Randomised controlled trial comparing immobilisation in above-knee plaster of Paris to controlled ankle motion boots in undisplaced paediatric spiral tibial fractures

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ABSTRACT

Background Management of common childhood spiral tibial fractures, known as toddler's fractures, has not significantly changed in recent times despite the availability of immobilisation devices known as controlled ankle motion (CAM) boots. We compared standard therapy with these devices on quality-of-life measures.

Methods A prospective randomised controlled trial, comparing immobilisation with an above-knee plaster of Paris cast (AK-POP) with a CAM boot in children aged 1–5 years with proven or suspected toddler's fractures presenting to a tertiary paediatric ED in Perth, Western Australia, between March 2018 and February 2020. The primary outcome measure was ease of personal care, as assessed by a Care and Comfort Questionnaire (eight questions scored from 0, very easy, to 8, impossible) completed by the caregiver and assessed during three treatment time-points and preintervention and postintervention. Secondary outcome measures included weight-bearing status as well as complications of fracture healing and number of pressure injuries.

Results 87 patients were randomised (44 CAM boot, median age 2 (IQR 1.5–2.3), 71% male; 43 AK-POP, median age 2 (IQR 1.7–2.8), 80% male), a significant difference in the care and comfort score was demonstrated at all treatment time-points; with the AK-POP group reporting greater personal care needs on assessment on day 2, day 7–10 and 4-week review (all p≤0.001). Weight-bearing status was significantly different at day 7–10 (77.5% CAM vs 53.8% AK-POP, p=0.027). There was no difference in fracture healing or pressure areas between the two treatment groups.

Conclusions Immobilisation of toddler's fractures in a CAM boot allows faster return to activities of daily living and weight-bearing without any effect on fracture healing.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN12618001311246).

Key messages

What is already known on this subject?
- Toddler's fractures are common paediatric injuries.
- Numerous retrospective chart reviews have shown the stability of this fracture type independent of immobilisation technique.
- However, there has been no randomised trial of immobilisation techniques.

What this study adds?
- In this randomised controlled trial comparing above-knee plaster of Paris with a CAM boot from the caretaker perspective, the CAM boot demonstrates less disruption to activities of daily living without a negative effect on fracture healing.

BACKGROUND

Undisplaced mid-shaft spiral fractures occur commonly in children when a minor twisting trauma is applied to the lower limb, frequently when the foot is in a fixed position. The term 'toddler's fracture' was first described in 1964 by Dunbar *et al*[1] with the recommended management being placement in a non-weight bearing above-knee plaster of Paris cast (AK-POP) for 6–8 weeks, as was common practice for adult tibial shaft fractures.

Management of many fractures has changed over the years with greater understanding of the importance of early weight-bearing to promote bone-healing through callus volume and faster time to union of the bone.[2] In addition, this prevents muscle wasting, altered gait mechanics and disruption of weight distribution.[3] Controlled ankle motion (CAM) boots are designed to control movement of fractures while allowing weight-bearing. They are routinely used for injuries of the ankle and have been shown to be effective and safe in the management of toddler's fractures.[4 5]

Systematic[6] and retrospective chart reviews[4 5 7] of toddler's fractures have repeatedly shown that these fractures are stable, independent of the immobilisation used. They concluded that 'large-scale prospective studies examining the clinical outcomes of toddler's fracture management techniques should be conducted to establish a consistent standardised guideline for toddler's fracture treatment across acute care settings'.[6]

The CAM boot has positive benefits on activities of daily living (ADL) in comparison to AK-POPs which cannot be removed for bathing/cleaning and do not allow the patient to weight-bear. CAM boots require minimal education for parents to learn how

to use, provide consistent and uniform support and can be easily tightened once any localised swelling resolves. They can be removed daily for washing and any pressure areas can be identified and treated.

To date, research in this area has been retrospective and highlighted the safety of different immobilisation techniques through cohort studies and case reviews. We hypothesised that children in CAM boots would have less disruption to normal ADL compared with AK-POP. Our study aim was to compare immobilisation devices in children with proven or presumed toddler's fracture.

METHODS

We conducted a prospective randomised controlled trial (RCT), comparing immobilisation with AK-POP to CAM boot in proven or suspected toddler's fractures presenting to the ED. This was a single-centre study, undertaken initially at Princess Margaret Hospital prior to the move to the newly built and renamed Perth Children's Hospital (PCH), the tertiary children's hospital in Western Australia, with an annual ED presentation of 70 000.

All patients, age 1–5 years inclusive, presenting with a radiologically confirmed toddler's fracture or significant suspicion based on clinician assessment without radiological findings, were eligible for enrolment into the study. Patients were excluded if there was concern for non-accidental injury, displacement of the tibial fracture, an associated concurrent fibula fracture, previous fracture within past 6 months, underlying bone condition or chronic disease, inability to attend follow-up and concerns regarding speaking or reading English well enough to complete the patient diary.

Once a patient had been identified as eligible, informed consent was obtained from the caregiver, by the treating physician. Following enrolment, the patient was then randomised to a study group. Randomisation was undertaken by selecting the lowest numbered study pack (next-pack system) from the study box located in ED. The opaque-sealed envelope indicated the treatment arm. Randomisation was by a computer-generated sequence in block sizes of 4, 6 and 8, prepared by an independent body not involved in the study. No stratification factors were used within the randomisation.

Patients were randomised to receive AK-POP or CAM boot sized to fit the patient's foot length. Nursing staff in ED are routinely trained in the process of measuring and fitting CAM boots as well as the application of AK-POP. As per standard treatment process children randomised to AK-POP had their plaster reinforced or replaced at 7–10 days with fibreglass cast or overlay to enable weight-bearing as tolerated. For study patients during the enrolment period this management was undertaken by trained ED research staff by appointment in ED. Routine care instructions were provided to the child's caregivers on ED discharge (online supplemental appendix figures 1 and 2).

The primary outcome was to assess ADL using a modified Care and Comfort Questionnaire (CCQ)[8] (online supplemental appendix figure 3) between the two immobilisation groups. The CCQ is divided into four sections and personal care (PC-CCQ) was chosen to be the primary outcome as it was deemed most relevant to the study population. All questions in the CCQ are scored from 0, very easy, to 8 impossible) (figure 1).

The remaining three domains of the CCQ Positioning (P-CCQ), Comfort (C-CCQ) and Interaction (I-CCQ) were assessed as secondary outcomes, along with complications of fracture healing, pressure areas and assessment of weight-bearing status. Assessment of pain and need for analgesia was undertaken using a parent and doctor reported 100 mm Visual Analogue Scale (VAS).

The CCQ and pain score were completed by the caregiver at five different time-points throughout the study. On day 1, a baseline CCQ was obtained documenting the child's normal ADL prior to injury and along with baseline pain score, assessed by treating physician and caregiver independently. Treatment time-point (T-TP) 2 was the following day when the caregiver completed the CCQ and pain score at home. T-TP 3 was at the 7–10-day ED review, where patients had a follow-up radiograph (out of CAM boot or in AK-POP) and were then reviewed by research staff where the radiograph was assessed for fracture healing, weight-bearing status was noted and any adverse events recorded (online supplemental appendix figure 4). A CCQ and pain score were again completed by the caregiver and the assessing physician completed a pain score. At T-TP 4, patients were reviewed in the orthopaedic fracture clinic and a further CCQ and pain score recorded by the caregiver and doctor (online supplemental appendix figure 5). Weight-bearing status was again documented and adverse events recorded. Finally, at 6–8 weeks (TP 5) a telephone follow-up by research staff was undertaken where a final CCQ and pain score was completed and weight-bearing status noted, as well as any ongoing parental concerns (figure 2).

Patient and public involvement

The PCH ED Research Consumer Group was first involved at inception of this study, the research question and relevance to consumer priorities has always been at the forefront of this

Personal Care (P-CCQ)	
1	Putting on pants (trousers)?
2	Taking off pants (trousers)?
3	Putting on a shirt?
4	Changing nappies?
5	Ease of sitting on a toilet seat/potty?
6	Ease of sitting in a bathtub
7	Ease of bathing?
8	Ease of putting on CAM boot?

All questions were scored 0, very easy to 8, impossible.

Figure 1 Primary outcome questions. CAM, controlledankle motion; P-CCQ, Care and Comfort Questionnaire Positioning.

Procedure	Pre-Treatment	Treatment Time-Points			Post Treatment
	Enrolment & Randomisation Time point 1	Time-Point 2	Time Point 3	Time Point 4	Time Point 5
	Day 1	Day 2	1 – 2 weeks	4 – 6 weeks	6 – 8 weeks
Obtain Informed consent and study enrolment and randomisation	✓				
Plaster check **for AK POP only**		✓			
Repeat X-ray and ED Review Clinic appointment			✓		
Pain Assessment	✓	✓	✓	✓	✓
Disruption to Daily activities score (CCQ)	✓	✓	✓	✓	✓
Orthopaedic Fracture Clinic appointment				✓	
Phone call follow up					✓

Figure 2 Timeline chart. AK-POP, above-knee plaster of Paris cast; CCQ, Care and Comfort Questionnaire.

study and the experience and preferences of the group was sought prior to protocol development. They were consulted throughout the design of the study protocol, especially relating to the number of recorded time-points and follow-up requirements. They reviewed study documents and consent forms and advised on participant recruitment and retention strategies. They received regular updates on study conduct and progress and have been notified regarding submission for publication and resulting change of practice.

Safety and ethics

An independent Data Safety Monitoring Board (DSMB) was established consisting of a paediatric emergency consultant, orthopaedic consultant and a biostatistician who received regular updates on patient enrolment and any adverse events or complications. The DSMB met two times during the study period and found no evidence of increased adverse events in the CAM boot group.

STATISTICAL ANALYSIS

Power/sample Size

Sample size was determined using the primary outcome measure of personal care component of the CCQ. We initially calculated a sample size of 60 (30 per group) using Analysis of variance (ANOVA): repeated measures between factors (G*power), power of 80%, alpha of 0.05, two groups, three measurements, a moderate effect size (cohen's f) of 0.3, correlation among repeated measures of 0.5, allowing for four study patient drop outs. A difference between groups of 2 was considered clinically meaningful; therefore, a SD of 3.2 is calculated from the moderate effect size. Given that we did not have prior data or literature to base our sample size/power we planned a sample size re-estimation once 50% of participants had completed the 6-week assessment. This was not a review of efficacy of the CAM versus AK-POP, but only a review of the sample size requirements through examining the SD of the trial data. We did not plan to cease the study early for sample size reasons but would increase participant numbers if required. The criteria for the sample size re-estimation remained the same as listed above, with the only addition of the SD determined by the study data. The SD was lower than the previous estimate of 3.2. Therefore, additional subjects were not recruited.

Statistical analysis

An intention to treat analysis was performed. Pain and activity scales were measured at all time-points and are reported across multiple time-points as means and SD. Linear mixed models were used to determine differences between the groups at each time-point accounting for correlation between time-points and allowing for missing data. All five time-points were included in the model. A group time interaction term was entered in the model for fixed effects, with subjects entered as a random effect. Multiple imputations were not used as the missing data were for the dependent variable. Cohen's d was calculated to represent between group effect size. A sensitivity analysis was conducted adjusting for sex and age for personal care, positioning, comfort, interaction, VAS: parents and VAS: doctor. There was no impact on effect sizes and statistical significance and these results are not presented. Secondary outcomes were collected at varying times. Each outcome was reported using a comparative table. Healing (on radiograph), weight-bearing status and complications were reported using frequencies and proportions). All adverse events were collated and the proportion with any adverse events recorded for each group. Differences in categorical variables were assessed using χ^2 test or Fisher's exact test (when expected cells counts <5). Statistical significance was set at $p<0.05$. All statistical analysis was performed using Stata V.14.1 (StataCorp).

RESULTS

Between March 2018 and February 2020, 116 patients aged 1–5 years (inclusive) presented to the tertiary paediatric ED in Perth, Western Australia with suspected toddler's fractures.

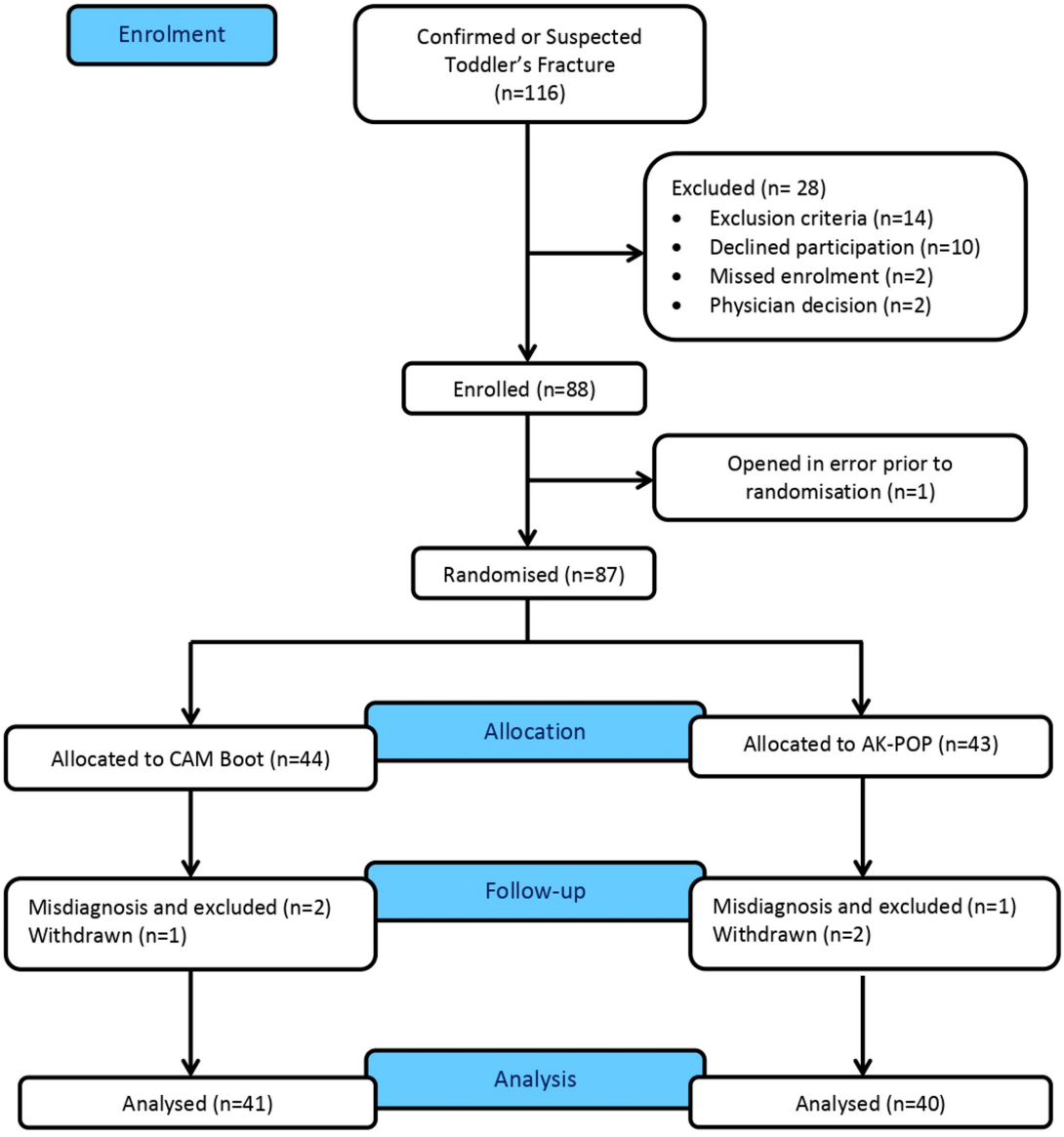

Figure 3 Consolidated Standards of Reporting Trials diagram. AK-POP, above-knee plaster of Paris cast; CAM, controlled ankle motion.

Based on preset exclusion criteria, 14 patients were excluded, 10 refused participation, 2 patients were missed and 2 patients presented 4 weeks after the initial injury, they were partially weight bearing and the radiograph showed a healing fracture. These two delayed presentation patients were discussed with the orthopaedic team and the decision to not immobilise was made, therefore they were not enrolled. Eighty-eight patients were enrolled, one pack was opened in error, prior to the radiograph being performed and the patient subsequently was not eligible for enrolment. Hence, 87 patients were randomised. Forty-four (50.6%) patients were randomised to CAM boot and 43 (49.4%) to AK-POP. Three patients were excluded after enrolment within 24 hours, for misdiagnosis, with one displaced spiral tibial fracture and two distal femoral buckle fractures. Three patients (two AK-POP, one CAM) withdrew from the study at parental request; the data collected up to the point of withdrawal was not used for analysis (figure 3).

In total, at enrolment, 59 (67.8%) patients (31 CAM, 28 AK-POP) had radiographic evidence of toddler's fracture, 25 (28.7%) patients (10 CAM, 15 AK-POP) had suspected fractures but with no fracture visible on radiograph. As is normal practice, they were immobilised if the history and clinical findings suggested a toddler's fracture with 7 (4 CAM, 3 AK-POP) of these 25 (28.0%) subsequently confirmed with radiological evidence of fracture on follow-up imaging.

The overall median age for the CAM group was 2 (IQR 1.5–2.3) and AK-POP group, median age 2 (IQR 1.7–2.8). There were 71% male patients in the CAM group and 80% in the AK-POP (table 1). The three most common injury mechanisms were; falling from standing (25%), descending a playground slide (23%) and falling from elevation, for example, a sofa (21%). Injury mechanisms were similar in both groups (table 1).

There was a significant difference in the primary outcome measure (PC-CCQ) at all time-points during treatment. On day 2: mean difference 1.36 (95% CI 0.8 to 1.93, $p<0.001$), on review on day 7–10; mean difference 1.89 (95% CI 1.4 to 2.39, $p<0.001$ and at 4-week orthopaedic review; mean difference 2.27 (95% CI 1.7 to 2.81, $p<0.001$) (table 2).

On assessment of the remaining three domains of the CCQ, P-CCQ scores were significantly different across the three T-TP; on day 2, P-CCQ score: mean difference 1.56 (95% CI 0.9 to 2.17, $p<0.001$) and at 7–10-day review: mean difference 1.41

Table 1 Study population demographics

	CAM n=41 n (%)	AK-POP n=40 n (%)
Male	29 (70.7)	32 (80.0)
Female	12 (29.2)	8 (20.0)
Age		
► Age 1–<2 years	21 (51.2)	22 (55.0)
► Age 2–<3 years	18 (43.9)	11 (27.5)
► Age 3–<4 years	2 (4.8)	4 (10.0)
► Age 4–≤5 years	0	3 (7.5)
Median age (IQR)	2 (1.5–2.3)	2 (1.7–2.8)
Time from injury to presentation		
► Same day	16 (39.0)	15 (37.5)
► 1 day	17 (41.4)	15 (37.5)
► 2–4 days	3 (7.3)	3 (7.5)
► 5–10 days	4 (9.7)	4 (10.0)
► 10–14 days	1 (2.4)	1 (2.5)
► > 15 days	0	2 (5.0)
Have you contacted or been seen by another medical practitioner regarding this injury prior to this presentation?		
► No	22 (55.0)	24 (58.5)
► Yes	18 (45.0)	17 (41.5)
Presenting complaint		
► Refusal to weight bear	37 (90.2)	35 (87.5)
► Limp	5 (12.2)	9 (22.5)
► Other	1 (2.44)	1 (2.5)
Mechanism of Injury		
► Fall from standing	13 (31.7)	9 (22.5)
► Fall from height	6 (14.6)	12 (30.0)
► Fall from scooter/bike	1 (2.4)	2 (5.0)
► Going down slide	10 (24.4)	10 (25.0)
► Trampoline or bouncy castle	3 (7.3)	2 (5.0)
► Unknown	4 (9.8)	2 (5.0)
► Other	4 (9.8)	3 (7.5)

AK-POP, above-knee plaster of Paris; CAM, controlled ankle motion boot.

(95% CI 0.9 to 1.92, p<0.001) and at 4-week orthopaedic follow-up, mean difference 1.59 (95% CI 1.1 to 2.11, p<0.001). Assessment of comfort and ease of interaction was statistically significant at 4-week orthopaedic review: C-CCQ, mean difference 0.82 (95% CI 0.3 to 1.34, p=0.002) and I-CCQ mean difference 1.08 (95% CI 0.6 to 1.54, p<0.001) (table 3).

Pain scores varied between parents and doctors at all time-points, with no significant difference noted between the two groups on day 2 or at 7–10 day review. At 4-week follow-up, there was no difference in pain as reported by parents but the pain score, reported by the orthopaedic surgeon, was noted to be significantly different, mean difference 3.52 (95% CI 1.2 to 5.81, p=0.003) (table 3).

Adverse events were minimal with only one patient (CAM boot) demonstrating fracture widening (assessed by radiological review at 7 days). This patient technically should have been excluded as the initial radiograph demonstrated a minimally displaced fracture that was not identified by the investigators until ED review. After review at 7 days and in consultation with the orthopaedic team (KS), the patient was changed to AK-POP and continued in the study, with analysis as per intention to treat. A further patient was changed from CAM to AK-POP following increased pain following a fall while mobilising in the CAM boot. Radiographs performed at the time of the second fall did not show any change in the fracture line as reported by the radiologist.

Both groups reported the presence of pressure areas on review in ED at 7–10 days (n=13 (33.3%) CAM, n=12 (31.6%) AK-POP, p=0.999) and at 4-week review 16 (41.0%) CAM, 17 AK-POP, p=0.999). No pressure wound was greater than stage 1 in the European Pressure Ulcer Advisory Panel classification system.[9]

There was a significant difference in weight-bearing status with patients either weight-bearing or partially weight-bearing at 7–10 days (77.5% CAM vs 53.8% AK-POP (p=0.027)). This difference was not seen at 4 weeks. However, there was a significant number of patients from AK-POP who were persistently partially weight-bearing, reported verbally by their parents, at 6–8 weeks phone follow-up (2 weeks after removal of the immobilisation device) (22.2% vs 3.3% (p=0.003)) (table 4). Parents were offered follow-up with orthopaedics, if there was ongoing concern, but there was no abnormality found in the two patients who were reviewed.

At phone follow-up (6–8 weeks postpresentation), parents were asked to rate their satisfaction with the immobilisation device on a numeric scale out of 5, with 5 being the 'very satisfied'. The results showed a significant difference, with the parents of children immobilised in CAM boot (mean score of 4) compared with AK-POP ((mean score 2) p<0.001).

DISCUSSION

Current practice in all tertiary paediatric teaching hospitals in Australia is AK-POP despite multiple retrospective chart reviews highlighting the safety of immobilisation in CAM boots, below knee POPs or even no immobilisation.[4 5] Immobilisation offers support to enable early return to activity and has been shown to confer analgesic benefits.[7] Due to the safety profile of this type of fracture we chose to evaluate the effect on personal care ADL as our primary objective, with our hypothesis being that CAM boot immobilisation was less disruptive to personal care and did not result in any delayed healing or other significant

Table 2 Primary outcome results

	Time-point 1 (preinjury)	Treatment time-point 2 (day 2)	Treatment time-point 3 (day 7–10)	Treatment time-point 4 (4–6 weeks)	Time-point 5 (6–8 weeks)
Personal care					
CAM: mean (SD)	1.60 (0.73)	3.24 (1.44)	2.10 (1.13)	1.48 (0.49)	1.20 (0.62)
AK-POP: mean (SD)	1.51 (0.94)	4.60 (1.06)	3.98 (1.16)	3.75 (1.49)	1.21 (0.41)
Mean diff (95% CI)	−0.09 (−0.5 to 0.28)	1.36 (0.8 to 1.93)	1.89 (1.4 to 2.39)	2.27 (1.7 to 2.81)	0.02 (−0.2 to 0.29)
P value		p<0.001	p<0.001	p<0.001	p=0.866
Cohens d	–	d=1.1	d=1.6	d=−2.1	–

AK-POP, above-knee plaster of Paris; CAM, controlled ankle motion boot.

Table 3 Secondary outcome results

	Time-point 1 (preinjury)	Treatment time-point 2 (day 2)	Treatment time-point 3 (day 7–10)	Treatment time-point 4 (4–6 weeks)	Time-point 5 (6–8 weeks)
Positioning					
CAM: mean (SD)	1.44 (0.71)	2.43 (1.49)	1.60 (0.71)	1.23 (0.41)	1.14 (0.42)
AK-POP: mean (SD)	1.17 (0.37)	3.97 (1.24)	3.01 (1.48)	2.82 (1.48)	1.07 (0.30)
mean diff (95% CI)	−0.26 (−0.5 to −0.02)	1.56 (0.9 to 2.17)	1.41 (0.9 to 1.92)	1.59 (1.1 to 2.11)	−0.09 (−0.3 to 0.11)
P value		p<0.001	p<0.001	p<0.001	p=0.367
Cohens d	–	d=1.1	d=1.2	d=1.5	–
Comfort					
CAM: mean (SD)	2.14 (1.39)	3.57 (1.27)	2.35 (1.11)	1.57 (0.65)	1.39 (0.55)
AK-POP: mean (SD)	1.59 (0.91)	3.44 (1.56)	2.63 (1.14)	2.42 (1.42)	1.60 (1.10)
Mean diff (95% CI)	−0.53 (−1.0 to −0.01)	−0.12 (−0.8 to 0.51)	0.29 (−0.2 to 0.79)	0.82 (0.3 to 1.34)	0.18 (−0.2 to 0.58)
P value		p=0.709	p=0.244	p=0.002	p=0.396
Cohens d	–	–	–	d=0.8	–
Interaction					
CAM: mean (SD)	1.76 (0.97)	3.36 (1.76)	2.16 (1.09)	1.27 (0.48)	1.26 (0.44)
AK-POP: mean (SD)	1.31 (0.52)	3.57 (1.54)	2.69 (1.44)	2.38 (1.28)	1.31 (0.50)
Mean diff (95% CI)	−0.47 (−0.8 to −0.12)	0.23 (−0.5 to 0.97)	0.54 (0.0 to 1.10)	1.08 (0.6 to 1.54)	0.00 (−0.2 to 0.24)
P value		p=0.537	p=0.058	p<0.001	p=0.996
Cohens d	–	–	–	d=1.1	–
VAS: parents					
CAM: mean (SD)	43.25 (29.02)	37.49 (22.23)	10.46 (12.51)	3.00 (5.53)	
AK-POP: mean (SD)	40.36 (31.84)	32.76 (20.08)	8.74 (11.99)	6.75 (10.75)	
Mean diff (95% CI)	−2.99 (−16.3 to 10.36)	−4.56 (−14.1 to 4.98)	−2.36 (−7.8 to 3.08)	2.30 (−1.9 to 6.53)	
P value	p=0.660	p=0.349	p=0.396	p=0.286	
VAS: doctor					
CAM: mean (SD)	37.56 (26.72)	NA	2.71 (4.18)	0.17 (0.64)	
AK-POP: mean (SD)	27.53 (23.00)	NA	3.18 (8.89)	3.33 (6.19)	
Mean diff (95% CI)	−10.04 (−21.1 to 1.01)	NA	0.49 (−2.7 to 3.72)	3.52 (1.2 to 5.81)	
P value	p=0.075	NA	p=0.768	p=0.003	

AK-POP, above-knee plaster of Paris; CAM, controlled ankle motion boot; VAS, Visual Analogue Scale.

adverse events. This study provides trial-evidence that CAM boots are not only safe in respect to fracture healing, but confer a benefit with regards to a quicker return to weight bearing and normal gait, with the potential to reduce hospital visits as well as improved ADL.

Toddler's fractures are unique in occurring in mobile children who are still heavily dependent on their caregiver providing or assisting with personal care. It was for this reason that the caregiver-focused outcome was chosen, in consultation with the PCH ED Research Consumer Group at all stages of study development. The parental satisfaction with CAM boots is a reflection of the speed of return to normal activities which occurred as well as the disruption an AK-POP can have on the life of a family with small children.

Table 4 Weight-bearing status

	CAM	AK-POP	P value
Treatment time-point 3	**n=40 n (%)**	**n=39 n (%)**	
Weight bearing/partially weight bearing	31 (77.5)	21 (53.8)	0.027
Non weight bearing	9 (22.5)	18 (46.2)	
Treatment time-point 4 (on removal of immobilisation device)	**n=37 n (%)**	**n=37 n (%)**	
Weight bearing/partially weight bearing	29 (90.6)	27 (90.0)	0.999
Non-weight bearing	3 (9.4)	3 (10.0)	
Treatment time-point 5	**n=30 n (%)**	**n=39 n (%)**	
Weight bearing	29 (96.7)	28 (77.8)	0.033
Partially weight bearing	1 (3.3)	8 (22.2)	
Non weight bearing	0 (0)	0 (0)	

AK-POP, above-knee plaster of Paris; CAM, controlled ankle motion boot.

There were notable differences between the pain scores reported by caregivers and doctors at time-points 3 and 4. However, there was no statistical significance between the two treatment groups (CAM boots and AK-POP) during the T-TPs 2 and 3 reported by either doctors or caregivers.

This difference in pain score between parents and doctors is in keeping with previous studies showing doctors often underestimate pain when compared with parental scores.[10] It is worth noting that the doctor scores were undertaken by three different doctors at the three time-points, the first two time-points were performed by ED staff whereas as the pain score at time-point four was done in clinic by the orthopaedic surgeon. The parental pain score by comparison was completed by the same person at all time-points. The significantly lower score reported by the orthopaedic surgeon can possibly be attributed to the short assessment time whereas the caregiver's score might be biased by prior patient knowledge and pain experienced prior to the short clinic visit.

Surprisingly, development of pressure areas were similar in both the AK-POP and CAM groups. The ability to remove the CAM boot daily for washing allowed pressure areas to be identified early and alterations made to CAM boot sizing or

application to prevent ongoing rubbing. However, we did note that inappropriate CAM boot sizing was common with a too large boot applied resulting in rubbing, along with incorrect advice regarding the application of the boot. These problems are easily avoided by ongoing education at the review visit, including use of guidelines and information handouts.

It was noted that there were more patients lost to follow-up in the CAM boot group at 4-week orthopaedic review. We had no reason to suspect that these patients had sought care elsewhere; rather that following the improvement in pain they were comfortable not to seek ongoing orthopaedic input after the first follow-up assessment. More patients in the CAM boot group were removed from immobilisation devices at 7 days when they were noted to be asymptomatic by the researchers, and had no evidence of fracture on repeat radiograph. This highlights the ease of conducting good clinical assessment when a child is immobilised in CAM boot compared with AK-POP and ensures less prolonged immobilisation for a presumed fracture, avoiding the potential gait disturbances resulting from prolonged immobilisation.

This study raises the possibility of developing a referral process, for ongoing care of toddler's fractures in general practice, similar to management of other simple fractures such as clavicle fractures[11] and potentially reducing healthcare costs through reduced orthopaedic clinic reviews.

LIMITATIONS

This study has several limitations. It was performed in a single centre and as such the intervention may not be generalisable. It was not possible to blind the intervention, therefore introducing potential bias from the medical and nursing staff, as well as the parents who often had a preference as to which treatment arm they would prefer their child to receive. The study was not a convenience sample; therefore, any physician could enrol patients, resulting in some inappropriate enrolment of patients with the wrong diagnosis but highlights normal ED practice. All patients (confirmed and suspected) were enrolled as per normal practice, demonstrating the usual ED management when the presence of a fracture is not certain, and the adverse events that may occur in those patients may still occur. The parents of 11 patients refused participation due to preference for AK-POP based on the belief that as it was a fracture a 'plaster' should be applied. There was no difference in the seniority of the physicians enrolling these patients to suggest that lack of knowledge of the study was related to this refusal rate. The power calculation performed prior to the commencement of the study used a between group difference combining time-points 2, 3 and 4, however, the final analysis displayed each time point separately, therefore there is misalignment between the methods chosen for power and the final analysis.

CONCLUSION

This study provides trial-level evidence for moving forward from current immobilisation techniques of AK-POPs established in the 1960s and supports recommendations that all undisplaced spiral mid-shaft tibial fractures be immobilised in a below knee CAM boot.

Correction notice Since this article was first published online minor grammatical changes have been made. The term men has been changed to male in the abstract section.

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Contributors KB conceived and coordinated the study from inception to completion and was the principle author of the paper. SOB assisted with study design and education, data collection and ongoing study supervision throughout the trial. SG assisted with data collection. KS and MB supervised and provided expert advice throughout the study design and review of the final paper. NB was involved in study design and analysis of results.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study protocol was supported by the orthopaedic department and approved by the Child and Adolescent Health Service (CAHS) Ethics Committee (HREC Ref No RGS0000000595).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information. All study data are stored in a single password protected database and hard copy data are being stored in accordance with WA Health Research Governance Policy and Procedures.

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Health Facts

CAM Boot

What is a CAM Boot?

A Controlled Ankle Movement (CAM) boot is an orthopaedic immobilisation device that provides bone and joint stability without the need for plaster of Paris application. It allows the patient to weight bear as tolerated and can be removed for washing.

How long do I have to wear the CAM boot?

The CAM boot is usually worn for 3-4 weeks, but your doctor may give you a different period of time. It should be worn both day and night but may be removed for bathing. You should not weight bear on the affected leg when not wearing the boot.

When can my child play sport?

All sports including swimming should be avoided while using the CAM boot. Your child should avoid PE, sports and rough play for a total of 6-8 weeks from the original injury to ensure complete healing.

My child won't keep the CAM boot on – what should I do?

If you have a small child who simply won't keep it on, the leg will have to be immobilised in a plaster cast. Please return to the emergency department and we will put one on.

Is there anything to look out for?

Your child may require painkillers for the first few days such as Paracetamol and/or Ibuprofen. There may also be some swelling which should settle after a few days. If your child gets any 'pins and needles' in their foot you should loosen the CAM boot, if this doesn't help call the Emergency Department for further advice. If you notice any redness or broken skin when you remove the CAM boot for bathing please contact the Emergency department or see your GP for further advice.

How do I put the CAM boot back on after bathing?

1. Place the heel firmly down in the back of the CAM boot

2. Place padding over foot (if required) and Velcro padding securely

3. Ensure the toes are within the firm sole of the boot and fasten outer Velcro straps

Health Facts

Patients with plasters

How to care for your plaster

It is important that you:

- Do not wet, heat or otherwise interfere with your plaster
- Do not scratch the skin under the plaster with pens, knitting needles, rulers etc. as this can result in sores
- Take extra care during the first 48 hours to allow the plaster to dry properly
- Cover the plaster with a tea towel or hand towel and place a plastic bag over the top to reduce condensation when bathing
- Check that fingers and/or toes do not slip inside of the plaster cast
- Observe the affected hand/fingers/foot/toes for:
    - temperature – should be warm or slightly cool to touch, same as the opposite limb
    - skin colour – should be the same as the opposite limb
    - movement – may be reduced
    - sensation – should be the same as the opposite limb (Report to a doctor if any numbness or pins and needles occur)
    - swelling – swollen toes, hands or fingers should gradually reduce in size over the next few days.

Daily activity

It is advised that you:

- Encourage active movement of fingers or toes of the affected limb
- Do not play any sport
- Do not attend school until comfortable
- See a doctor if your child is unsettled, irritable, or has reduced appetite
- Keep the limb in a raised position for the first 24–48 hours after the injury
    - arm or hand injury – a sling or collar and cuff should be worn during the day and at night in the first 48 hours; then may be worn only during the day when walking around, unless otherwise instructed
    - leg or foot injury – keep elevated on a pillow as much as possible especially in the first 24–48 hours
- Keep the plaster firm for good support
    - the plaster back slab needs to be firmly bandaged over the original bandage to ensure adequate support. Do not remove the original bandage
    - the nurse will show you how to bandage starting from the fingers or toes and working up the limb
    - you will be given a crepe bandage before leaving the hospital.

Health Facts

Pain relief

It is advised that you:

- Give paracetamol, Painstop Day-time® or ibuprofen for pain if required as per the manufacturer's instructions
- Report to a doctor if pain is not relieved by the medication.

*Next dose can be given at _____

Follow-up care

- An appointment for the fracture clinic will be made within 7–14 days after discharge
- If your plaster was put on in the emergency department, you will need to go to the GP or return to the emergency department to have the plaster checked within 24 hours of having the plaster put on. This is to make sure the plaster is not too tight.

Contact

If you have any concerns following discharge please take your child to the GP or return to the PMH Emergency Department.

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This information is available in other formats upon request

Appendix Online Figure 3 - Modified Care and Comfort Questionnaire (CCQ)

Personal Care (P-CCQ)				
1. Putting on pants (trousers)?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
3. Putting on a shirt?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
4. Changing nappies?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1 2 3 4 5 6 7	Impossible	N/A
7. Ease of bathing?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
Positioning (P-CCQ)				
9. Ease of positioning in a wheelchair/pram?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
11. Ease of getting out of a car?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
12. Ease of getting in a car?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
Comfort (C-CCQ)				
13. Is there pain or discomfort during position changes?	No Pain	1 2 3 4 5 6 7	Severe Pain	N/A
14. Is there pain or discomfort during nappy changes?	No Pain	1 2 3 4 5 6 7	Severe Pain	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
16a. Is your child using pain control medicine? 16b. **If Yes,** how many doses in the past 24 hours? 16c. If yes, name of medication (s) given?	Yes No Number of doses:_____ _____			
Interaction (I-CCQ)				
18. How easy is it for your child to play alone?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
20. Describe your child.	Very happy	1 2 3 4 5 6 7	Very unhappy	

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation
Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Step 1: ToFI Study - Please complete the following:

Date: □□/□□/□□□□

Immobilisation Device Review:

Note: CAM/POP does not need to be taken off unless there is concern

1. Is patient in immobilisation device:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □
2. Any problems with Boot/POP:
   ……
   ……
   ……
3. Any pressure or "rubbing" areas?
   ……
   ……
   ……
4. Any other concerns?
   ……
   ……
   ……
5. ED Doctor/NP 7-10 day X-Ray review:

Fracture visible?	Yes	□	No	□
Callous Formation?	Yes	□	No	□
Periosteal reaction?	Yes	□	No	□
Fracture widening?	Yes	□	No	□

   Any other findings?
   ……
   ……
6. Additional information:
   Time taken off work? ……

   Time taken off school/day care? ……

   How did they get to hospital today? ……

   Any unscheduled doctor appointments required? ……

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation
Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Assessment: Care and Comfort Questionnaire and Pain Score

Name of person completing form: _____

Please rate how easy or difficult it is for you or your child to perform the following tasks today.

Care and Comfort Questionnaire

Personal Care

1. Putting on pants (trousers)?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
3. Putting on a shirt?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
4. Changing nappies?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy 1 2 3 4 5 6 7	Impossible	N/A
7. Ease of bathing?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy 1 2 3 4 5 6 7	Impossible	N/A

Positioning/Transferring

9. Ease of positioning in a wheelchair/pram?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
11. Ease of getting out of a car?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
12. Ease of getting in a car?	Very easy 1 2 3 4 5 6 7	Impossible	N/A

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation

Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Comfort

	E.g. No Pain		Severe Pain
13. Is there pain or discomfort during position changes?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
14. Is there pain or discomfort during nappy changes?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
16a. Is your child using pain control medicine?	Yes No		
16b. **If Yes,** how many doses in the past 24 hours?	Number of doses:_____		
16c. If yes, name of medication (s) given?	_____		
17. Does your child sleep through the night?	Always 1 2 3 4 5 6 7	Never	N/A

Interaction/Communication

18. How easy is it for your child to play alone?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
20. Describe your child.	Very happy 1 2 3 4 5 6 7	Very unhappy	

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation

Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Parent to complete – VAS Pain Score at this exact moment

|_____|

No Pain **Worst Imaginable Pain**

Doctor to Complete – VAS Pain Score at this exact moment

|_____|

No Pain **Worst Imaginable Pain**

Step 2: Collect patient Care & Comfort Diary

Step 3: Complete Fracture clinic appointment request form – ensuring ToFI Study sticker is on the form.

Step 4: Give parents 'purple' Fracture clinic appointment card – advising them to call the next day to arrange a follow-up appointment in Fracture clinic for 4- 6 weeks from injury.

Step 5: If the patient has an AK POP, the cast needs to be reinforced at the heel with fibreglass to allow weight bearing as tolerated.

ToFI CRF 3 V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number

□□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Please complete the following: Date: □□/□□/□□□□

Immobilisation Device Review:

1. In the immobilisation device, is the patient:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □

2. Any problems with Boot/POP:
   ……
   ……
   ……
3. Any pressure or "rubbing" areas?
   ……
   ……
   ……
4. When the immobilisation device is removed, is the patient:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □

5. Any other concerns?
   ……
   ……
   ……

Parent to complete – VAS Pain Score

Please place a mark across the line to indicate what your child's pain intensity is currently, post removal of immobilisation device.

|_____|

No Pain **Worst Imaginable Pain**

Doctor to Complete – VAS Pain Score

Please place a mark across the line to indicate what your child's pain intensity is currently, post removal of immobilisation device.

|_____|

No Pain **Worst Imaginable Pain**

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number □□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Care and Comfort Questionnaire

Please rate how easy or difficult it is for you or your child to perform the following tasks today.

Personal Care

1. Putting on pants (trousers)?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
3. Putting on a shirt?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
4. Changing nappies?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1	2	3	4	5	6	7	Impossible	N/A
7. Ease of bathing?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy	1	2	3	4	5	6	7	Impossible	N/A

Positioning/Transferring

9. Ease of positioning in a wheelchair/pram?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
11. Ease of getting out of a car?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
12. Ease of getting in a car?	Very easy	1	2	3	4	5	6	7	Impossible	N/A

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number □□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Comfort

	E.g. No Pain							Severe Pain	
13. Is there pain or discomfort during position changes?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
14. Is there pain or discomfort during nappy changes?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
16a. Is your child using pain control medicine?	Yes							No		
16b. **If Yes,** how many doses in the past 24 hours?	Number of doses:_____									
16c. If yes, name of medication (s) given?	_____									
17. Does your child sleep through the night?	Always	1	2	3	4	5	6	7	Never	N/A

Interaction/Communication

18. How easy is it for your child to play alone?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
20. Describe your child.	Very happy	1	2	3	4	5	6	7	Very unhappy	

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017

Health Facts

CAM Boot

What is a CAM Boot?

A Controlled Ankle Movement (CAM) boot is an orthopaedic immobilisation device that provides bone and joint stability without the need for plaster of Paris application. It allows the patient to weight bear as tolerated and can be removed for washing.

How long do I have to wear the CAM boot?

The CAM boot is usually worn for 3-4 weeks, but your doctor may give you a different period of time. It should be worn both day and night but may be removed for bathing. You should not weight bear on the affected leg when not wearing the boot.

When can my child play sport?

All sports including swimming should be avoided while using the CAM boot. Your child should avoid PE, sports and rough play for a total of 6-8 weeks from the original injury to ensure complete healing.

My child won't keep the CAM boot on – what should I do?

If you have a small child who simply won't keep it on, the leg will have to be immobilised in a plaster cast. Please return to the emergency department and we will put one on.

Is there anything to look out for?

Your child may require painkillers for the first few days such as Paracetamol and/or Ibuprofen. There may also be some swelling which should settle after a few days. If your child gets any 'pins and needles' in their foot you should loosen the CAM boot, if this doesn't help call the Emergency Department for further advice. If you notice any redness or broken skin when you remove the CAM boot for bathing please contact the Emergency department or see your GP for further advice.

How do I put the CAM boot back on after bathing?

1. Place the heel firmly down in the back of the CAM boot

2. Place padding over foot (if required) and Velcro padding securely

3. Ensure the toes are within the firm sole of the boot and fasten outer Velcro straps

Health Facts

Patients with plasters

How to care for your plaster

It is important that you:

- Do not wet, heat or otherwise interfere with your plaster
- Do not scratch the skin under the plaster with pens, knitting needles, rulers etc. as this can result in sores
- Take extra care during the first 48 hours to allow the plaster to dry properly
- Cover the plaster with a tea towel or hand towel and place a plastic bag over the top to reduce condensation when bathing
- Check that fingers and/or toes do not slip inside of the plaster cast
- Observe the affected hand/fingers/foot/toes for:
    - temperature – should be warm or slightly cool to touch, same as the opposite limb
    - skin colour – should be the same as the opposite limb
    - movement – may be reduced
    - sensation – should be the same as the opposite limb (Report to a doctor if any numbness or pins and needles occur)
    - swelling – swollen toes, hands or fingers should gradually reduce in size over the next few days.

Daily activity

It is advised that you:

- Encourage active movement of fingers or toes of the affected limb
- Do not play any sport
- Do not attend school until comfortable
- See a doctor if your child is unsettled, irritable, or has reduced appetite
- Keep the limb in a raised position for the first 24–48 hours after the injury
    - arm or hand injury – a sling or collar and cuff should be worn during the day and at night in the first 48 hours; then may be worn only during the day when walking around, unless otherwise instructed
    - leg or foot injury – keep elevated on a pillow as much as possible especially in the first 24–48 hours
- Keep the plaster firm for good support
    - the plaster back slab needs to be firmly bandaged over the original bandage to ensure adequate support. Do not remove the original bandage
    - the nurse will show you how to bandage starting from the fingers or toes and working up the limb
    - you will be given a crepe bandage before leaving the hospital.

Health Facts

Pain relief

It is advised that you:

- Give paracetamol, Painstop Day-time® or ibuprofen for pain if required as per the manufacturer's instructions
- Report to a doctor if pain is not relieved by the medication.

*Next dose can be given at _____

Follow-up care

- An appointment for the fracture clinic will be made within 7–14 days after discharge
- If your plaster was put on in the emergency department, you will need to go to the GP or return to the emergency department to have the plaster checked within 24 hours of having the plaster put on. This is to make sure the plaster is not too tight.

Contact

If you have any concerns following discharge please take your child to the GP or return to the PMH Emergency Department.

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This information is available in other formats upon request

Appendix Online Figure 3 - Modified Care and Comfort Questionnaire (CCQ)

Personal Care (P-CCQ)				
1. Putting on pants (trousers)?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
3. Putting on a shirt?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
4. Changing nappies?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1 2 3 4 5 6 7	Impossible	N/A
7. Ease of bathing?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
Positioning (P-CCQ)				
9. Ease of positioning in a wheelchair/pram?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
11. Ease of getting out of a car?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
12. Ease of getting in a car?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
Comfort (C-CCQ)				
13. Is there pain or discomfort during position changes?	No Pain	1 2 3 4 5 6 7	Severe Pain	N/A
14. Is there pain or discomfort during nappy changes?	No Pain	1 2 3 4 5 6 7	Severe Pain	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
16a. Is your child using pain control medicine? 16b. **If Yes,** how many doses in the past 24 hours? 16c. If yes, name of medication (s) given?	Yes No Number of doses:_____ _____			
Interaction (I-CCQ)				
18. How easy is it for your child to play alone?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy	1 2 3 4 5 6 7	Impossible	N/A
20. Describe your child.	Very happy	1 2 3 4 5 6 7	Very unhappy	

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation
Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Step 1: ToFI Study - Please complete the following:

Date: □□/□□/□□□□

Immobilisation Device Review:

Note: CAM/POP does not need to be taken off unless there is concern

1. Is patient in immobilisation device:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □
2. Any problems with Boot/POP:
   ……
   ……
   ……
3. Any pressure or "rubbing" areas?
   ……
   ……
   ……
4. Any other concerns?
   ……
   ……
   ……
5. ED Doctor/NP 7-10 day X-Ray review:

Fracture visible?	Yes	□	No	□
Callous Formation?	Yes	□	No	□
Periosteal reaction?	Yes	□	No	□
Fracture widening?	Yes	□	No	□

   Any other findings?
   ……
   ……
6. Additional information:
   Time taken off work? ……

   Time taken off school/day care? ……

   How did they get to hospital today? ……

   Any unscheduled doctor appointments required? ……

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation
Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Assessment: Care and Comfort Questionnaire and Pain Score

Name of person completing form: _____

Please rate how easy or difficult it is for you or your child to perform the following tasks today.

Care and Comfort Questionnaire

Personal Care

1. Putting on pants (trousers)?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
3. Putting on a shirt?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
4. Changing nappies?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy 1 2 3 4 5 6 7	Impossible	N/A
7. Ease of bathing?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy 1 2 3 4 5 6 7	Impossible	N/A

Positioning/Transferring

9. Ease of positioning in a wheelchair/pram?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
11. Ease of getting out of a car?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
12. Ease of getting in a car?	Very easy 1 2 3 4 5 6 7	Impossible	N/A

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation

Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Comfort

	E.g. No Pain		Severe Pain
13. Is there pain or discomfort during position changes?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
14. Is there pain or discomfort during nappy changes?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
16a. Is your child using pain control medicine?	Yes No		
16b. **If Yes,** how many doses in the past 24 hours?	Number of doses:_____		
16c. If yes, name of medication (s) given?	_____		
17. Does your child sleep through the night?	Always 1 2 3 4 5 6 7	Never	N/A

Interaction/Communication

18. How easy is it for your child to play alone?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy 1 2 3 4 5 6 7	Impossible	N/A
20. Describe your child.	Very happy 1 2 3 4 5 6 7	Very unhappy	

Appendix Online Figure 4

ToFI Study:
Toddler Fracture Immobilisation

Study Number □□□

CRF 3: Emergency Review Clinic 7-10 Days

Parent to complete – VAS Pain Score at this exact moment

|_____|

No Pain **Worst Imaginable Pain**

Doctor to Complete – VAS Pain Score at this exact moment

|_____|

No Pain **Worst Imaginable Pain**

Step 2: Collect patient Care & Comfort Diary

Step 3: Complete Fracture clinic appointment request form – ensuring ToFI Study sticker is on the form.

Step 4: Give parents 'purple' Fracture clinic appointment card – advising them to call the next day to arrange a follow-up appointment in Fracture clinic for 4- 6 weeks from injury.

Step 5: If the patient has an AK POP, the cast needs to be reinforced at the heel with fibreglass to allow weight bearing as tolerated.

ToFI CRF 3 V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number

□□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Please complete the following: Date: □□/□□/□□□□

Immobilisation Device Review:

1. In the immobilisation device, is the patient:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □

2. Any problems with Boot/POP:
   ……
   ……
   ……
3. Any pressure or "rubbing" areas?
   ……
   ……
   ……
4. When the immobilisation device is removed, is the patient:
   - Weight bearing? □
   - Partially weight bearing? □
   - Not weight bearing? □

5. Any other concerns?
   ……
   ……
   ……

Parent to complete – VAS Pain Score

Please place a mark across the line to indicate what your child's pain intensity is currently, post removal of immobilisation device.

|_____|

No Pain **Worst Imaginable Pain**

Doctor to Complete – VAS Pain Score

Please place a mark across the line to indicate what your child's pain intensity is currently, post removal of immobilisation device.

|_____|

No Pain **Worst Imaginable Pain**

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number □□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Care and Comfort Questionnaire

Please rate how easy or difficult it is for you or your child to perform the following tasks today.

Personal Care

1. Putting on pants (trousers)?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
2. Taking off pants (trousers)?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
3. Putting on a shirt?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
4. Changing nappies?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
5. Ease of sitting on a toilet seat/potty?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
6. Ease of sitting in a bathtub	Very easy	1	2	3	4	5	6	7	Impossible	N/A
7. Ease of bathing?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
8. Ease of putting on CAM boot?	Very easy	1	2	3	4	5	6	7	Impossible	N/A

Positioning/Transferring

9. Ease of positioning in a wheelchair/pram?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
10. Ease of transferring in and out of a wheelchair/pram?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
11. Ease of getting out of a car?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
12. Ease of getting in a car?	Very easy	1	2	3	4	5	6	7	Impossible	N/A

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017

Appendix Online Figure 5

Toddler Fracture Immobilisation Study

Study Number □□□

CRF 4: Orthopaedic Review Clinic 4-5 Weeks

Comfort

	E.g. No Pain							Severe Pain	
13. Is there pain or discomfort during position changes?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
14. Is there pain or discomfort during nappy changes?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
15. Does the pain or discomfort prevent your child from participating in school, various programs, or other activities?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
16a. Is your child using pain control medicine?	Yes							No		
16b. **If Yes,** how many doses in the past 24 hours?	Number of doses:_____									
16c. If yes, name of medication (s) given?	_____									
17. Does your child sleep through the night?	Always	1	2	3	4	5	6	7	Never	N/A

Interaction/Communication

18. How easy is it for your child to play alone?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
19. How easy is it for your child to play with other children?	Very easy	1	2	3	4	5	6	7	Impossible	N/A
20. Describe your child.	Very happy	1	2	3	4	5	6	7	Very unhappy	

ToFI CRF 4 Orthopaedic Clinic Review V2 9 November 2017