Comparison of cast materials for the treatment of congenital idiopathic clubfoot using the Ponseti method: a prospective randomized controlled trial

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Background: The Ponseti method of congenital idiopathic clubfoot correction has traditionally specified plaster of Paris (POP) as the cast material of choice; however, there are negative aspects to using POP. We sought to determine the influence of cast material (POP v. semirigid fibreglass [SRF]) on clubfoot correction using the Ponseti method.

Methods: Patients were randomized to POP or SRF before undergoing the Ponseti method. The primary outcome measure was the number of casts required for clubfoot correction. Secondary outcome measures included the number of casts by severity, ease of cast removal, need for Achilles tenotomy, brace compliance, deformity relapse, need for repeat casting and need for ancillary surgical procedures.

Results: We enrolled 30 patients: 12 randomized to POP and 18 to SRF. There was no difference in the number of casts required for clubfoot correction between the groups (p = 0.13). According to parents, removal of POP was more difficult (p < 0.001), more time consuming (p < 0.001) and required more than 1 method (p < 0.001). At a final follow-up of 30.8 months, the mean times to deformity relapse requiring repeat casting, surgery or both were 18.7 and 16.4 months for the SRF and POP groups, respectively.

Conclusion: There was no significant difference in the number of casts required for correction of clubfoot between the 2 materials, but SRF resulted in a more favourable parental experience, which cannot be ignored as it may have a positive impact on psychological well-being despite the increased cost associated.

Contexte : La méthode de Ponseti pour la correction du pied bot congénital idiopathique a de tout temps spécifié l'utilisation du plâtre de Paris comme matériau de choix; il y a toutefois certains inconvénients associés au plâtre de Paris. Nous avons voulu déterminer l'influence du matériau utilisé (plâtre de Paris c. fibre de verre semirigide) sur la correction du pied bot selon la méthode de Ponseti.

Méthodes : Les patients ont été assignés aléatoirement soit au plâtre de Paris soit à la fibre de verre semi-rigide en vue de l'intervention de Ponseti. Le principal paramètre mesuré était le nombre de plâtres requis pour corriger le pied bot. Les paramètres secondaires incluaient le nombre de plâtres en fonction de la gravité, la facilité de retrait du plâtre, la nécessité de sectionner le tendon d'Achille, le port assidu de l'attelle, le retour de la difformité, la nécessité d'autres plâtres et interventions chirurgicales auxiliaires.

Résultats : Nous avons inscrit 30 patients : 12 ont été assignés au plâtre de Paris et 18 à la fibre de verre. On n'a noté aucune différence entre les groupes quant au nombre de plâtres requis pour la correction du pied bot (p = 0,13). Selon les parents, le retrait du plâtre de Paris était plus difficile (p < 0,001), prenait plus de temps (p < 0,001) et nécessitait le recours à plus d'une méthode (p < 0,001). Au moment du dernier suivi à 30,8 mois, les intervalles moyens avant un retour de la difformité nécessitant la pose d'un autre plâtre et/ou une chirurgie ont été de 18,7 et 16,4 mois dans les groupes traités au moyen de la fibre de verre semi-rigide et du plâtre de Paris, respectivement.

Conclusion : On n'a noté aucune différence significative entre les 2 matériaux quant au nombre de plâtres requis pour corriger le pied bot, mais la fibre de verre a donné lieu à une expérience plus agréable pour les parents, ce qui ne peut être ignoré en raison de l'impact potentiellement positif sur le bien-être psychologique, et ce, malgré un coût plus élevé.

ongenital idiopathic clubfoot is a 3-dimensional deformity that includes cavus and adductus of the midfoot, combined with hindfoot varus and equinus.¹⁻¹³ The goal of treatment is to correct all components of the deformity, such that a pain-free, plantigrade foot with good mobility is achieved for the long term. Initiation of timely and appropriate treatment is paramount to achieve these successful long-term outcomes. Though nonoperative management of clubfoot had been the standard for centuries, modern treatment of clubfoot has, until recently, been primarily surgical.^{1,14} The resurgence of the Ponseti method in recent years has been punctuated by less than favourable long-term outcomes for surgically treated feet.4,7,9,10,12,15-17 The Ponseti method consists of weekly serial manipulations and above-knee plaster casting.^{1,3,4,9,11,14,16,17} With more recent studies confirming its long-term success, it is the current gold standard of treatment.^{5,9,15,16,18} After cast correction of the cavus, adductus and varus components of the deformity, a percutaneous achilles tenotomy is required for definitive equinus correction in more than 70% of cases.⁷

The 2 most common casting materials currently used in the treatment of idiopathic clubfoot are plaster of Paris (POP) and semirigid fibreglass (SRF). The Ponseti method of clubfoot correction has traditionally specified POP as the cast material of choice. It is a cheaper and stiffer material than SRF and is easily mouldable. Some negative aspects associated with its use, however, may include a small risk of injury associated with the exothermic reaction that occurs during curing, more difficult cast removal and the potential for cast saw accidents (Fig. 1).¹⁹⁻²¹

Fibreglass casting materials were introduced in the 1970s and have the advantages of radiolucency, lighter weight, improved durability, faster curing time, lower risk of thermal burn, cleaner application and potentially easier removal.^{19–23} Semirigid fibreglass materials have been previ-



Fig. 1. Infant with substantial skin injury following removal of a Ponseti plaster cast with oscillating saw. This incident caused substantial parental anxiety, such that subsequent casts were removed using prolonged soaking in warm water and unwrapping of the plaster roll.

ously used for clubfoot correction and the treatment of resistant metatarsus adductus with some success.^{21,22} Scotchcast Soft Cast Casting Tape (3M) is a popular fibreglass casting material that was originally developed for extremity injuries not requiring rigid immobilization. This material is semirigid when dry and has the benefit of not tightly adhering to itself, thus allowing easy removal by unwrapping.^{21,22} Many centres ask parents to remove their children's Ponseti casts just before their clinic visits to avoid injury during removal with a cast knife or saw, which may give SRF an advantage over POP. In a related study investigating parental satisfaction and clubfoot casting, SRF was preferred to POP owing to improved durability, performance, ease of removal, ulcer prevention, weight, appearance, ease of cleaning and water resistance.²² Despite these advantages, a recent study by Zmurko and colleagues²¹ demonstrated that SRF costs about 7 times more than POP and is biomechanically inferior to both POP and traditional rigid fibreglass material. They suggested the need for a prospective trial to evaluate these materials for clinical significance.

Our goal was to determine whether the choice of cast material influenced the number of casts required for correction of clubfoot deformity using the Ponseti method. We also assessed the parents' experience with the cast material, particularly with respect to ease of removal.

METHODS

Study design and patient selection

We conducted a prospective randomized controlled trial, completed in a tertiary-level children's hospital. We enrolled consecutive patients with congenital idiopathic clubfoot presenting to the regional tertiary-level children's hospital between July 2007 and December 2008. Patient referrals were screened through a central intake within the orthopedic clinic and were distributed equally and sequentially among the 7 pediatric orthopedic surgeons participating in the study. Following ethics approval from our institutional review board, we obtained written informed consent from the parents of all patients included in our study.

Clubfoot casting was initiated at the first clinical visit and subsequently at weekly intervals using serial manipulation and above-knee casting according to the Ponseti method.^{4,7,9,12,13,24-27} Clubfoot etiology was determined by a thorough history and physical examination (and additional tests as necessary) performed by the treating surgeon. Once the diagnosis of congenital idiopathic clubfoot was made, the patient was randomly assigned to receive either POP or SRF casts. Patients were excluded from this study if the cause of clubfoot was nonidiopathic (e.g., arthrogryposis), or if they had been previously treated for clubfoot. Patients with positional clubfoot deformities were also excluded.

Ponseti method and Pirani classification

Each of the participating pediatric orthopedic surgeons had considerable previous experience and specialized training in the Ponseti method. To ensure that the indications for cessation of cast treatment were reasonably uniform, each surgeon was required to attend a refresher training session in the Ponseti method and the Pirani classification system. The Pirani classification was used to measure initial clubfoot severity and allowed for surveillance during treatment. This 6-grade ordinal system is scored based on the status of the midfoot and hindfoot during correction and has been shown to have excellent intra- and interobserver reliability.28 A Pirani score of 6 is the most severe grading, and a score of 0 represents a fully corrected foot (Fig. 2). A poster outlining the Pirani classification and the indications for cessation of casting and/or tenotomy was displayed for reference in the clubfoot casting room for the duration of the study.

Assessment and outcomes

Photographs were taken before initiation of casting and at the end of casting during foot-abduction orthosis fitting. At each visit, a Pirani grade was given and tabulated using standardized data collection forms. The parents were told to remove the cast at home before each clinic visit. A clinic nurse provided instructions for cast removal specific to each material. After the first cast and fourth casts were removed, the parents were asked to complete a questionnaire (see the Appendix, available at canjsurg.ca) relating to their experience with the selected casting material. The questions were primarily related to the ease of cast removal, the time needed for removal and the number of methods required. The primary outcome variable in this study was the number of casts required for correction of the clubfoot deformity to the point where the foot was ready for a percutaneous tendo-Achilles tenotomy, if necessary, or when dorsiflexion of the ankle greater than or equal to 15° was achieved. A percutaneous tendo-Achilles tenotomy was performed when there was sufficient abduction of the foot, verified by palpation of the anterior process of the calcaneus as it externally rotates from beneath the talus; foot abduction of approximately 60° in relation to the frontal plane of the tibia; and neutral or slight valgus of the calcaneus. According to the Ponseti method, the foot should be casted in 15° of dorsiflexion and abducted to 70° for 3 weeks after tenotomy. This cast was not included in the analysis, as each foot was fully corrected at the time of its application.

Secondary outcome variables included the need for percutaneous tendo-Achilles tenotomy, total time in casts (weeks), ease of cast removal, duration of cast removal (minutes), method(s) of cast removal, complications relating to the casting material, compliance with postcorrection foot-abduction orthosis (FAO), deformity relapse, the need for repeat Ponseti casting and the need for ancillary surgical procedures.

Sample size and randomization

Based on the results of a pilot study of SRF and POP materials performed at our institution involving 10 patients with idiopathic clubfoot, we determined that a sample size of 30 was required. Our calculation was based on a desired assessment of the primary outcome variable with a clinically significant difference of 2 casts and an equal standard deviation of 1.88 (from pilot data) for a power of 80% based on a 2 sample *t* test at a significance level of $\alpha = 0.05$.

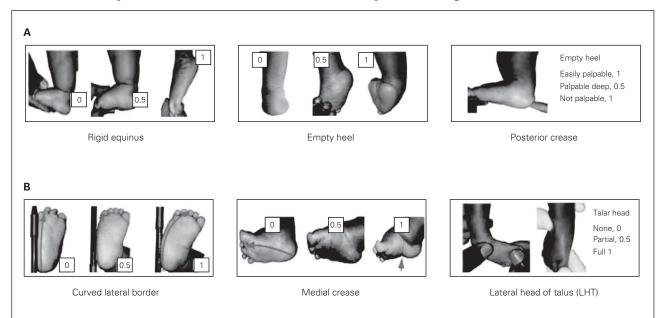


Fig. 2. Pirani scoring system for clubfeet. **(A)** Hindfoot score (HS); **(B)** midfoot score (MS). Total score = (HS + MS) \div 6. Reprodued with permission from Global HELP organization.¹⁰

Randomization of patients was performed using concealed number tracked envelopes according to a computergenerated randomization list. The envelope remained sealed and was opened by the surgeon just before the initiation of cast treatment. Only 1 type of cast material was used for each patient to prevent crossover (i.e., randomization was by patient, not by foot). Block randomization was not applied.

Statistical analysis

Collected data are reported as descriptive statistics (mean \pm standard deviation) for continuous variables and percentages for categorical variables. We generated box plots for the primary variable. Confidence intervals (CIs) were determined where appropriate. We used a Student *t* test at a 5% significance level to determine if there was a significant difference between the means of the number of casts needed per material. Other tests for analysis of secondary outcomes were χ^2 or Fisher exact test (as appropriate) for categorical variables. A PhD statistician (A.N.-A.) performed the data analysis.

RESULTS

Forty-five patients with clubfoot were initially assessed for eligibility in the study; 15 were excluded for various reasons (Fig. 3). Of the 30 patients identified for inclusion, 18 (60%) were randomized to SRF and 12 (40%) to POP. No patients were lost to follow-up during the casting phase of this study. The mean ages at first visit for the SRF and POP groups

were 2.0 (range 1–11.7) and 2.3 (range 0.7–5.7) weeks, respectively. In the SRF group, a unilateral clubfoot was present in 10 of 18 patients (56%), and bilateral clubfeet were present in the remaining 8 patients, for a total of 26 clubfeet. In the POP group, a unilateral clubfoot was present in 6 of 12 patients (50%), and bilateral clubfeet were present in the remaining 6 patients, for a total of 18 clubfeet. Whenever bilateral clubfeet were present, the primary outcome (number of casts) was taken from the more severe foot (i.e., higher Pirani score at initial assessment). The mean initial Pirani score was 5.3 (range 2–6) and 4.9 (range 3–6) in the SRF and POP groups, respectively. In addition, patients were grouped according to clubfoot severity, with more severe deformities having Pirani scores of 5 or more and less severe deformities having Pirani scores less than 5. Assigning levels of severity using the Pirani score has been suggested previously by other authors.²⁹ The number of more severe clubfeet was 22 of 26 feet (85%) in the SRF group and 12 of 18 feet (67%) in the POP group. For bilateral cases, the most severe clubfoot was analyzed for consistency. A tendo-Achilles tenotomy was performed for 15 of 26 clubfeet (58%) in the SRF group and 14 of 18 clubfeet (78%) in the POP group.

There was no significant difference in the mean number of casts required for clubfoot correction between the groups (SRF: 5.7 ± 2.8 casts; POP: 4.4 ± 1.6 casts, p =0.13). The distributions for the groups are displayed as box plots in Figure 4. The 95% CI for the difference in the mean number of casts (μ_{SRF} - μ_{POP}) was (-0.41 to 3.0). When

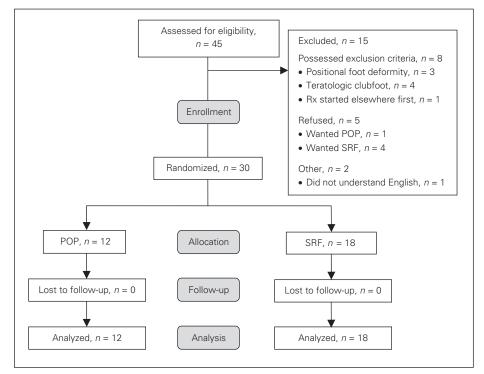


Fig. 3. CONSORT diagram demonstrating the flow of participants through the initial casting phase of the trial. POP = plaster of Paris; SRF = semirigid fibreglass.

analyzed by clubfoot severity, the mean number of casts for both materials in the less severe group was 3. In the more severe group, the mean number of casts was 6.4 in the SRF group and 4.7 in the POP group.

Twenty-four of 30 (80%) parental questionnaires were completed after the first visit and subsequently analyzed. The response rate for the fourth cast questionnaire was too low to provide useful results and thus they were not included in the analysis. According to parents, POP removal was rated as "manageable" or "difficult" by 8 of 12 (67%) parents compared with 1 of 12 (8%) parents in the SRF group (p < 0.001). The remaining parents in each group rated cast removal as "easy" or "very easy." The 95% CI for the difference in the proportion of "easy/very easy" removals between groups $(\rho_{SRF}-\rho_{POP})$ was (0.317–0.916). Plaster of Paris took longer than 30 minutes for removal in 8 of 12 (67%) patients compared with 1 of 12 (8%) patients in the SRF group (p < 0.001). The remaining patients in each group had removal durations of 0-29 minutes. The 95% CI for the difference in the proportion of "0–29 minutes" removals between groups (P_{SRF} - P_{POP})

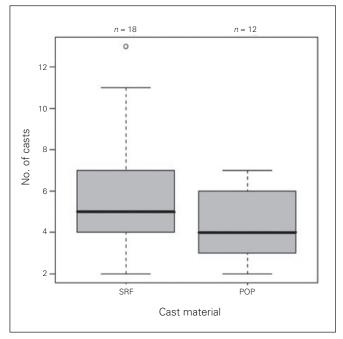


Fig. 4. Number of casts necessary for clubfoot correction, by material. POP = plaster of Paris; SRF = semirigid fibreglass.

was (0.317–0.916). Plaster of Paris casts required more than 1 method for removal in 9 of 12 (75%) patients compared with 2 of 12 (17%) patients in the SRF group (p < 0.001). The 95% CI for the difference in the proportion of removals that needed 1 method ($\rho_{SRF}-\rho_{POP}$) was (0.341–0.926).

Data for secondary outcome measures, including compliance with FAO, deformity relapse, need for repeat Ponseti casting and need for ancillary surgical procedures following successful initial clubfoot correction by the Ponseti method, were collected at a mean final follow-up of $30.8 \pm$ 14.2 months. A summary of these results is provided in Table 1. The mean final follow-up for the SRF and POP groups was 35.8 ± 11.3 months and 23.7 ± 14.4 months, respectively. Two of 30 patients (1 in each treatment group) were lost to final follow-up. The mean times to deformity relapse requiring repeat Ponseti casting, surgery or both were 18.7 ± 15.0 and 16.4 ± 21.1 months for the SRF and POP groups, respectively. Surgical interventions were varied, but included posterior release, posterior eccession.

DISCUSSION

The Ponseti method of clubfoot management has revolutionized the treatment of this common condition through the reduction in extensive surgical procedures and improved long-term outcomes.¹⁷ Despite this, there are important emotional and psychological impacts associated with the execution of this treatment regimen that may have an impact on parental compliance with the Ponseti protocol. As such, measures that serve to shorten treatment duration and improve parental satisfaction while still achieving clinical success should be sought. The present study was designed to determine whether the choice of cast material influenced the number of casts required for correction of clubfoot deformity using the Ponseti method. Parental experience with the cast material, particularly with respect to ease of removal, was also investigated to determine if there was a preference for one material over the other.

Successful treatment of idiopathic clubfoot through serial manipulation and casting by the Ponseti method requires strict adherence to the ordered reduction of the components of the deformity, followed by subsequent immobilization in the corrected position for a defined time

Cast material	Group; no. (%)			
	FAO compliance	Deformity relapse	Need for repeat Ponseti casting	Need for surgery after casting
Semirigid fibreglass	12 (70.6)	8 (47.1)	5 (29.4)	7 (41.2)
Plaster of Paris	11 (91.7)	3 (25.0)	2 (16.7)	2 (16.7)
Total	23 (74.2)	11 (35.0)	7 (23.3)	9 (29.0)

period. This method has been purported to allow for gradual ligamentous and muscular lengthening through creep and stress relaxation in keeping with the viscoelastic properties of the tissues involved.25 Theoretically, a more rigid casting material (e.g., POP) would allow for a more rapid correction, given the increased stretch imposed on the target tissues. In our study this theory appeared to have some merit, given the indication of a reduction in casts required for more severe clubfeet (Pirani \geq 5) when POP was used than when SRF was used. For clubfeet with a Pirani score less than 5, SRF seemed to perform as well as POP, suggesting that the stiffness of this material was sufficient for less severe cases. Although it seems that POP provided a more rapid correction for severe clubfeet, our study was not designed to have the power to statistically test this result. To verify whether the superior material properties of POP would be advantageous for the treatment of more severe clubfeet would require a larger sample size.

Several technical points concerning casting during clubfoot correction have been emphasized by Ponseti.²⁵ Given that the talonavicular joint is the fulcrum about which midfoot and hindfoot correction is achieved, cast moulding over the lateral aspect of the talar head is one of the tenets of this procedure. Stabilization of the talar head seems to be more effectively achieved with POP, given the stiffness of the material and the reported difficulties with moulding SRF casts.^{19,22} In addition, Ponseti also suggested providing adequate posterior moulding superior to the calcaneus to help prevent cast slippage; this is more difficult to perform with SRF than with POP. Despite these theoretical advantages, POP was not shown to be superior to SRF for correction of idiopathic clubfoot (p = 0.13), and cast slippage was not a significant problem in the present study.

Since the commencement of the present study, Pittner and colleagues³⁰ have reported the results of the first randomized trial comparing POP to SRF. As in the present study, there was no significant difference in the mean number of casts required for Ponseti correction between the 2 groups (6.1 in the SRF group v. 5.2 in the POP group, p = 0.20). They did, however, note a statistically significant difference in the final severity scores (according to the Dimeglio system) post-Ponseti casting, with the SRF and POP groups each having residual scores of 6.4 (moderate) and 4.1 (benign), respectively.³⁰ This suggests incomplete clubfoot correction on average (at least for the SRF group). As such, it is unclear whether further casting would have reduced the deformity to a more benign Dimeglio score, in turn increasing the number of casts to final correction even further. In the present study, the indications for cessation of clubfoot casting and/or tentomy were clearly defined and, as such, we were satisfied that the number of casts reported for each treatment group was accurate.

A previous study investigating cast treatment for clubfoot and metatarsus adductus reported that 94% of parents had a definite preference for SRF-type casting over POP.²² This preference was supported by our study, in which a higher proportion of parents whose children had SRF reported positive outcomes with respect to ease and time of removal of casts. Semirigid fibreglass can be quickly removed by simply unwrapping the cast tape, whereas prolonged soaking in warm water and/or other agents (e.g., vinegar) was required to soften POP to facilitate its removal. In the present study, the poor response rate for the parental questionnaire after the fourth cast may indicate a decreasing learning curve with successive cast removals, which might diminish the importance of material choice overall. One could surmise, however, that the emotional stress associated with having a child born with clubfoot might be compounded by the need for more onerous parental involvement with POP - especially for the initial few casts. A recent study showed that the psychological well-being and coping strategies for mothers of children with clubfoot are negatively impacted.³¹ This situation might be further exacerbated by difficulties with cast handling and removal. Interestingly, in the study by Pittner and colleagues,³⁰ there was no difference in parental satisfaction between the 2 casting groups. Further study using validated questionnaires is required to definitively answer the question relating psychological well-being to ease of cast removal and the relative importance of a parental preference in clubfoot casting material.

Despite some clear disadvantages with respect to parental satisfaction, POP has been shown to be more economical than SRF, although this was not investigated in the present study. Zmurko and colleagues²¹ showed that the cost of SRF was purported to be up to 7 times that of POP. The question remains whether the advantages in parental experience warrant the increased cost of SRF given the lack of improvement in clinical outcomes compared with the substantially cheaper POP.

In the present study, more patients in the SRF than the POP group had a deformity relapse, requiring repeat Ponseti casting, surgical intervention or both. There may be several reasons for this unrelated to the choice of cast material used for initial clubfoot correction. The mean duration of final follow-up for the SRF group was significantly longer than for the POP group (35.8 v. 23.7 months, respectively), allowing more time for the deformity to relapse. Despite this, the mean times to deformity relapse and initiation of further treatment were similar for the SRF and POP groups (18.7 v. 16.4 mo, respectively). More importantly, FAO compliance post-Ponseti casting was markedly reduced in the SRF group compared with the POP group (70.6% v. 91.7%, respectively). Noncompliance with the standard Ponseti bracing protocol (FAO worn 3 months full-time, then at night and naptime for 3 years) has been shown to be the factor most related to the risk of relapse in several previous studies and may be the most likely reason why the SRF group in the present study had an increased prevalence of repeat casting and surgery.^{29,32}

The strength of this study lies in its design. It is a prospective, randomized controlled trial, with sample size and power calculations determined from the results of a pilot study conducted before the commencement of data collection. Applying block randomization techniques would have resulted in a more even distribution of patients between the treatment groups but would not likely have had an effect on the results obtained with respect to number of casts. Our sample size was determined based on pilot data with a standard deviation of 1.88 casts and a power of 0.8. Prestudy calculations using a standard deviation of 1 cast called for 7 patients in each group. As such, the current treatment group numbers were adequate for the desired study power. The Ponseti technique and Pirani classification was reviewed before commencing the study with all participating surgeons, to control the casting technique. Despite this, the sample size was not large enough for subgroup analysis according to clubfoot severity or deformity relapse. The main weakness of the study was the use of a nonvalidated questionnaire to evaluate parental experience.

CONCLUSION

There was no significant difference in the number of casts required for correction of clubfoot between the 2 materials, SRF and POP. There may be an advantage in using POP both economically and in the correction of more severe clubfeet (Pirani score \geq 5), but our study was not powered or designed to determine these aspects. In addition, the significant improvement in parental experience with SRF determined in this study cannot be ignored, as it may have a positive impact on psychological well-being despite the increased cost associated.

Competing interests: None declared.

Contributors: C. Hui, A. Nettel-Aguirre and J.J. Howard designed the study. C. Hui, V. Joughin, S. Goldstein, G. Kiefer, D. Parsons, C. Brauer and J.J. Howard acquired the data, which C. Hui, V. Joughin, A. Nettel-Aguirre and J.J. Howard analyzed. C. Hui and J.J. Howard wrote the article, which all authors reviewed and approved for publication.

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