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Authors

Kelley, S

Feeney, M

Maddock, C

et al.

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Expert-Based Consensus on the Principles of Pavlik Harness Management of Developmental Dysplasia of the Hip

S.P. Kelley, MBChB, PhD, FRCS(Tr&Orth), M.M. Feeney, BSc, MSc, BMBS, C.L. Maddock, BSc, MMASc, M.L. Murnaghan, MD, MEd, FRCS, C.S. Bradley, BScPT, MSc, and the International Hip Dysplasia Institute (IHDI) Study Group*

Investigation performed at The Hospital for Sick Children, Toronto, and the Department of Surgery, University of Toronto, Toronto, Ontario, Canada

Background: Developmental dysplasia of the hip (DDH) is the most common orthopaedic disorder in newborns. While the Pavlik harness is one of the most frequently used treatments for DDH, there is immense variability in treatment parameters reported in the literature and in clinical practice, leading to difficulties in standardizing teaching and comparing outcomes. In the absence of definitive quantitative evidence for the optimal Pavlik harness management strategy for DDH, we addressed this problem by obtaining international expert-based consensus on the subject.

Methods: An initial list of items relevant to Pavlik harness treatment was derived by a review of the literature. Delphi methodology was used to guide serial rounds of surveying and obtaining feedback from content matter experts from the International Hip Dysplasia Institute (IHDI), which continued in the same manner until consensus based on standard statistical analysis was reached. This was followed by a corroboration of face validity to derive the final set of management principles.

Results: Four rounds of structured surveying were required to reach consensus. Following 2 rounds of peer review, and from an initial list of 66 items in 8 categories, we were able to derive 2 simplified, yet comprehensive, print-friendly tables consisting of 28 items in 8 categories to assist clinicians in managing DDH with a Pavlik harness. The tables contain principles of treatment initiation, application and follow-up of the harness, complications, weaning, and end-of-treatment decision-making as well as specific criteria based on the severity of the DDH. Furthermore, highly contentious items were identified as important areas of future study.

Conclusions: We developed a comprehensive set of principles based on expert consensus to assist clinicians in the management of DDH using the Pavlik harness. This study also generated a list of the most controversial areas in the nonoperative management of DDH, which should be considered high priority for future study to further refine and optimize outcomes.

Level of Evidence: Therapeutic Level V. See Instructions for Authors for a complete description of levels of evidence.

Developmental dysplasia of the hip (DDH) is the most common musculoskeletal disorder in neonates[1-3]. Late-presenting DDH often requires surgical management[4]. There is substantial morbidity associated with surgical treatments of DDH, including osteonecrosis, redislocation, and the need for future surgery to correct residual dysplasia[4-8]. Even following complication-free surgical management, a substantial proportion of hips will require an arthroplasty in young adulthood[9-11].

Alternatively, if DDH is detected in a newborn, treatment can be initiated with nonsurgical methods[12,13]. One of the most common nonoperative treatment methods is the Pavlik harness

*A list of the IHDI Study Group members is included as a note at the end of the article.

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because of its ease of use and excellent results. The Pavlik harness can be used to correct stable dysplasia, unstable dysplasia, or hips that are dislocated at rest, with success rates of up to 95%[12-18]. It is therefore widely agreed that the gold standard of DDH management is early detection and nonoperative treatment. What is not clear, however, is the optimum nonoperative treatment strategy.

The range of management options published in the literature is confusing and does little to assist trainees, physicians with smaller-volume practices, and practitioners in underresourced settings to determine the optimum, or even the acceptable, standards for nonoperative care of an infant with DDH.

Experts in the field are divided in their views on best practice. Differences of opinion arise over many aspects of management—for example, which types of DDH to treat, when to initiate treatment, how long to treat, best use of imaging, monitoring of patients during brace treatment, when to discontinue treatment, whether to wean from the harness, and how to manage complications. To date, there is no strong scientific evidence or expert-based consensus to guide nonoperative management of DDH using the Pavlik harness.

The American Academy of Orthopaedic Surgeons (AAOS) has published evidence-based guidelines on these specific issues in DDH management[19] but were able to reach only a "limited" (meaning low) strength of recommendation (or a designation of conflicting evidence) for each item. More recently, the AAOS published Appropriate Use Criteria (AUC) for the management of DDH in infants, which are helpful to supplement guidelines based on low-strength evidence, but these AUC were restricted to advising on the decision to initiate treatment and did not cover the critical aspects of management strategy after[20].

Our primary aim was to construct a valid set of expert-consensus-based principles to inform acceptable practice for anyone treating DDH using a Pavlik harness. Our secondary aim was to systematically identify the specific areas of greatest controversy regarding Pavlik harness use, for which consensus could not be easily achieved, to provide guidance on the most important areas of DDH management to study in the future.

Materials and Methods

Delphi methodology was used to achieve consensus on Pavlik harness treatment. The Delphi methodology is an iterative process in which a structured survey is filtered through several rounds of expert review until consensus is reached[21,22].

An initial list of items relevant to Pavlik harness treatment was derived by systematic review of the literature according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria (www.prisma-statement.org). This generated items for the survey and was purposefully not restricted to specific levels of evidence. We included studies that reported on children with DDH who presented at <6 months of age and were treated with a Pavlik harness. We excluded studies that reported on children with other diagnoses, teratologic dislocations, or non-Pavlik-harness treatment; opinion or review articles; and those not available in English. The literature search was conducted in MEDLINE, Embase, Evidence-Based Medicine Reviews (EBMR), Cochrane Central Register of Controlled Trials (CENTRAL), and Health Technology Assessment (HTA) from the earliest available dates in the OvidSP search platform (1946). A combination of search terms related to DDH and Pavlik harness use were inputted. Eligible complete articles were reviewed, and a preliminary list of items relevant to Pavlik harness treatment was reviewed by 2 expert clinicians (independent of the consensus experts) to identify any additional items or obvious omissions.

The resulting list of items was distributed to 13 members of the Medical Advisory Panel (MAP) of the International Hip Dysplasia Institute (IHDI) via the web-based survey application SurveyMonkey. The IHDI MAP is a collaborative group of pediatric orthopaedic surgeons with clinical expertise in the management of DDH who reside in Australia, Canada, Mexico,

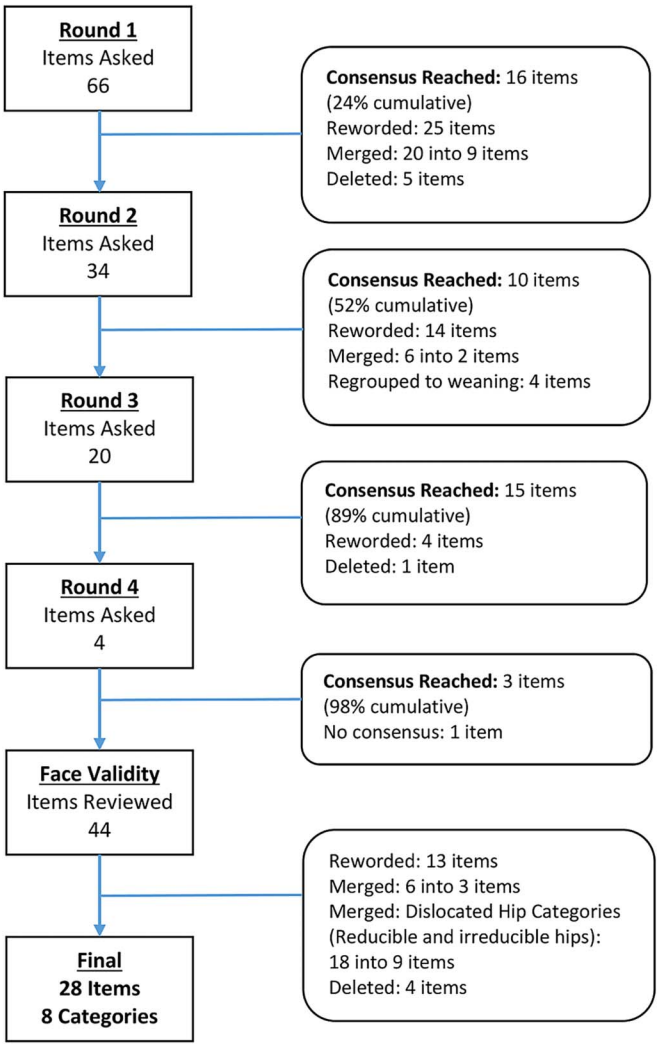

Fig. 1

Flow diagram of consensus development: from preliminary to final principles.

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TABLE I Principles of Pavlik Harness Treatment for DDH

Treatment initiation
1. Treatment is generally, but not always, started before age 6 months
2. A clinical examination is necessary prior to starting treatment
3. An ultrasound is recommended prior to starting treatment

Application and follow-up
1. A health-care professional should apply the harness at the start of treatment
2. A health-care professional should check that the harness is applied correctly at each clinic visit

Complications
1. If femoral nerve palsy occurs, treatment should be temporarily discontinued until return of nerve function and then reinstituted

Weaning
1. There is a role for weaning (night-time use only)
2. Weaning (night-time use only) may be instituted once the hip is normal on ultrasound*

End of treatment
1. At the conclusion of treatment, hips should be assessed via ultrasound or radiograph for normality*
2. As long as the harness is tolerated, there is no maximum duration of Pavlik harness treatment

*According to the AAOS AUC, normality on ultrasound is defined as an alpha angle of ≥60° and femoral head coverage of >45% and normality on radiographs is defined as IHDI grade I.

the United Kingdom, and the United States. Eight to 10 participants were considered necessary to provide adequate power to the study[22]. Respondents were asked to rate each statement on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree." Respondents then provided feedback and comments, which were incorporated into the list of items for

TABLE II Pavlik Harness Treatment by Severity of DDH

Stable dysplastic hip
1. Treatment should ideally begin at, but not before, 6 weeks of age
2. The harness may be worn 23 hours/day at the outset of treatment
3. A clinic visit should occur every 2-4 weeks to check and adjust the harness and assess for complications
4. The hip should be monitored via ultrasound every 4-6 weeks
5. Treatment should be continued until the hip is normal on ultrasound*, and for a minimum of 6 weeks

Dislocatable hip
1. Treatment should ideally begin before 7 weeks of age
2. The harness may be worn for 23 hours/day at the outset of treatment
3. A clinic visit should occur every 2-4 weeks to check and adjust the harness and assess for complications
4. The hip should be monitored via ultrasound every 2-4 weeks
5. Treatment should continue until the hip is normal on ultrasound*, and for a minimum of 8 weeks

Dislocated hip (reducible or irreducible)
1. Treatment should begin immediately following diagnosis, ideally before 7 weeks of age
2. The harness should be worn 24 hours/day until the hip is reduced, at which point it may be worn for 23 hours/day
3. The hip should be monitored weekly for reduction via clinical examination without stress maneuvers
4. The hip should be monitored weekly via ultrasound until it is reduced
5. Once the hip is reduced, a clinic visit should then occur every 2-4 weeks to check and adjust the harness and assess for complications
6. Once reduced, hip progress should be monitored via ultrasound every 2-4 weeks
7. If hip reduction is not achieved within 3-4 weeks as determined by clinical examination and ultrasound, harness treatment should be abandoned
8. If hip reduction, determined via ultrasound, is achieved within 3-4 weeks, harness treatment should continue until the hip is normal on ultrasound*, and for a minimum of 8 weeks

*According to the AAOS AUC, normality on ultrasound is defined as an alpha angle of ≥60° and femoral head coverage of >45% and normality on radiographs is defined as IHDI grade I.

the following round of surveying[21,22]. After each round, items for which consensus was reached were excluded from subsequent rounds. Based on feedback from the expert reviewers, remaining items were reworded, merged with other items, or deleted as necessary. Newly identified items were also added at each stage as indicated. Once updated, the new list of items was redistributed to the panel. Experts were then asked to re-rate each item while factoring in comments and results from previous rounds. Rounds of surveying continued in the same manner until consensus was reached.

Statistical Analysis

Importance ratings were derived from each round of surveying by calculating median score responses on the 5-point Likert scale for each item. Items requiring clarification or those with a median score of <4.00 ("agree") were modified as needed prior to each subsequent round. Consensus was considered to have been reached when ≥90% of the items had an interquartile range (IQR) of ≤1. This value indicates low sample deviation and is generally accepted as indicating consensus[21,23]. Once the consensus was achieved, 2 experts reviewed the final item list, and this was followed by 2 rounds of peer review to achieve final face validity.

Results

The literature search and expert review identified a preliminary list of 66 items in 8 categories relevant to Pavlik harness management for DDH (see Appendix 1). Four rounds of structured surveying were required to reach consensus. Figure 1 demonstrates the number of items posed at each round of surveying and the ensuing results.

Following round 1, consensus was reached on 24% (16) of the 66 items, with an IQR of ≤1. Following round 2, consensus was reached on 52% (26) of the 50 revised cumulative items, and additional items on weaning from the harness were created. Following round 3 and round 4, consensus was reached on 89% (41 of 46) and 98% (44 of 45), respectively. Surveying was ended based on the statistical parameter that consensus had been reached on >90% of items. During face validity analysis and following peer review, 6 pairs of items were each merged into 3 items and 4 items were deleted. In addition, all 9 items in each of the categories for dislocated-reducible and dislocated-irreducible hips were identical and thus these items were merged. The outcome of the 4 rounds of surveying, face validity analysis, and peer review produced the final list of 28 items in 8 categories.

As a result, we were able to derive 2 comprehensive tables to assist clinicians in managing DDH with a Pavlik harness. Table I details the general principles of Pavlik harness treatment initiation, application and follow-up of the harness, complications, weaning, and end-of-treatment decision-making. Table II provides guidance on Pavlik harness treatment according to the severity of the hip dysplasia—i.e., dysplastic, dislocatable, and dislocated (both reducible and irreducible). Print-friendly versions of these tables are provided in Appendix 2.

Discussion

The goal of this study was to obtain consensus by an international group of experts on the critical steps in the nonoperative management of DDH using the Pavlik harness. Delphi methodology was used because of its advantages in ensuring engagement and participation from a geographically diverse collaboration of experts, particularly when multiple rounds of surveying are required to tease out consensus on controversial topics. The primary reported limitations of the Delphi process were not considered important for this study in that the expert panel was highly motivated, and thus unlikely to drop out between rounds, and the panel members are widely recognized as experts in this field[22]. Our study also fit the acceptable parameters of Delphi methodology with 13 reviewers and required 4 rounds of surveying[22].

With Delphi-based consensus, not every expert reviewer is obliged to agree equally with each item. In fact, some expert reviewers were strongly opposed to a particular principle on which, regardless, formal consensus was achieved using this process. This is not a limitation of the study, but rather it reflects a powerful scientific approach to gaining consensus in a highly controversial area. This is relevant to the management of DDH, for which there is great diversity of management strategies. The current lack of standardization of Pavlik harness management prevents clinicians from forming research collaborations and comparing results, and it makes it difficult to standardize teaching. In today's environment of competency-based residency training programs, the use of evidence-based guidelines has become a critical educational aid when time and resources for learning are more limited[24-26]. Prior to the present study, there was no strong scientific evidence and no expert-based consensus regarding nonoperative management of DDH using the Pavlik harness. This study is the first to address this important issue.

A limitation of the Delphi process is that the consensus may not reflect an individual's opinion on specific items or how each individual may manage the nuances of a specific case of DDH. Training and experience, supported by systematically derived principles, will always be critical elements for successfully managing the range of DDH cases encountered in an orthopaedic clinic. For example, the indicated age range for Pavlik harness use in the principles is <6 months of age, but reviewers stressed that they have successfully employed the harness for patients beyond this age. Consensus was therefore reached by specifying that harness treatment is "generally, but not always, started before age 6 months." Another example is the item "An ultrasound is recommended prior to starting treatment." All of the experts acknowledged that they would indeed order an ultrasound prior to initiating treatment, especially when a patient has a stable dysplastic hip, which cannot be diagnosed with clinical examination alone. However, during consensus the decision was made to clarify that an ultrasound is not obligatory, with the understanding that there are geographic regions where orthopaedic surgeons successfully manage DDH in infants with no access to hip ultrasound because of resource constraints. The principles are designed to be globally relevant. The specific wording of the 28 items set

out in the tables should therefore be carefully noted, with the understanding that they offer expert-guided general principles for sound decision-making in the absence of more robust evidence rather than a set of absolute indications or contraindications for Pavlik harness management.

Following 4 rounds of surveying, face validity testing was employed. This allowed clarification regarding a controversial item on which consensus had not yet been reached. This item was "Pavlik harness treatment is indicated for a hip that is dislocatable." Expert feedback revealed that creating a definitive statement that treatment is "always" indicated would not reflect the practices of the contributing experts. A number of experts suggested that no treatment was necessary for a dislocatable hip in the neonatal period whereas treatment was considered mandatory at 6 weeks of age. This suggests that disagreements were not related to the principle of a dislocatable hip needing treatment per se, but rather that the timing of such treatment was more important—i.e., all agreed treatment was needed in an older child, but observation could be implemented for a newborn infant with a dislocatable hip. Face validity testing also allowed the combination of certain items to declutter the principles and to offer a simplified framework for training in Pavlik harness management.

The AAOS previously published evidence-based guidelines on the management of DDH in infants[19] but concluded that the evidence is generally of low strength, limiting its usefulness in guiding clinical management. The AAOS subsequently published AUC for DDH management[20], based on expert opinion, which are useful considering the lack of robust evidence-based guidelines. A limitation of the AUC is that they focus only on treatment initiation and offer no guidance on the broader aspects of nonoperative management of DDH. Our study builds substantially on the 2 AAOS publications by offering expert consensus on the principles governing management decisions when treating infants with DDH in the Pavlik harness.

We, and the IHDI, do not conclude that these principles are the last word on Pavlik harness management; rather, they set the stage for future advances in the field. However, we do believe that we have reported a validated consensus with practical guidance on the nonoperative treatment of DDH using the Pavlik harness. These principles will have immediate applicability for trainees as well as provide a template to refresh current concepts for experienced clinicians. Of equal importance, this study has also highlighted the most controversial areas of Pavlik harness management that should be addressed in larger prospective randomized trials.

The structured feedback of Delphi methodology also functioned as a hypothesis generator, by highlighting the most controversial areas of Pavlik harness management of DDH. We believe that these are the most impactful areas for future study. It is important to note that controversy about an item was not necessarily related to how many rounds of surveying were necessary gain consensus regarding that item. For example, an item that required 4 rounds of surveying to reach consensus may have generated difficulties with the nuances of wording rather than the concept and importance of the item itself. Below is a list of 6 of the most controversial questions concerning Pavlik harness treatment, with a small selection of the accompanying feedback comments below to highlight the controversies.

1. What is the optimal use of ultrasound during harness treatment?
   - "Good for research and perhaps validating clinical exam but {ultrasound} not always necessary."
   - "The role of clinical exam is limited, and I rely on ultrasound to assess reduction."
   - "I'm not convinced enough by clinical exam."
2. What is the role of weaning?
   - "Still controversial exactly when to wean."
   - "Patient compliance may be an issue."
   - "There is a need to test with monitoring devices."
   - "I do it, but not based on any data; just anecdotal."
   - "There is a psychological benefit to weaning."
3. How does one define when a hip is reduced and stable during Pavlik harness treatment?
   - "We need to stop using the term 'normal' to define when to stop."
   - "I think that an Ortolani hip should be reduced in Pavlik harness but this may not necessarily be so."
   - "Some studies show less time is needed in harness, but those studies define success as return to within 2 SD {standard deviations}."
4. What is the definition of a normal hip?
   - "Why would you stop treatment with a normal hip that is defined as −2SD? It's still abnormal until the mean alpha angle is reached."
   - "We say that the harness should be removed when the hip is normal, but there are different definitions of normal."
5. When should a dislocatable hip be treated with a harness?
   - "Err on the side of safety as some will not spontaneously improve."
   - "There is no downside to treatment. (I've never seen AVN {avascular necrosis} in the opposite hip or in a stable dysplasia.)"
   - "Depends a bit on age."
   - "Only if not remodeling normally or >3 months {of age}."
6. How long should Pavlik harness treatment be instituted for?
   - "Depends on age; sometimes it's a year."
   - "Should consider age and size of child."
   - "Treat until normality."
   - "No maximum in my book."
   - "I tend to usually treat for 12 weeks."

In conclusion, we developed a comprehensive set of principles based on expert consensus to assist clinicians in the nonoperative management of DDH using the Pavlik harness.

We gained consensus on both the general principles of Pavlik harness treatment and the detailed treatment of hip subtypes seen across the spectrum of pathology of DDH. We hope that these principles will offer a much-needed standardized teaching resource for clinicians treating DDH.

Furthermore, this study enabled us to generate a list of the most controversial areas in the nonoperative management of DDH that should be considered high priority for future study to further refine and optimize the outcomes of children with developmental dysplasia of the hip.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A115; http://links.lww.com/JBJSOA/A117). ■

Note: In addition to the authors listed in the byline, members of the IHDI Study Group include P. Castaneda, MD, NYU Langone Medical Center, New York, NY; N.M. Clarke, ChM, DM, FRCS, FRCS(Ed), Southampton General Hospital, Southampton, United Kingdom; B.K Foster, MBBS, MD, FRACS, Women's and Children's Hospital, North Adelaide, South Australia, Australia; J.A. Herrera-Soto, MD, Arnold Palmer Hospital for Children, Orlando, Florida; J.R. Kasser, MD, Boston Children's Hospital, Boston, Massachusetts; H.K. Kim, MD, MS, FRCS, Texas Scottish Rite Hospital for Children, Dallas, Texas; T.H. Matheney, MD, MLA, Boston Children's Hospital, Boston, Massachusetts; C.F. Moseley, MD, CM, FRCS, Shriners Hospital for Children–Los Angeles, Pasadena, California; S.J. Mubarak, MD, Rady Children's Hospital, San Diego, California; K. Mulpuri, MBBS, MS, MHSc, British Columbia Children's Hospital, Vancouver, British Columbia, Canada; U.G. Narayanan, MBBS, MSc, FRCS, The Hospital for Sick Children, Toronto, Ontario, Canada; C.T. Price, MD, Arnold Palmer Hospital for Children, Orlando, Florida; W.N. Sankar, MD, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; V.V. Upasani, MD, Rady Children's Hospital, San Diego, California; and J.H. Wedge, MD, FRCSC, The Hospital for Sick Children, Toronto, Ontario, Canada.

S.P. Kelley, MBChB, PhD, FRCS(Tr&Orth)[1,2]
M.M. Feeney, BSc, MSc, BMBS[1]
C.L. Maddock, BSc, MMASc[1]
M.L. Murnaghan, MD, MEd, FRCS[1,2]
C.S. Bradley, BScPT, MSc[1,2]

[1]The Hospital for Sick Children, Toronto, Ontario, Canada

[2]Departments of Surgery (S.P.K. and M.L.M.) and Rehabilitation Sciences (C.S.B.), University of Toronto, Toronto, Ontario, Canada

Email address for S.P. Kelley: simon.kelley@sickkids.ca

ORCID iD for S.P. Kelley: 0000-0001-8458-2033
ORCID iD for M.M. Feeney: 0000-0002-8931-6049
ORCID iD for C.L. Maddock: 0000-0003-3162-330X
ORCID iD for M.L. Murnaghan: 0000-0002-9086-9193
ORCID iD for C.S. Bradley: 0000-0001-9697-5475

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Update

This article was updated on August 14, 2020, because of a previous error. On page 1, in the byline, the text that had read "S.P. Kelley, MBChB, PhD, FRCS(Tr&Orth), M.M. Feeney, BSc, MSc, BMBS, C.L. Maddock, BSc, MMASc, M.L. Murnaghan, MD, MEd, FRCS, and C.S. Bradley, BScPT, MSc, on behalf of the International Hip Dysplasia Institute (IHDI) Study Group*" now reads "S.P. Kelley, MBChB, PhD, FRCS(Tr&Orth), M.M. Feeney, BSc, MSc, BMBS, C.L. Maddock, BSc, MMASc, M.L. Murnaghan, MD, MEd, FRCS, C.S. Bradley, BScPT, MSc, and the International Hip Dysplasia Institute (IHDI) Study Group*".

An erratum has been published: JBJS Open Access. 2020;5(3):e18.00054ER.