study in young mice (Williams, 1978) showed a significant reduction in soleus ML after 3-weeks immobilised in a lengthened position, which differs to the present study findings. Like the adult animal studies, two paediatric CP studies have shown no significant change in ML following 2-weeks of serial casting with a 5-6° increase in DF ROM (Martín Lorenzo, Rocon, et al., 2017; Peeters et al., 2020). Overall, these findings differ to ours.

ITW TL increased significantly at all joint angles following serial casting; 0.6cm (2% normalised to fibula length) at rest, 0.3cm (1%) at neutral, and 0.4cm (2%) at maximal DF. However as previously discussed, this degree of change does not meet the threshold for clinical significance as reported by Barber, Barrett, et al. (2011). In contrast to the present study, Kalkman et al. (2019) reported no significant change in TL following a 10-week stretch program with a 5° increase in ankle DF ROM in a CP group. However, Peeters et al. (2020) found a significant increase in TL at maximal DF of 0.8cm following 2-weeks of serial casting in a CP group, with a 6° increase in DF ROM. These changes are much larger than those seen in the present study (0.4cm), yet over a much smaller time period (2-weeks versus 6 weeks of casting). Similarly, a study of young mice (Williams, 1978) showed a significant reduction in soleus ML after 3-weeks immobilised in a lengthened position. Thus, it was suggestive of TL increase, although this was not directly measured. Of note, the muscle and tendon length increases seen in the present study are greater than those which would be expected with normal growth over 7-weeks (Bénard et al., 2011).

Overall, in the present study, there were significant increases in both TL, and ML, and thus MTL, yet these did not appear to be clinically significant in magnitude.

5.4.3 Fascicle Length

Following serial casting, FL was significantly decreased at the 40°PF (0.57cm or 2% normalised to fibula length) and neutral (0.78cm or 3%) ankle angles. There was no significant difference at the maximal DF angle. The magnitude of FL decrease is greater than the minimal detectable change values of 0.20-0.35cm reported in paediatric CP and TDC studies (Cenni et al., 2018; Legerlotz et al., 2010), and thus can be thought to be clinically significant.

There are contrasting findings within the literature on the effect of serial casting or prolonged stretch with immobilisation on FL, muscle fibre length, or sarcomere length. Williams (1978) showed a decrease in sarcomere length in the soleus muscle of both adult and young mice, immobilised in the lengthened position, yet with an increase in sarcomere number in the adults and a decrease in sarcomere number in the young mice. Whereas Spector et al. (1982) found no significant change in fibre length or sarcomere length of MG after 4 weeks immobilised in a lengthened position. Yet, within the same study, soleus fibre length was significantly increased, with no change in sarcomere length. In the paediatric CP population, Martín Lorenzo, Rocon, et al. (2017) assessed change in FL following two weeks of serial casting and found no significant change at the resting or maximal DF ankle angles, with a 5° increase in DF ROM. By contrast, Hösl et al. (2015) found that FL was significantly decreased (11% compared to baseline) across the range of ankle motion, following 16-weeks within an AFO, with no significant change in ankle DF ROM. This suggests that the decrease in FL was related to immobilisation per se rather than to a change in DF ROM, as M_{Th} was also significantly decreased at the maximal DF angle.

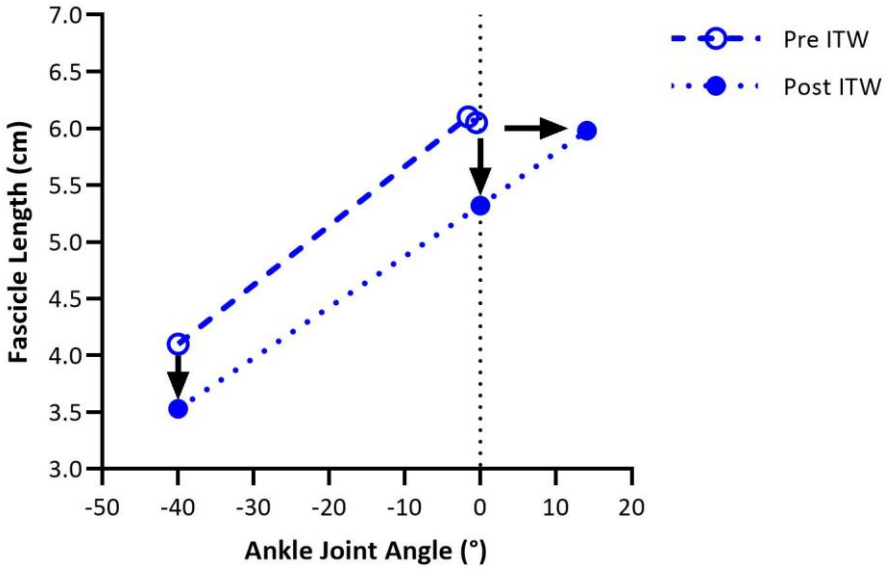
Studies which have examined the effects of stretch alone, without immobilisation, have shown differing results. Static stretching programmes of shorter duration (3-8 weeks) in adults have shown no significant changes in FL or PA of ankle plantarflexor muscles (Freitas et al., 2018; Nakamura et al., 2012). Within the paediatric CP literature, one study (Kalkman et al., 2019) showed no change in MG FL after a 10-week stretching program, whereas another (Zhao et al., 2011) showed a statistically significant, although seemingly small, increase in MG FL (+0.1cm) following a 6-week combined static stretching and active movement training program. Yet longer duration adult stretching programs have shown significant increases in MG FL associated with increases in DF ROM in both healthy adults over 12-weeks (Andrade et al., 2020) and stroke participants over 1-year (Pradines et al., 2019).

Considering the present study results in light of the previous literature, it seems that stretch alone may cause either no change in FL or an increase in FL, whereas with the addition of immobilisation, as is present with serial casting, a decrease in FL may be seen. Thus, it could be argued that the decrease in FL seen at 40°PF and neutral, with no change in FL at maximal DF despite a large increase in DF ROM, is an effect of

immobilisation. Disuse muscle atrophy has been shown to be less when muscle is immobilised in a lengthened position (Gossman et al., 1986; Herbert & Balnave, 1993; Spector et al., 1982), however, it still causes significant decreases in cross-sectional area of the muscle or muscle fibres (Nicks et al., 1989; Spector et al., 1982). Yet with the addition of some isometric contractile activity, as you would expect with walking in serial casts, the degree of atrophy is even less (Baewer et al., 2004). Alternatively, it could be said that as the total FL (measured at maximal DF), did not change following serial casting, the changes at the 40°PF and neutral ankle angles are due to a shift in the ankle ROM in which the FL operates within, rather than a true change in length. To appreciate these thoughts concerning changes in FL across the ROM, Figure 5.1 provides an illustration.

Figure 5.1

Medial gastrocnemius fascicle length at the measured joint angles, pre- and post-casting



Note. Data points are means. ITW = idiopathic toe walkers.

5.4.4 Pennation Angle

PA was significantly increased at 40°PF following serial casting (1.6°), unchanged at neutral and significantly decreased at maximal DF (1.0°). There are few studies for comparison, and within those, reported changes are small. Psatha et al. (2012) showed that MG PA measured with MRI decreased 3° in adults when compared to a control limb, following 4-weeks cast immobilisation post ankle fracture. Hösl et al. (2015) utilised prolonged AFO use (16 weeks) in a paediatric CP population and showed no

change in PA despite a significant decrease in FL and M_{Th}. Within shorter duration stretch-alone studies, Zhao et al. (2011) reported a significant 1° decrease in PA (along with a 0.1cm increase in FL) following 6-weeks of stretching and active movement training in children with CP. Interestingly, a systematic review of 3-8 week stretching interventions in adults, showed no change in PA or FL (Freitas et al., 2018).

In the present study, FL was unchanged at the maximal DF angle, yet M_{Th} was decreased and thus it makes sense that PA was also decreased in order for FL to be unchanged. Yet these changes of 1.6° (8% increase from baseline) and 1.0° (6% decrease from baseline) should be interpreted with caution. They are at the lower end of reported minimal detectable change values, which are 1.0°-1.7° (5-10% change) in paediatric US studies (Cenni et al., 2018; Legerlotz et al., 2010), and 2.5-6.4° (9-30% change) in adult studies (May et al., 2021; McMahon et al., 2016; Ritsche et al., 2022).

5.4.5 Muscle thickness

Our study found that M_{Th} was significantly decreased at each joint angle following serial casting; 0.1cm at 40°PF, 0.18cm at neutral and 0.12cm at max DF. This equated to a range of 7% to 11% change compared to the baseline values. This finding is not surprising. Muscle atrophy has been shown in animal models with muscles immobilised in a lengthened position. For example, Spector et al. (1982) found that MG muscle weight was 84% of control weight in rats after 4-weeks. Similarly, adult studies have reported decreased cross-sectional area with immobilisation following ankle fracture. Christensen et al. (2008) found a 15% decrease in triceps-surae muscle cross-sectional area on CT scan after 7-weeks and Psatha et al. (2012) found a 23% decrease in MG cross-sectional area on MRI scan at 4-weeks. Within a paediatric CP population, Hösl et al. (2015) reported a 12% decrease in M_{Th} measured with 2D-US after 16-weeks of AFO use, which blocked PF but allowed DF. It seems likely that the decrease in M_{Th} seen in the above studies and in our results, is due to the effect of immobilisation rather than stretch, as stretch alone studies have shown no significant change in MG M_{Th} (Andrade et al., 2020; Pradines et al., 2019).

Regarding the magnitude of decrease in M_{Th} in the present study, there are several studies which provide evidence for comparison. Adult studies using 2D-US to assess MG M_{Th}, have variously reported minimal detectable change of 0.32cm (May et al.,

2021), smallest detectable difference of 0.26cm or 11% (McMahon et al., 2016) and standard error of measurement of 0.09cm or 6% (Ritsche et al., 2022). More specifically, there are two paediatric studies which discuss minimal detectable change for M_{Th} measured between sessions. Legerlotz et al. (2010) suggest that greater than 0.05cm change in M_{Th} (based on a 3% coefficient of variation) should be detectable; however, this seems highly improbable on an individual basis. A range of 0.11 to 0.38cm minimal detectable change was reported by Boulard et al. (2021) and the changes in the present study would fit at the lower end of this range. Thus, overall, based on the range of previous adult and paediatric literature, it seems likely that the M_{Th} changes following serial casting in the present study are clinically significant.

Muscle is adaptable, just as it can atrophy with immobilisation, it can hypertrophy and remodel with loading (Blazevich, 2006). Atrophy has been shown to be associated with a decrease in muscle strength (Christensen et al., 2008). Thus, from a clinical perspective, rehabilitation including triceps surae muscle strengthening post-casting is important for restoring muscle strength.

5.5 Relationship between ankle dorsiflexion and muscle architecture

No significant correlations were found between the changes in ankle DF ROM and muscle architecture length changes. Although MTL and its components did significantly increase in length post-casting this was not significantly correlated with the increase in DF ROM. There is very little found in the literature which might explain this finding. Studies which have shown an increase in DF ROM and examined MTL changes have been in the CP literature, with one not reporting correlations (Martín Lorenzo, Rocon, et al., 2017). The other (Peeters et al., 2020) only showed a moderate positive correlation ($r = 0.56$) between the change in ankle angle and the change in TL at maximal DF, but there were no other significant correlations. Neither have any correlations between changes in ankle DF ROM and changes in FL been identified in these studies. Thus, the relationship between gains in ankle DF ROM and changes in MG muscle architecture is still not well quantified.

FL change was not correlated with ML change in the present study. The previously discussed studies on serial casting have not examined this correlation and thus there is little to inform us on what the relationship may be. FL either decreased (40°PF and

neutral) or was unchanged (maximal DF) post-casting. ML was increased at the resting and maximal DF angles, yet these changes did not reach clinically significant levels. Fascicles are just one component of the muscle belly, and our results suggest that any increase in ML seen following serial casting is likely not due to changes in the contractile elements of the muscle but rather to other tissues.

Given the lack of correlation found between MG muscle architecture changes and the large change in DF ROM seen, the contribution of other tissues such as nerve and fascia should be considered, as it is thought that they effect maximal joint ROM to varying degrees (Nordez et al., 2017). Andrade et al. (2020) showed that maximal ankle DF ROM could be affected differentially with a nerve-directed stretch compared to a muscle-directed stretch. The nerve-directed group showed a reduction in sciatic nerve stiffness with an improvement in ankle DF ROM with the hip at 90° whereas the muscle-directed group showed a reduction in triceps surae stiffness and an increase in MG FL with an improvement in ankle DF ROM with the hip at neutral. In an adult stretch study, Nakamura et al. (2012) found no change in FL despite an increase in ankle DF ROM and MTJ displacement. However passive torque was significantly decreased, suggesting that reduced muscle stiffness contributed to an improvement in DF ROM. Given the FL did not change, this was attributed to connective tissue (fascia) within the muscle.

5.6 Limitations of the study

There are a number of limitations to be considered. Firstly, the data collection and analysis procedures were all completed by one person (the candidate). Blinding was not possible in relation to data collection although, a standard data collection protocol was followed. To reduce bias within the analysis, all practical steps were taken to blind the assessor to the participant identity during image analysis.

ITW study participants were recruited from children on the waitlist for serial casting and the degree of ankle DF limitation present was not one of the inclusion criteria. Thus, there were ITW participants who did not have fixed ankle DF restrictions prior to casting, defined as less than 0° when measured with the knee extended (Sobel et al., 1997). There may be a difference in muscle architecture between children with ITW and concomitant DF limitations compared to those with ITW without DF limitations.

The ITW participants were limited in number and thus did not provide large enough groups to make this comparison.

Nordez et al. (2017) suggest that other tissues (fascia and/or nerve) in combination with the muscle-tendon unit, contribute to maximal joint ROM to varying degrees, however these were not measured in our study. Furthermore, the contribution of other muscle groups in the triceps-surae complex and other muscles (e.g., the deep toe flexors) that might contribute resistance to ankle joint DF ROM were not examined. MG was chosen as previous research (DiGiovanni et al., 2002; Le Sant et al., 2017) suggests that this muscle contributes the most to any reduced DF ROM with the knee extended. Additionally, it is the most commonly measured muscle and hence allowed better comparison with the literature. Of note, the added time it would take to measure multiple muscle groups, would make data collection sessions impractical due to the tolerance levels of young children.

The MG is a biarticular muscle and crosses both the ankle and the knee joint. It is assumed that children are standing and walking in the casts with the ankle angle fixed and the knee in an extended position, however levels of physical activity were not recorded. Thus, it is not known how much of the day participants may have been sitting or lying with a flexed knee, thus reducing the stretch on MG at the level of the knee. The intensity and duration of the stretch on MG is therefore not known.

2D-US was chosen to examine MG muscle architecture as it is more readily available in a clinic setting and more cost effective than other measurement techniques, such as MRI. However, it has a lower level of precision in measuring small changes in muscle architecture. 3D-US would provide a greater degree of accuracy for MTL measurement; however, this is more challenging to set up and thus not as practical for use in a clinical setting (Barber, Barrett, et al., 2011). Furthermore, while M_{Th} is a partial evaluation of muscle atrophy, 3D-US would enable a more complete view with the measurement of muscle volume enabling determination of cross-sectional area (Barber et al., 2009).

The US technique used to measure MTL did not visualise the proximal MG muscle insertion. Instead, it used the most superficial point on the posterior aspect of the medial femoral condyle as a standardised landmark. This may introduce a small

measurement error, although this technique has been established as reliable and valid (Barber, Barrett, et al., 2011). At the level of the Achilles tendon, the US-tape method gives a linear measure of length and does not take into account curvature in the tendon, which is likely to be more significant in positions of greater ankle PF. Despite these limitations, the measurement used was consistent across participants, thus the effect across groups should be small. Another limitation of the US-tape method is that it was not possible to accurately visualise the Achilles tendon insertion when the ankle was held in a plantarflexed position on the Biodex plate (40°PF angle), due to the small size of the participants. Thus, it was chosen to measure MTL and TL at the resting ankle angle, whilst not attached to the Biodex plate, whereas FL, PA and M_{Th} were measured with the ankle held at 40°PF.

The method used to measure FL on the US images assumes a linear path and does not take into account fascicle curvature. However, the impact of this is thought to be negligible (Seynnes & Cronin, 2020). Furthermore, when the fascicle is not fully visible in the US image, the SMA tool uses extrapolation to provide a measure of total FL. This may introduce some error. However, this also occurs with manual measurement of US images, which require the person analysing the data to extrapolate the aponeuroses outside the field of view to measure the total FL.

The participants did incredibly well to lie still for 30-40 minutes for US data collection. Without the use of electromyography, we can't be completely certain that muscles were fully relaxed during all data collection. However, care was taken to exclude measures with obvious muscle contraction and collect extra ultrasound images when required.

A final limitation was the difficulty in participant recruitment and data collection due to the impact of COVID-19 restrictions. Standard clinical care at the NCRS was interrupted during this period (March 2020 - December 2021) and thus the number of children undergoing serial casting was significantly decreased. In normal conditions, based on unpublished audits from NCRS, 20-25 children have serial casting for ITW a year. The reduced numbers of children with ITW available for recruitment impacted upon the level of statistical power attainable.

5.7 Conclusions and clinical implications

Although decreased ankle DF ROM is a common finding in ITW, changes in triceps-surae muscle architecture have not been widely examined. Furthermore, the effect of serial casting on muscle architecture in ITW, a modality commonly used to treat reduced ankle DF ROM, has not previously been investigated. Thus, the present study provides novel data to further our understanding of this condition.

Our findings showed that while children with ITW have significantly decreased resting and maximal ankle DF ROM, the overall MG muscle architecture is not wholly different to that of TDC. The exception to this was increased M_{Th} at all joint angles, which could be attributed to the change in MG function during toe-walking, with the plantarflexor muscles active for a greater portion of the gait cycle.

Our findings suggest that ankle ROM and MG muscle architecture are improved to a normal range following serial casting for ITW. While changes in muscle architecture following casting were small, lengthening that occurred across the muscle-tendon unit was across both the tendon and the muscle (as well as other tissue potentially), not one or the other. This finding is reassuring for clinicians who are utilising serial casting as a treatment modality for ITW. M_{Th} was decreased at every joint angle, in keeping with the effect of muscle atrophy due to immobilisation. Thus, post-casting rehabilitation, including targeted strengthening of the triceps surae complex, is of importance.

Finally, we did not find any correlation between the large changes in ankle DF ROM and changes in MG muscle architecture length measures following casting. The changes in muscle architecture were relatively small, which suggests that other tissues (fascia, nerve) also contribute to changes in ankle ROM, however, it remains uncertain what the contributions of individual tissues may be. Given the variable effectiveness in current interventions for ITW, these findings may encourage clinicians to investigate other treatment methods for restoring ankle DF ROM in this population.

5.8 Future research recommendations

Several areas for future research were identified from this study:

- Longer term follow-up is warranted to examine what the effect of serial casting is at 12 months and longer in the ITW population, given the aim is to resolve the toe-walking.
- While serial casting improves DF ROM in the short-term, there is currently no evidence on how to maintain these gains in regard to utilising the ROM gained in function. Investigation into the effect of different types of stretch, strength training and gait re-education would be beneficial to guide physiotherapy intervention post-casting.
- Given the lack of association found between changes in ankle DF ROM and muscle architecture, it would be of interest to further examine the contribution of other tissues, for example, with the use of shear wave elastography as a measure of tissue stiffness. Furthermore, it may be worthwhile investigating other treatments which influence fascia and nerve stiffness regarding their effect on ankle ROM and toe-walking.
- It would be of interest to establish if there are differences in TL ratio between those within the ITW diagnostic category that have DF limitations compared with those who habitually toe-walk yet without DF limitations. Testing of a larger group of ITW and TDC may enable further investigation of whether reduced TL is related to ITW or is present as a normal variation across the TDC population.
- A study utilising patient reported outcome measures to assess perceived function before and after serial casting would provide important data related to the efficacy of the treatment, as currently this is not well established.
- The current study did not measure differences in strength or power between groups. The addition of this information may provide further insights into how muscle function is altered in ITW.

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Appendices

Appendix A. Ethics Approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

11 December 2018

Dr Nichola Wilson
Dept of Surgery
The University of Auckland
Private Bag
Auckland 1142

Dear Dr Wilson

Re:	**Ethics ref:**	**18/STH/197**
	Study title:	Outcomes of serial casting for idiopathic toe walking

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

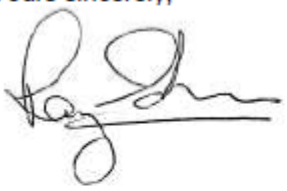
Your next progress report is due by 10 December 2019.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Auckland Uni HOD approval	1	19 September 2018
Evidence of scientific review: Scientific review	1	20 September 2018
CV for CI: CV	1	25 September 2018
Protocol: Protocol	1	25 September 2018
PIS/CF: Assent	1	25 September 2018
PIS/CF: Assent	1	25 September 2018
PIS/CF: Info / consent	1	25 September 2018
PIS/CF: Info / consent	1	25 September 2018
PIS/CF for persons interested in welfare of non-consenting participant: Info / consent	1	25 September 2018
PIS/CF for persons interested in welfare of non-consenting participant: Info / consent	1	25 September 2018
Application		
Covering Letter	1	23 October 2018
Appendices for Cover Letter	1	23 August 2018
Protocol: Marked protocol	2	01 November 2018
PIS/CF: ITW Kids Information Sheet - Version 2 (marked)	2	01 November 2018
PIS/CF: ITW Older Child Information Sheet Version 2 (marked copy)	2	01 November 2018
PIS/CF: ITW Parents Information Sheet Version 2 (marked copy)	2	01 November 2018
PIS/CF: Control Kids Information Sheet Version 2 (marked copy)	2	01 November 2018
PIS/CF: Control Older Child Information Sheet Version 2 (marked copy)	2	01 November 2018
PIS/CF: Control Parents Information Sheet Version 2 (marked copy)	2	01 November 2018
Standard care information from WDHB on serial casting	1	01 November 2016
Advertisement	1	07 November 2018
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

Appendix B. Participant Information Sheets

Control – Kids aged 4-7 Assent Form

We were wondering if you would like to be involved in some research about kids who walk on their toes.

Why are we doing this?

We are trying to work out if casting changes how you walk and what it does to the muscles and tendons in your legs. We are looking at kids who walk on their toes and those that don't.

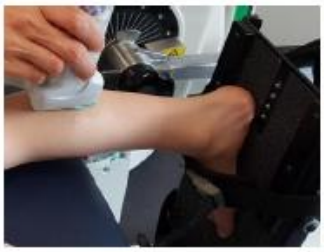
Do I have to take part?

No, you don't have to take part, it is ok to say no.

If you have any questions, talk to your Mum or Dad (they have a paper with even more stuff about this) or else you can talk to the doctor or physio.

What happens?

We will look at your legs with an ultrasound (like they look at babies in mummies tummies) – it doesn't hurt, and ask you to walk over a mat. This will happen again in six weeks and then a year later.
The ultrasound looks like this ….



The pressure mat looks like this …

Then what?

All the stuff measured is put in a computer, and then it helps the researcher work out how casting helps toe walking.

If you think it is ok to be in our study – please write your name here or colour the smiley face. You can say no even if your parents say yes.
I agree to be in the study

Your name _____

Date _____

Version 2: 1 November 2018

Controls: Participant Information Sheet

For children aged 7 – 15 years

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Study title:	**Outcomes of serial casting for idiopathic toe walking**	
Locality:	**ADHB**	Ethics committee ref.: 18/STH/197
Lead investigator:	**Dr Nichola Wilson**	Contact phone number: 021 1441162

You are invited to take part in a research study about the outcomes of serial casting in children who walk on their toes. Please take your time to think about it and decide whether you wish to take part in it. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

To help you decide if you want to take part in this study please read all of the information carefully together with your family / whanau. The doctors and physiotherapists carrying out this research will also talk to you and are able to answer your questions.

For you to take part in this study we need written consent (an okay!) from you and an adult from your family / whanau.

WHAT IS THE PURPOSE OF THE STUDY?

Many children who toe walk over the age of two have casting to help treat the toe walking. How effective this is unknown. It is also not known how casting for toe walking affects the muscles and tendons. We are looking at children who walk on their toes and are treated with casting as well as children who don't walk on their toes and have no casts.

This study has been approved by the Southern Health and Disability Ethics Committee.

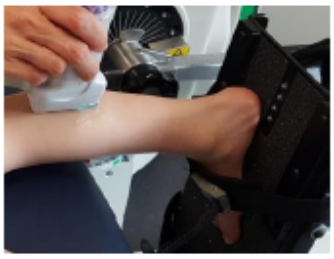
WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

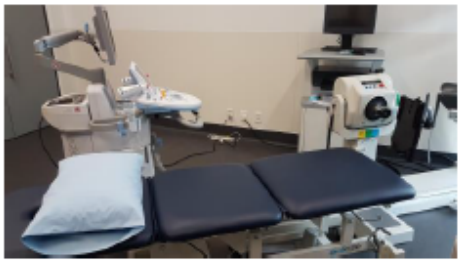
You have been chosen for the study as you don't walk on your toes.

We will measure how much your ankle moves, ask you to walk across a mat and ultrasound your calf (this is not painful). This testing is expected to take 1 hour.

Seven weeks later and one year later we will do the same thing.

Picture of ultrasound





Picture of mat

WHAT ARE MY RIGHTS?

Your participation in this study is entirely voluntary (your choice and your parent's choice). You do not have to take part in this study. You can say no even if your parents say yes.

If you agree to take part, you can stop doing the study at any time, without having to give a reason.

What we learn about you will be kept private and people who read the reports will not know which children participated. Data will be stored at the Auckland University of Technology and University of Auckland, School of Medicine in a secure location.

A copy of all results collected will be held at the University of Auckland. The overall results of this study will be published in the medical literature and presented at medical conferences. A summary of the findings will be sent to you if you would like.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Nichola Wilson, Coordinating Investigator
Telephone number: 021 1441162
Email: n.wilson@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori health support :
Please talk to your whanau in the first instance, alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 42324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 43204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Participant's Confirmation for Assent

_____
Name of Participant (Print)

_____ _____
Signature of Participant Date

Statement of Person Obtaining Informed Assent

I, the undersigned, have fully explained the details of this research study to the participant named above.

_____
Name of Person Conducting Assent Discussion (Print)

_____ _____
Signature of Person Conducting Assent Discussion Date

Controls: Participant Information Sheet

For parents / guardians

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Study title:	**Outcomes of serial casting for idiopathic toe walking**	
Locality:	**ADHB**	Ethics committee ref.: 18/STH/197
Lead investigator:	**Dr Nichola Wilson**	Contact phone number: 021 1441162

You and your child are invited to take part in a study on serial casting in toe walking. Whether or not your child takes part is your (and your child's) choice. If you don't want your child to take part, you don't have to give a reason. If your child does take part now, but you or your child changes their mind later, they can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like your child to take part. It sets out why we are doing the study, what your child's participation would involve, what the benefits and risks to your child might be, and what would happen after the study ends. There is also a separate information sheet for your child. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not your child will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree that your child takes part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is five pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Many children who toe walk over the age of two have serial casting to help treat the toe walking. How effective this is unknown. It is also not known how serial casting for toe walking affects the muscles and tendons.

The study has received funding from the University of Auckland.

This study has been approved by the Southern Health and Disability Ethics Committee.

The Coordinating Investigator for the study in Dr Nichola Wilson, The University of Auckland and Consultant Orthopaedic Surgeon at Starship Children's Health. If you have any questions about the study, please feel free to contact Dr Wilson – her contact details are listed on the front page of this document.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your child has been chosen for the study as they are typically developing and are age / gender matched to a child in the study who walks on their toes.

We will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure and ultrasound the calf (this is not painful). This testing is expected to take 1 hour.

Seven weeks later we will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure and ultrasound the calf. This testing is expected to take 1 hour.

One year later we will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure and ultrasound the calf. This testing is expected to take 1 hour.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There may be no direct benefit to you or your child from being part of the study. However, the information gained in the study will help guide us in the management of many children with toe walking.

We think that the risks of being in this study are very small. Ultrasound is commonly used, and should any discomfort be felt during the testing it will be stopped.

The investigator will ensure that care is provided to your child throughout the study and should they wish to withdraw the same level of care will still be provided.

WHO PAYS FOR THE STUDY?

There is no cost for your child to be involved in the study. Petrol vouchers will be provided to cover petrol costs for travel to North Shore Hospital and the parking will be paid for.

WHAT IF SOMETHING GOES WRONG?

If your child was injured in this study, they would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that the claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, they will receive funding to assist in their recovery.

If your child has private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Your child's participation in this study is entirely voluntary (your choice and your child's choice). Your child does not have to take part in this study.

If you and your child do agree to take part, you/your child are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your child's future health care.

Participants have the right to access information about them collected as part of the study.

No material which could personally identify your child will be used in any reports on this study.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

A copy of all results collected will be held at The University of Auckland. Dr Nichola Wilson, Department of Surgery, The University of Auckland, will be responsible for safe keeping of the data.

Members of the Research Group (present and future) will have access to the raw data and / or your clinical records during, or after, the study but only where ethical approval has been attained. Future studies may wish to include this data. Where such use goes beyond that outlined in the present application, further ethical approval will be sought.

We are happy to send you a lay summary of the results upon its completion. It is expected results will be published as a journal article and presented at various international conferences. Please note that a significant delay may occur between data collection and publication of results.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Nichola Wilson, Coordinating Investigator
Telephone number: 021 1441162
Email: n.wilson@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
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If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Please tick to indicate you consent to the following;

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.	☐	
I have been given sufficient time to consider whether or not I want my child to participate in this study.	☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	☐	
I understand that my child taking part in this study is voluntary (my/ their choice) and that I may withdraw my child from the study at any time without this affecting their medical care.	☐	
I consent to the research staff collecting and processing my child's information, including information about their health.	☐	
If I decide to withdraw my child from the study, I agree that the information collected about them up to the point when they withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my child's GP or current provider being informed about their participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	☐	
I understand that my child's participation in this study is confidential and that no material, which could identify them personally, will be used in any reports on this study.	☐	
I understand the compensation provisions in case of injury during the study.	☐	
I know who to contact if I have any questions about the study in general.	☐	
I understand my child's responsibilities as a study participant.	☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by parent/guardian of participant:
I hereby consent for my child to take part in this study.

Participant's name: _____

Parent/Guardian's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and their parent/guardian and have answered their questions about it.

I believe that the participant and their parent/guardian understand the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

ITW – Kids aged 4-7 Assent Form

We were wondering if you would like to be involved in some research about kids who walk on their toes.

Why are we doing this?

We are trying to work out if casting changes how you walk and what it does to the muscles and tendons in your legs.

Do I have to take part?

You don't have to take part, and if you say no, it will not change how you are looked after.

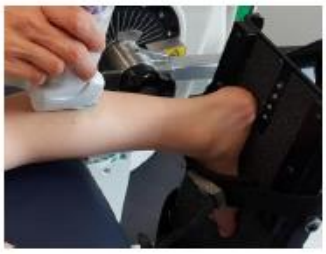
If you have any questions, talk to your Mum or Dad (they have a paper with even more stuff about this) or else you can talk to the doctor or physio.

Version 2: 1 November 2018

What happens?

When you have your casts to help your toe walking we will look at your legs with an ultrasound (like they look at babies in mummies tummies) – it doesn't hurt, and ask you to walk over a mat. We will ask your Mum or Dad to answer some questions about your legs. This will happen again a week after your casts come off and then a year later.

The ultrasound looks like this ….



The pressure mat looks like this ….

Then what?

All the stuff measured is put in a computer, and then it helps the researcher work out how casting helps toe walking.

If you think it is ok to be in our study – please write your name here or colour the smiley face. You can say no even if your parents say yes.
I agree to be in the study

Your name _____

Date _____

ITW: Participant Information Sheet

For children aged 7 – 15 years

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Study title:	**Outcomes of serial casting for idiopathic toe walking**	
Locality:	**ADHB**	Ethics committee ref.: 18/STH/197
Lead investigator:	**Dr Nichola Wilson**	Contact phone number: 021 1441162

You are invited to take part in a research study about the outcomes of serial casting in children who walk on their toes. Please take your time to think about it and decide whether you wish to take part in it. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If they do want to take part now, but change your mind later, you can pull out of the study at any time.

To help you decide if you want to take part in this study please read all of the information carefully together with your family / whanau. The doctors and physiotherapists carrying out this research will also talk to you and are able to answer your questions.

For you to take part in this study we need written consent (an okay!) from you and an adult from your family / whanau.

WHAT IS THE PURPOSE OF THE STUDY?

Many children who walk on their toes over the age of two have serial casting to help treat the toe walking. How effective this is, is unknown. It is also not known how serial casting for toe walking affects the muscles and tendons.

This study has been approved by the Southern Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen for the study as you walk on your toes and we are treating this with serial casting.

Prior to starting serial casting we will measure how much your ankle moves, ask you to walk across a mat, ultrasound your calf, and ask your parents to answer some questions about your feet. This testing is expected to take 1 hour and will be followed by the first set of casts being put on.

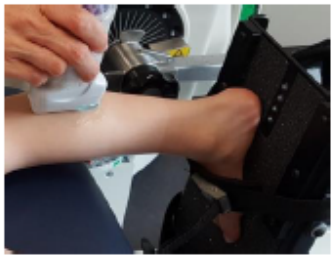
One week after the casts have come off, we will measure how much your ankle moves, ask you to walk across a mat and ultrasound your calf. This testing is expected to take 1 hour and will be followed by a physiotherapy session.

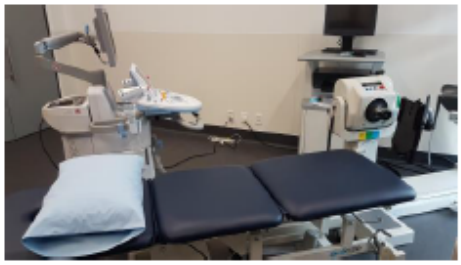
One year after the casts have come off, we will measure how much your ankle moves, ask you to walk across a mat, ultrasound your calf and ask your parents to answer some questions about your feet. This testing is expected to take 1 hour.

We would usually see you at these points for a clinic appointment. The extra things we are asking you to do are:

- Walk across a mat to measure foot pressure
- Have an ultrasound of your calf (this is not painful)
- Answer some questions about your feet

Picture of ultrasound





Picture of mat

WHAT ARE MY RIGHTS?

Your participation in this study is entirely voluntary (your choice and your parent's choice). You do not have to take part in this study, and if you/your parent choose not to take part, you will receive the usual care. You can say no even if your parents say yes.

If you agree to take part, you can stop doing the study at any time, without having to give a reason, and this will in no way affect your treatment.

What we learn about you will be kept private and people who read the reports will not know which children participated. Data will be stored at the Auckland University of Technology and University of Auckland, School of Medicine in a secure location.

A copy of all results collected will be held at the University of Auckland. The overall results of this study will be published in the medical literature and presented at medical conferences. A summary of the findings will be sent to you if you would like.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Nichola Wilson, Coordinating Investigator
Telephone number: 021 1441162
Email: n.wilson@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

For Maori health support :
Please talk to your whanau in the first instance, alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 42324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 43204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz

Participant's Confirmation for Assent

_____
Name of Participant (Print)

_____ _____
Signature of Participant Date

Statement of Person Obtaining Informed Assent

I, the undersigned, have fully explained the details of this research study to the participant named above.

_____
Name of Person Conducting Assent Discussion (Print)

_____ _____
Signature of Person Conducting Assent Discussion Date

ITW: Participant Information Sheet

For parents / guardians

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Study title:	**Outcomes of serial casting for idiopathic toe walking**	
Locality:	**ADHB**	Ethics committee ref.: 18/STH/197
Lead investigator:	**Dr Nichola Wilson**	Contact phone number: 021 1441162

You and your child are invited to take part in a study on serial casting in toe walking. Whether or not your child takes part is your (and your child's) choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care your child receives. If your child does take part now, but you or your child changes their mind later, they can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like your child to take part. It sets out why we are doing the study, what your child's participation would involve, what the benefits and risks to your child might be, and what would happen after the study ends. There is also a separate information sheet for your child. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not your child will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree that your child takes part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is six pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Many children who toe walk over the age of two have serial casting to help treat the toe walking. How effective this is, is unknown. It is also not known how serial casting for toe walking affects the muscles and tendons.

The study has received funding from the University of Auckland.

This study has been approved by the Southern Health and Disability Ethics Committee.

The Coordinating Investigator for the study is Dr Nichola Wilson, The University of Auckland and Consultant Orthopaedic Surgeon at Starship Children's Health. If you have any questions about the study, please feel free to contact Dr Wilson – her contact details are listed on the front page of this document.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your child has been chosen for the study as they have idiopathic toe walking and we are treating their toe walking with serial casting.

Prior to starting serial casting we will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure, ultrasound the calf and ask you to fill in a questionnaire about your child's foot and ankle. This testing is expected to take 1 hour and will be followed by the first cast being put on.

One week after the casts have come off, we will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure and ultrasound the calf. This testing is expected to take 1 hour and will be followed by a physiotherapy session.

One year after the casts have come off, we will measure their ankle range of motion, ask them to walk across a mat to measure foot pressure, ultrasound the calf and ask you to fill in a questionnaire about your child's foot and ankle. This testing is expected to take 1 hour.

We would usually see your child at these points for a clinic appointment. The extra things we are asking your child to do are:

- Walk across a mat to measure foot pressure
- Have an ultrasound of their calf (this is not painful)
- Fill in the questionnaire about your child's foot and ankle

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There may be no direct benefit to your child from being part of the study. However, the information gained in the study will help guide us in the management of many other children with toe walking.

We think that the risks of being in this study are very small. Ultrasound is commonly used, and should any discomfort be felt during the testing it will be stopped.

The investigator will ensure that care is provided to your child throughout the study and should they wish to withdraw the same level of care will still be provided.

WHO PAYS FOR THE STUDY?

There is no cost for your child to be involved in the study. Petrol vouchers will be provided to cover petrol costs for travel to North Shore Hospital and the parking will be paid for.

WHAT IF SOMETHING GOES WRONG?

If your child was injured in this study, they would be eligible to **apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that the claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If their claim is accepted, they will receive funding to assist in their recovery.

If your child has private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Your child's participation in this study is entirely voluntary (your choice and your child's choice). Your child does not have to take part in this study, and if you or your child choose not to take part, your child will receive the usual care.

If you and your child do agree to take part, you/your child are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your child's future health care.

Participants have the right to access information about them collected as part of the study.

No material which could personally identify your child will be used in any reports on this study.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

A copy of all results collected will be held at The University of Auckland. Dr Nichola Wilson, Department of Surgery, The University of Auckland, will be responsible for safe keeping of the data.

Members of the Research Group (present and future) will have access to the raw data and / or your clinical records during, or after, the study but only where ethical approval has been attained. Future studies may wish to include this data. Where such use goes beyond that outlined in the present application, further ethical approval will be sought.

We are happy to send you a lay summary of the results upon its completion. It is expected results will be published as a journal article and presented at various international conferences. Please note that a significant delay may occur between data collection and publication of results.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Nichola Wilson, Coordinating Investigator
Telephone number: 021 1441162
Email: n.wilson@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
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Email: advocacy@hdc.org.nz

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Please talk to your whanau in the first instance, alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Please tick to indicate you consent to the following;

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.	☐	
I have been given sufficient time to consider whether or not I want my child to participate in this study.	☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	☐	
I understand that my child taking part in this study is voluntary (my/ their choice) and that I may withdraw my child from the study at any time without this affecting their medical care.	☐	
I consent to the research staff collecting and processing my child's information, including information about their health.	☐	
If I decide to withdraw my child from the study, I agree that the information collected about them up to the point when they withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my child's GP or current provider being informed about their participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	☐	
I understand that my child's participation in this study is confidential and that no material, which could identify them personally, will be used in any reports on this study.	☐	
I understand the compensation provisions in case of injury during the study.	☐	
I know who to contact if I have any questions about the study in general.	☐	
I understand my child's responsibilities as a study participant.	☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by parent/guardian of participant:
I hereby consent for my child to take part in this study.

Participant's name: _____

Parent/Guardian's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Appendix C. ROBIN-I assessment tool

The Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) assessment tool

(version for cohort-type studies)

Developed by: Jonathan AC Sterne, Miguel A Hernán, Barnaby C Reeves, Jelena Savović, Nancy D Berkman, Meera Viswanathan, David Henry, Douglas G Altman, Mohammed T Ansari, Isabelle Boutron, James Carpenter, An-Wen Chan, Rachel Churchill, Asbjørn Hróbjartsson, Jamie Kirkham, Peter Jüni, Yoon Loke, Terri Pigott, Craig Ramsay, Deborah Regidor, Hannah Rothstein, Lakhbir Sandhu, Pasqualina Santaguida, Holger J Schünemann, Beverly Shea, Ian Shrier, Peter Tugwell, Lucy Turner, Jeffrey C Valentine, Hugh Waddington, Elizabeth Waters, Penny Whiting and Julian PT Higgins

Version 1 August 2016

ROBINS-I tool (Stage I): At protocol stage

Specify the review question

Participants	
Experimental intervention	
Comparator	
Outcomes	

List the confounding domains relevant to all or most studies

List co-interventions that could be different between intervention groups and that could impact on outcomes

ROBINS-I tool (Stage II): For each study

Specify a target randomized trial specific to the study

Design	Individually randomized / Cluster randomized / Matched (e.g. cross-over)
Participants	
Experimental intervention	
Comparator	

Is your aim for this study…?

- ☐ to assess the effect of *assignment to* intervention
- ☐ to assess the effect of *starting and adhering to* intervention

Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

Specify the numerical result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Preliminary consideration of confounders

Complete a row for each important confounding domain (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as potentially important.

"Important" confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the confounding variable or variables fully measure the domain, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

(i) Confounding domains listed in the review protocol				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information

(ii) Additional confounding domains relevant to the setting of this particular study, or which the study authors identified as important				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information

* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that "no statistically significant association" is not the same as "not predictive".

Preliminary consideration of co-interventions

Complete a row for each important co-intervention (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as important.

"Important" co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention.

(i) Co-interventions listed in the review protocol		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

(ii) Additional co-interventions relevant to the setting of this particular study, or which the study authors identified as important		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

Risk of bias assessment (cohort-type studies)

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Bias domain	Signalling questions	Elaboration	Response options
Bias due to confounding	1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	In rare situations, such as when studying harms that are very unlikely to be related to factors that influence treatment decisions, no confounding is expected and the study can be considered to be at low risk of bias due to confounding, equivalent to a fully randomized trial. There is no NI (No information) option for this signalling question.	Y / PY / PN / N
	If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
	1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, proceed to question 1.3.	If participants could switch between intervention groups then associations between intervention and outcome may be biased by time-varying confounding. This occurs when prognostic factors influence switches between intended interventions.	NA / Y / PY / PN / N / NI
	1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)	If intervention switches are unrelated to the outcome, for example when the outcome is an unexpected harm, then time-varying confounding will not be present and only control for baseline confounding is required.	NA / Y / PY / PN / N / NI
	Questions relating to baseline confounding only		
	1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	Appropriate methods to control for measured confounders include stratification, regression, matching, standardization, and inverse probability weighting. They may control for individual variables or for the estimated propensity score. Inverse probability weighting is based on a function of the propensity score. Each method depends on the assumption that there is no unmeasured or residual confounding.	NA / Y / PY / PN / N / NI

	1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	Appropriate control of confounding requires that the variables adjusted for are valid and reliable measures of the confounding domains. For some topics, a list of valid and reliable measures of confounding domains will be specified in the review protocol but for others such a list may not be available. Study authors may cite references to support the use of a particular measure. If authors control for confounding variables with no indication of their validity or reliability pay attention to the subjectivity of the measure. Subjective measures (e.g. based on self-report) may have lower validity and reliability than objective measures such as lab findings.	NA / Y / PY / PN / N / NI
	1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	Controlling for post-intervention variables that are affected by intervention is not appropriate. Controlling for mediating variables estimates the direct effect of intervention and may introduce bias. Controlling for common effects of intervention and outcome introduces bias.	NA / Y / PY / PN / N / NI
	Questions relating to baseline and time-varying confounding		
	1.7. Did the authors use an appropriate analysis method that adjusted for all the important confounding domains and for time-varying confounding?	Adjustment for time-varying confounding is necessary to estimate the effect of starting and adhering to intervention, in both randomized trials and NRSI. Appropriate methods include those based on inverse probability weighting. Standard regression models that include time-updated confounders may be problematic if time-varying confounding is present.	NA / Y / PY / PN / N / NI
	1.8. **If Y/PY to 1.7**: Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	See 1.5 above.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to confounding?	Can the true effect estimate be predicted to be greater or less than the estimated effect in the study because one or more of the important confounding domains was not controlled for? Answering this question will be based on expert knowledge and results in other studies and therefore can only be completed after all of the studies in the body of evidence have been reviewed. Consider the potential effect of each of the unmeasured domains and whether all important confounding domains not controlled for in the analysis would be likely to change the estimate in the same direction, or if one important confounding domain that was not controlled for in the analysis is likely to have a dominant impact.	Favours experimental / Favours comparator / Unpredictable

Bias in selection of participants into the study	2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **If N/PN to 2.1:** go to 2.4	This domain is concerned only with selection into the study based on participant characteristics observed *after* the start of intervention. Selection based on characteristics observed *before* the start of intervention can be addressed by controlling for imbalances between experimental intervention and comparator groups in baseline characteristics that are prognostic for the outcome (baseline confounding). Selection bias occurs when selection is related to an effect of either intervention or a cause of intervention **and** an effect of either the outcome or a cause of the outcome. Therefore, the result is at risk of selection bias if selection into the study is related to both the intervention and the outcome.	Y / PY / PN / N / NI
	2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention?		NA / Y / PY / PN / N / NI
	2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?		NA / Y / PY / PN / N / NI
	2.4. Do start of follow-up and start of intervention coincide for most participants?	If participants are not followed from the start of the intervention then a period of follow up has been excluded, and individuals who experienced the outcome soon after intervention will be missing from analyses. This problem may occur when prevalent, rather than new (incident), users of the intervention are included in analyses.	Y / PY / PN / N / NI
	2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?	It is in principle possible to correct for selection biases, for example by using inverse probability weights to create a pseudo-population in which the selection bias has been removed, or by modelling the distributions of the missing participants or follow up times and outcome events and including them using missing data methodology. However such methods are rarely used and the answer to this question will usually be "No".	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to selection of participants into the study?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in classification of interventions	3.1 Were intervention groups clearly defined?	A pre-requisite for an appropriate comparison of interventions is that the interventions are well defined. Ambiguity in the definition may lead to bias in the classification of participants. For individual-level interventions, criteria for considering individuals to have received each intervention should be clear and explicit, covering issues such as type, setting, dose, frequency, intensity and/or timing of intervention. For population-level interventions (e.g. measures to control air pollution), the question relates to whether the population is clearly defined, and the answer is likely to be 'Yes'.	Y / PY / PN / N / NI
	3.2 Was the information used to define intervention groups recorded at the start of the intervention?	In general, if information about interventions received is available from sources that could not have been affected by subsequent outcomes, then differential misclassification of intervention status is unlikely. Collection of the information at the time of the intervention makes it easier to avoid such misclassification. For population-level interventions (e.g. measures to control air pollution), the answer to this question is likely to be 'Yes'.	Y / PY / PN / N / NI
	3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	Collection of the information at the time of the intervention may not be sufficient to avoid bias. The way in which the data are collected for the purposes of the NRSI should also avoid misclassification.	Y / PY / PN / N / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to measurement of outcomes or interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias due to deviations from intended interventions	**If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2**		
	4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	Deviations that happen in usual practice following the intervention (for example, cessation of a drug intervention because of acute toxicity) are part of the intended intervention and therefore do not lead to bias in the effect of assignment to intervention. Deviations may arise due to expectations of a difference between intervention and comparator (for example because participants feel unlucky to have been assigned to the comparator group and therefore seek the active intervention, or components of it, or other interventions). Such deviations are not part of usual practice, so may lead to biased effect estimates. However these are not expected in observational studies of individuals in routine care.	Y / PY / PN / N / NI
	4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?	Deviations from intended interventions that do not reflect usual practice will be important if they affect the outcome, but not otherwise. Furthermore, bias will arise only if there is imbalance in the deviations across the two groups.	NA / Y / PY / PN / N / NI
	If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
	4.3. Were important co-interventions balanced across intervention groups?	Risk of bias will be higher if unplanned co-interventions were implemented in a way that would bias the estimated effect of intervention. Co-interventions will be important if they affect the outcome, but not otherwise. Bias will arise only if there is imbalance in such co-interventions between the intervention groups. Consider the co-interventions, including any pre-specified co-interventions, that are likely to affect the outcome and to have been administered in this study. Consider whether these co-interventions are balanced between intervention groups.	Y / PY / PN / N / NI
	4.4. Was the intervention implemented successfully for most participants?	Risk of bias will be higher if the intervention was not implemented as intended by, for example, the health care professionals delivering care during the trial. Consider whether implementation of the intervention was successful for most participants.	Y / PY / PN / N / NI
	4.5. Did study participants adhere to the assigned intervention regimen?	Risk of bias will be higher if participants did not adhere to the intervention as intended. Lack of adherence includes imperfect compliance, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention. Consider available information on the proportion of study participants who continued with their assigned	Y / PY / PN / N / NI

		intervention throughout follow up, and answer 'No' or 'Probably No' if this proportion is high enough to raise concerns. Answer 'Yes' for studies of interventions that are administered once, so that imperfect adherence is not possible. We distinguish between analyses where follow-up time after interventions switches (including cessation of intervention) is assigned to (1) the new intervention or (2) the original intervention. (1) is addressed under time-varying confounding, and should not be considered further here.	
	4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?	It is possible to conduct an analysis that corrects for some types of deviation from the intended intervention. Examples of appropriate analysis strategies include inverse probability weighting or instrumental variable estimation. It is possible that a paper reports such an analysis without reporting information on the deviations from intended intervention, but it would be hard to judge such an analysis to be appropriate in the absence of such information. Specialist advice may be needed to assess studies that used these approaches. If everyone in one group received a co-intervention, adjustments cannot be made to overcome this.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	
	Optional: What is the predicted direction of bias due to deviations from the intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	

Bias due to missing data	5.1 Were outcome data available for all, or nearly all, participants?	"Nearly all" should be interpreted as "enough to be confident of the findings", and a suitable proportion depends on the context. In some situations, availability of data from 95% (or possibly 90%) of the participants may be sufficient, providing that events of interest are reasonably common in both intervention groups. One aspect of this is that review authors would ideally try and locate an analysis plan for the study.	Y / PY / PN / N / NI
	5.2 Were participants excluded due to missing data on intervention status?	Missing intervention status may be a problem. This requires that the *intended* study sample is clear, which it may not be in practice.	Y / PY / PN / N / NI
	5.3 Were participants excluded due to missing data on other variables needed for the analysis?	This question relates particularly to participants excluded from the analysis because of missing information on confounders that were controlled for in the analysis.	Y / PY / PN / N / NI
	5.4 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across interventions?	This aims to elicit whether either (i) differential proportion of missing observations or (ii) differences in reasons for missing observations could substantially impact on our ability to answer the question being addressed. "Similar" includes some minor degree of discrepancy across intervention groups as expected by chance.	NA / Y / PY / PN / N / NI
	5.5 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Is there evidence that results were robust to the presence of missing data?	Evidence for robustness may come from how missing data were handled in the analysis and whether sensitivity analyses were performed by the investigators, or occasionally from additional analyses performed by the systematic reviewers. It is important to assess whether assumptions employed in analyses are clear and plausible. Both content knowledge and statistical expertise will often be required for this. For instance, use of a statistical method such as multiple imputation does not guarantee an appropriate answer. Review authors should seek naïve (complete-case) analyses for comparison, and clear differences between complete-case and multiple imputation-based findings should lead to careful assessment of the validity of the methods used.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to missing data?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in measurement of outcomes	6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	Some outcome measures involve negligible assessor judgment, e.g. all-cause mortality or non-repeatable automated laboratory assessments. Risk of bias due to measurement of these outcomes would be expected to be low.	Y / PY / PN / N / NI
	6.2 Were outcome assessors aware of the intervention received by study participants?	If outcome assessors were blinded to intervention status, the answer to this question would be 'No'. In other situations, outcome assessors may be unaware of the interventions being received by participants despite there being no active blinding by the study investigators; the answer this question would then also be 'No'. In studies where participants report their outcomes themselves, for example in a questionnaire, the outcome assessor is the study participant. In an observational study, the answer to this question will usually be 'Yes' when the participants report their outcomes themselves.	Y / PY / PN / N / NI
	6.3 Were the methods of outcome assessment comparable across intervention groups?	Comparable assessment methods (i.e. data collection) would involve the same outcome detection methods and thresholds, same time point, same definition, and same measurements.	Y / PY / PN / N / NI
	6.4 Were any systematic errors in measurement of the outcome related to intervention received?	This question refers to differential misclassification of outcomes. Systematic errors in measuring the outcome, if present, could cause bias if they are related to intervention or to a confounder of the intervention-outcome relationship. This will usually be due either to outcome assessors being aware of the intervention received or to non-comparability of outcome assessment methods, but there are examples of differential misclassification arising despite these controls being in place.	Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to measurement of outcomes?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in selection of the reported result	Is the reported effect estimate likely to be selected, on the basis of the results, from... 7.1. ... multiple outcome *measurements* within the outcome domain?	For a specified outcome domain, it is possible to generate multiple effect estimates for different measurements. If multiple measurements were made, but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / PN / N / NI
	7.2 ... multiple *analyses* of the intervention-outcome relationship?	Because of the limitations of using data from non-randomized studies for analyses of effectiveness (need to control confounding, substantial missing data, etc), analysts may implement different analytic methods to address these limitations. Examples include unadjusted and adjusted models; use of final value vs change from baseline vs analysis of covariance; different transformations of variables; a continuously scaled outcome converted to categorical data with different cut-points; different sets of covariates used for adjustment; and different analytic strategies for dealing with missing data. Application of such methods generates multiple estimates of the effect of the intervention versus the comparator on the outcome. If the analyst does not pre-specify the methods to be applied, and multiple estimates are generated but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / PN / N / NI
	7.3 ... different *subgroups*?	Particularly with large cohorts often available from routine data sources, it is possible to generate multiple effect estimates for different subgroups or simply to omit varying proportions of the original cohort. If multiple estimates are generated but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to selection of the reported result?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall bias	**Risk of bias judgement**	See Table 3.	Low / Moderate / Serious / Critical / NI
	Optional: What is the overall predicted direction of bias for this outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Table 1. Reaching risk of bias judgements in ROBINS-I: pre-intervention and at-intervention domains

Judgement	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions
Low risk of bias (the study is comparable to a well-performed randomized trial with regard to this domain)	No confounding expected.	(i) All participants who would have been eligible for the target trial were included in the study; *and* (ii) For each participant, start of follow up and start of intervention coincided.	(i) Intervention status is well defined; *and* (ii) Intervention definition is based solely on information collected at the time of intervention.
Moderate risk of bias (the study is sound for a non-randomized study with regard to this domain but cannot be considered comparable to a well-performed randomized trial):	(i) Confounding expected, all known important confounding domains appropriately measured and controlled for; *and* (ii) Reliability and validity of measurement of important domains were sufficient, such that we do not expect serious residual confounding.	(i) Selection into the study may have been related to intervention and outcome; *and* The authors used appropriate methods to adjust for the selection bias; *or* (ii) Start of follow up and start of intervention do not coincide for all participants; *and* (a) the proportion of participants for which this was the case was too low to induce important bias; *or* (b) the authors used appropriate methods to adjust for the selection bias; *or* (c) the review authors are confident that the rate (hazard) ratio for the effect of intervention remains constant over time.	(i) Intervention status is well defined; *and* (ii) Some aspects of the assignments of intervention status were determined retrospectively.

Serious risk of bias (the study has some important problems);	(i) At least one known important domain was not appropriately measured, or not controlled for; *or* (ii) Reliability or validity of measurement of an important domain was low enough that we expect serious residual confounding.	(i) Selection into the study was related (but not very strongly) to intervention and outcome; *and* This could not be adjusted for in analyses; *or* (ii) Start of follow up and start of intervention do not coincide; *and* A potentially important amount of follow-up time is missing from analyses; *and* The rate ratio is not constant over time.	(i) Intervention status is not well defined; *or* (ii) Major aspects of the assignments of intervention status were determined in a way that could have been affected by knowledge of the outcome.
Critical risk of bias (the study is too problematic to provide any useful evidence on the effects of intervention);	(i) Confounding inherently not controllable *or* (ii) The use of negative controls strongly suggests unmeasured confounding.	(i) Selection into the study was very strongly related to intervention and outcome; *and* This could not be adjusted for in analyses; *or* (ii) A substantial amount of follow-up time is likely to be missing from analyses; *and* The rate ratio is not constant over time.	(Unusual) An extremely high amount of misclassification of intervention status, e.g. because of unusually strong recall biases.
No information on which to base a judgement about risk of bias for this domain.	No information on whether confounding might be present.	No information is reported about selection of participants into the study or whether start of follow up and start of intervention coincide.	No definition of the intervention or no explanation of the source of information about intervention status is reported.

Table 2. Reaching risk of bias judgements in ROBINS-I: post-intervention domains

Judgement	Bias due to deviations from intended intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Low risk of bias (the study is comparable to a well-performed randomized trial with regard to this domain)	**Effect of assignment to intervention:** (i) Any deviations from intended intervention reflected usual practice; *or* (ii) Any deviations from usual practice were unlikely to impact on the outcome. **Effect of starting and adhering to intervention:** The important **co-interventions** were balanced across intervention groups, and there were no deviations from the intended interventions (in terms of **implementation or adherence**) that were likely to impact on the outcome.	(i) Data were reasonably complete; *or* (ii) Proportions of and reasons for missing participants were similar across intervention groups; *or* (iii) The analysis addressed missing data and is likely to have removed any risk of bias.	(i) The methods of outcome assessment were comparable across intervention groups; *and* (ii) The outcome measure was unlikely to be influenced by knowledge of the intervention received by study participants (i.e. is objective) or the outcome assessors were unaware of the intervention received by study participants; *and* (iii) Any error in measuring the outcome is unrelated to intervention status.	There is clear evidence (usually through examination of a pre-registered protocol or statistical analysis plan) that all reported results correspond to all intended outcomes, analyses and sub-cohorts.

Moderate risk of bias (the study is sound for a non-randomized study with regard to this domain but cannot be considered comparable to a well-performed randomized trial):	**Effect of assignment to intervention:** There were deviations from usual practice, but their impact on the outcome is expected to be slight. **Effect of starting and adhering to intervention:** (i) There were deviations from intended intervention, but their impact on the outcome is expected to be slight. *or* (ii) The important co-interventions were not balanced across intervention groups, or there were deviations from the intended interventions (in terms of implementation and/or adherence) that were likely to impact on the outcome; *and* The analysis was appropriate to estimate the effect of starting and adhering to intervention, allowing for deviations (in terms of implementation, adherence and co-intervention) that were likely to impact on the outcome.	(i) Proportions of and reasons for missing participants differ slightly across intervention groups; *and* (ii) The analysis is unlikely to have removed the risk of bias arising from the missing data.	(i) The methods of outcome assessment were comparable across intervention groups; *and* (ii) The outcome measure is only minimally influenced by knowledge of the intervention received by study participants; *and* (iii) Any error in measuring the outcome is only minimally related to intervention status.	(i) The outcome measurements and analyses are consistent with an *a priori* plan; or are clearly defined and both internally and externally consistent; *and* (ii) There is no indication of selection of the reported analysis from among multiple analyses; *and* (iii) There is no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.

Serious risk of bias (the study has some important problems);	**Effect of assignment to intervention:** There were deviations from usual practice that were unbalanced between the intervention groups and likely to have affected the outcome. **Effect of starting and adhering to intervention:** (i) The important co-interventions were not balanced across intervention groups, or there were deviations from the intended interventions (in terms of implementation and/or adherence) that were likely to impact on the outcome; *and* (ii) The analysis was not appropriate to estimate the effect of starting and adhering to intervention, allowing for deviations (in terms of implementation, adherence and co-intervention) that were likely to impact on the outcome.	(i) Proportions of missing participants differ substantially across interventions; *or* Reasons for missingness differ substantially across interventions; *and* (ii) The analysis is unlikely to have removed the risk of bias arising from the missing data; *or* Missing data were addressed inappropriately in the analysis; *or* The nature of the missing data means that the risk of bias cannot be removed through appropriate analysis.	(i) The methods of outcome assessment were not comparable across intervention groups; *or* (ii) The outcome measure was subjective (i.e. vulnerable to influence by knowledge of the intervention received by study participants); *and* The outcome was assessed by assessors aware of the intervention received by study participants; *or* (iii) Error in measuring the outcome was related to intervention status.	(i) Outcomes are defined in different ways in the methods and results sections, or in different publications of the study; *or* (ii) There is a high risk of selective reporting from among multiple analyses; *or* (iii) The cohort or subgroup is selected from a larger study for analysis and appears to be reported on the basis of the results.

Critical risk of bias (the study is too problematic to provide any useful evidence on the effects of intervention);	**Effect of assignment to intervention:** There were substantial deviations from usual practice that were unbalanced between the intervention groups and likely to have affected the outcome. **Effect of starting and adhering to intervention:** (i) There were substantial imbalances in important co-interventions across intervention groups, or there were substantial deviations from the intended interventions (in terms of implementation and/or adherence) that were likely to impact on the outcome; *and* (ii) The analysis was not appropriate to estimate the effect of starting and adhering to intervention, allowing for deviations (in terms of implementation, adherence and co-intervention) that were likely to impact on the outcome.	(i) (Unusual) There were critical differences between interventions in participants with missing data; *and* (ii) Missing data were not, or could not, be addressed through appropriate analysis.	The methods of outcome assessment were so different that they cannot reasonably be compared across intervention groups.	(i) There is evidence or strong suspicion of selective reporting of results; *and* (ii) The unreported results are likely to be substantially different from the reported results.

No information on which to base a judgement about risk of bias for this domain.	No information is reported on whether there is deviation from the intended intervention.	No information is reported about missing data or the potential for data to be missing.	No information is reported about the methods of outcome assessment.	There is too little information to make a judgement (for example, if only an abstract is available for the study).

Table 3. Interpretation of domain-level and overall risk of bias judgements in ROBINS-I

Judgement	Within each domain	Across domains	Criterion
Low risk of bias	The study is comparable to a well-performed randomized trial with regard to this domain	The study is comparable to a well-performed randomized trial	The study is judged to be at **low risk of bias for all domains**.
Moderate risk of bias	The study is sound for a non-randomized study with regard to this domain but cannot be considered comparable to a well-performed randomized trial	The study provides sound evidence for a non-randomized study but cannot be considered comparable to a well-performed randomized trial	The study is judged to be at **low or moderate risk of bias for all domains**.
Serious risk of bias	the study has some important problems in this domain	The study has some important problems	The study is judged to be at **serious risk of bias** in at least one domain, but not at critical risk of bias in any domain.
Critical risk of bias	the study is too problematic in this domain to provide any useful evidence on the effects of intervention	The study is too problematic to provide any useful evidence and should not be included in any synthesis	The study is judged to be at **critical risk of bias in at least one domain.**
No information	No information on which to base a judgement about risk of bias for this domain	No information on which to base a judgement about risk of bias	There is no clear indication that the study is at serious or critical risk of bias *and* there is a lack of information in one or more key domains of bias (*a judgement is required for this*).

Appendix D. Mean data for muscle-tendon length

Medial gastrocnemius muscle-tendon length, tendon length, and muscle length values (mean ± 1SD)

		Idiopathic toe walkers		Typically developing	
	Joint angle	Length (cm)	Normalised length (%)	Length (cm)	Normalised length (%)
MTL baseline	Resting	32.26 (2.89)	113.8 (2.1)	32.70 (3.2)	115.1 (2.2)
	Neutral	34.32 (3.00)	121.1 (2.3)	34.03 (3.28)	119.8 (2.2)
	Max DF	34.37 (2.99)	121.3 (2.3)	34.94 (3.45)	123.0 (2.5)
MTL follow-up	Resting	33.37 (3.04)	117.7 (2.3)	32.95 (3.13)	116.0 (2.2)
	Neutral	34.46 (3.22)	121.6 (2.5)	34.30 (3.25)	120.8 (1.8)
	Max DF	35.36 (3.16)	124.8 (2.5)	35.18 (3.39)	123.9 (2.2)
TL baseline	Resting	15.49 (1.85)	54.7 (4.7)	15.70 (2.18)	55.1 (4.0)
	Neutral	16.04 (1.92)	56.6 (4.6)	15.91 (2.21)	55.9 (4.3)
	Max DF	16.06 (1.93)	56.6 (4.6)	16.22 (2.25)	57.0 (4.7)
TL follow-up	Resting	16.12 (1.79)	56.9 (4.0)	15.58 (1.99)	54.8 (4.0)
	Neutral	16.34 (1.77)	57.7 (3.9)	15.83 (2.02)	55.7 (3.8)
	Max DF	16.46 (1.75)	58.1 (3.8)	16.10 (2.00)	56.6 (3.8)
ML baseline	Resting	16.77 (1.93)	59.2 (4.5)	17.00 (1.52)	60.0 (3.4)
	Neutral	18.28 (1.97)	64.5 (4.7)	18.12 (1.76)	63.9 (4.3)
	Max DF	18.32 (1.94)	64.7 (4.7)	18.72 (1.94)	66.0 (4.2)
ML follow-up	Resting	17.24 (1.98)	60.8 (4.2)	17.37 (1.67)	61.2 (3.4)
	Neutral	18.12 (2.16)	63.9 (4.7)	18.46 (1.80)	65.1 (3.8)
	Max DF	18.90 (2.16)	66.7 (4.8)	19.08 (1.89)	67.2 (3.4)

Note. MTL = muscle-tendon length. TL = tendon length. ML = muscle belly length. DF = dorsiflexion. Normalised length = as a percentage of fibula length.

Appendix E. Mean data for tendon length ratio

Medial gastrocnemius tendon length as a percentage of muscle-tendon length

		Mean (± 1 SD)		Range	
	Joint angle	ITW	TDC	ITW	TDC
Baseline	Resting	48.0 (3.9)	47.9 (3.1)	40.4 - 55.3	43.3 - 54.7
	Neutral	46.7 (3.8)	46.7 (3.5)	39.4 - 54.9	41.6 - 53.4
	Max DF	46.7 (3.7)	46.3 (3.5)	39.4 - 54.9	41.3 - 53.6
Follow-up	Resting	48.3 (3.3)	47.2 (3.1)	43.3 - 54.5	43.0 - 54.0
	Neutral	47.4 (3.4)	46.1 (3.1)	41.7 - 54.6	42.0 – 52.7
	Max DF	46.6 (3.3)	45.7 (2.8)	41.5 - 53.5	41.5 - 51.5

Note. Data are percentages. ITW = idiopathic toe walking. TDC = typically developing child. DF = dorsiflexion.

Appendix F. Mean data for fascicle length

Medial gastrocnemius fascicle length and normalised fascicle length values (mean ± 1SD)

		Idiopathic toe walkers		Typically developing	
	Joint angle	Length (cm)	Normalised length (%)	Length (cm)	Normalised length (%)
FL baseline	40°PF	4.10 (0.91)	14.6 (3.5)	3.46 (0.40)	12.2 (1.1)
	Neutral	6.10 (1.07)	21.6 (4.1)	5.28 (0.67)	18.7 (2.0)
	Max DF	6.05 (1.05)	21.5 (4.0)	6.17 (0.90)	21.7 (2.3)
FL follow-up	40°PF	3.53 (0.63)	12.5 (2.2)	3.43 (0.44)	12.1 (1.2)
	Neutral	5.32 (0.92)	18.8 (3.1)	5.44 (0.69)	19.2 (2.0)
	Max DF	5.98 (1.12)	21.2 (4.2)	6.31 (0.84)	22.2 (2.2)

Note. FL = fascicle length. PF = plantarflexion. DF = dorsiflexion. Normalised length = as a percentage of fibula length.

Appendix G. Mean data for pennation angle and muscle thickness

Medial gastrocnemius pennation angle and muscle thickness values (mean ± 1SD)

		Idiopathic toe walkers		Typically developing	
	Joint angle	PA (°)	M_{Th} (cm)	PA (°)	M_{Th} (cm)
Baseline	40°PF	21.27 (3.08)	1.45 (0.19)	22.79 (3.48)	1.32 (0.15)
	Neutral	15.61 (1.79)	1.62 (0.18)	15.57 (2.53)	1.40 (0.15)
	Max DF	15.60 (1.79)	1.61 (0.19)	13.67 (2.36)	1.43 (0.16)
Follow-up	40°PF	22.88 (3.13)	1.35 (0.15)	23.04 (3.51)	1.32 (0.15)
	Neutral	15.86 (2.01)	1.43 (0.16)	15.11 (2.25)	1.40 (0.16)
	Max DF	14.65 (1.88)	1.49 (0.15)	13.43 (2.11)	1.44 (0.15)

Note. PA = pennation angle. M_{Th} = muscle thickness. PF = plantarflexion. DF = dorsiflexion.