

- and performance tests in patients with or without radiographic osteoarthritis compared to matched controls. *Osteoarthritis Cartilage* 2001;9:316-324.
182. Roos EM, Roos HP, Ryd L, Lohmander LS. Substantial disability 3 months after arthroscopic partial meniscectomy: A prospective study of patient-relevant outcomes. *Arthroscopy* 2000;16:619-626.
 183. W-Dahl A, Toksvig-Larsen S, Roos EM. A 2-year prospective study of patient-relevant outcomes in patients operated on for knee osteoarthritis with tibial osteotomy. *BMC Musculoskelet Disord* 2005;6:18.
 184. Mohtadi N. Development and validation of the quality of life outcome measure (questionnaire) for chronic anterior cruciate ligament deficiency. *Am J Sports Med* 1998;26:350-359.
 185. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833-1840.
 186. Bellamy N. Outcome measurement in osteoarthritis clinical trials. *J Rheumatol Suppl* 1995;43:49-51.
 187. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br* 1998;80:63-69.
 188. Mann G, Nyska M, Hetsroni I, Karlsson J. Scoring systems for evaluating ankle function. *Foot Ankle Clin* 2006;11:509-519.
 189. Zengerink M, Struijs PA, Tol JL, van Dijk CN. Treatment of osteochondral lesions of the talus: A systematic review. *Knee Surg Sports Traumatol Arthrosc* 2010;18:238-246.
 190. Junge A, Langevoort G, Pipe A, et al. Injuries in team sport tournaments during the 2004 Olympic Games. *Am J Sports Med* 2006;34:565-576.
 191. Good CJ, Jones MA, Lingstone BN. Reconstruction of the lateral ligament of the ankle. *Injury* 1975;7:63-65.
 192. Sefton GK, George J, Fitton JM, McMullen H. Reconstruction of the anterior talofibular ligament for the treatment of the unstable ankle. *J Bone Joint Surg Br* 1979;61:352-354.
 193. St Pierre R, Allman F Jr, Bassett FH III, Goldner JL, Fleming LL. A review of lateral ankle ligamentous reconstructions. *Foot Ankle* 1982;3:114-123.
 194. Karlsson J, Peterson L. Evaluation of ankle joint function: The use of a scoring scale. *Foot Ankle Int* 1991;1:15-19.
 195. Kaikkonen A, Kannus P, Jarvinen M. A performance test protocol and scoring scale for the evaluation of ankle injuries. *Am J Sports Med* 1994;22:462-469.
 196. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hind-foot, midfoot, hallux, and lesser toes. *Foot Ankle Int* 1994;15:349-353.
 197. de Bie RA, de Vet HC, van den Wildenberg FA, Lenssen T, Knipschild PG. The prognosis of ankle sprains. *Int J Sports Med* 1997;18:285-289.
 198. Parker J, Nester CJ, Long AF, Barrie J. The problem with measuring patient perceptions of outcome with existing outcome measures in foot and ankle surgery. *Foot Ankle Int* 2003;24:56-60.
 199. Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. *Health Technol Assess* 1998;2:1-74.
 200. Rozzi SL, Lephart SM, Sterner R, Kuligowski L. Balance training for persons with functionally unstable ankles. *J Orthop Sports Phys Ther* 1999;29:478-486.
 201. Roos EM, Brandsson S, Karlsson J. Validation of the foot and ankle outcome score for ankle ligament reconstruction. *Foot Ankle Int* 2001;22:788-794.
 202. Hale SA, Hertel J. Reliability and sensitivity of the foot and ankle disability index in subjects with chronic ankle instability. *J Athl Train* 2005;40:35-40.
 203. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). *Foot Ankle Int* 2005;26:968-983.
 204. Eechaute C, Vaes P, Van Aerschoot L, Asman S, Duquet W. The clinimetric qualities of patient-assessed instruments for measuring chronic ankle instability: A systematic review. *BMC Musculoskelet Disord* 2007;8:6.
 205. Dobbs HS. Survivorship of total hip replacements. *J Bone Joint Surg Br* 1980;62:168-173.
 206. Murray DW. Survival analysis. In: Pynsent PB, Fairbank JCT, Carr AJ, eds. *Assessment methodology in orthopaedics*. Oxford: Reed Educational and Professional Publishing, 1997; 19-28.
 207. Fennema P, Lubsen J. Survival analysis in total joint replacement. *J Bone Joint Surg Br* 2010;92:701-706.
 208. Murray DW, Carr AJ, Bulstrode C. Survival analysis of joint replacements. *J Bone Joint Surg Br* 1993;75:697-704.
 209. Rosenberg N, Neumann L, Modi A, Mersich IJ, Wallace AW. Improvements in survival of the uncemented Nottingham total shoulder prosthesis: A prospective comparative study. *BMC Musculoskeletal Disorders* 2007;8:76.
 210. Carr AJ, Morris RW, Murray DW, Pynsent PB. Survival analysis in joint replacement surgery. *J Bone Joint Surg Br* 1993;75:178-182.
 211. Ferdinand RD, Pinder IM. Survival analysis of joint replacements. *J Bone Joint Surg Br* 1997;79:878.
 212. Rothman KJ. Estimation of confidence limits for the cumulative probability of survival in life table analysis. *J Chronic Dis* 1978;31:557-560.
 213. Dawson-Saunders B, Trapp RG. *Basic & clinical biostatistics*. Ed 2. Norwalk, CT: Appleton & Lange, 1994;200-201.
 214. *Mars Climate Orbiter Mishap Investigation Board Phase I Report*. 1999. Available at: ftp://ftp.hq.nasa.gov/pub/pao/reports/1999/MCO_report.pdf. Accessed March 8, 2011.
 215. Kraemer HC. Pitfalls of multisite randomized clinical trials of efficacy and effectiveness. *Schizophr Bull* 2000;26:533-541.
 216. Bhandari M, Tornetta P III, Ellis T, et al. Hierarchy of evidence: Differences in results between non-randomized studies and randomized trials in patients with femoral neck fractures. *Arch Orthop Trauma Surg* 2004;124:10-16.
 217. Dijkman BG, Kooistra BW, Pemberton J, Sprague S, Hanson BP, Bhandari M. Can orthopedic trials change practice? *Acta Orthop* 2010;81:122-125.
 218. Hayes K, Walton JR, Szomor ZR, Murrell GA. Reliability of five methods for assessing shoulder range of motion. *Aust J Physiother* 2001;47:289-294.
 219. van Trijffel E, van de Pol RJ, Oostendorp RA, Lucas C. Inter-rater reliability for measurement of passive physiological movements in lower extremity joints is generally low: A systematic review. *J Physiother* 2010;56:223-235.
 220. van de Pol RJ, van Trijffel E, Lucas C. Inter-rater reliability for measurement of passive physiological range of motion of upper extremity joints is better if instruments are used: A systematic review. *J Physiother* 2010;56:7-17.
 221. Jordan K, Dziedzic K, Jones PW, Ong BN, Dawes PT. The reliability of the three-dimensional FASTRAK measurement system in measuring cervical spine and shoulder range of motion in healthy subjects. *Rheumatology (Oxford)* 2000;39:382-388.
 222. Gerhardt JJ, Rondinelli RD. Goniometric techniques for range-of-motion assessment. *Phys Med Rehabil Clin N Am* 2001;12:507-527.
 223. Terwee CB, Mokkink LB, Steultjens MP, Dekker J. Performance-based methods for measuring the physical function of patients with osteoarthritis of the hip or knee: A systematic review of measurement properties. *Rheumatology (Oxford)* 2006;45:890-902.
 224. Impellizzeri FM, Marcora SM. Test validation in sport phys-

- iology: Lessons learned from clinimetrics. *Int J Sports Physiol Perform* 2009;4:269-277.
225. Robinson ME, Dannecker EA. Critical issues in the use of muscle testing for the determination of sincerity of effort. *Clin J Pain* 2004;20:392-398.
 226. Constant CR. Schulterfunktionsbeurteilung. *Orthopade* 1991;20:289-294.
 227. Widler KS, Glatthorn JF, Bizzini M, et al. Assessment of hip abductor muscle strength. A validity and reliability study. *J Bone Joint Surg Am* 2009;91:2666-2672.
 228. Thomason K, Smith KL. The reliability of measurements taken from computer-stored digitalised x-rays of acute distal radius fractures. *J Hand Surg Eur Vol* 2008;33:369-372.
 229. Bossoussan L, Viton JM, Barotsis N, Delarque A. Evaluation of patients with gait abnormalities in physical and rehabilitation medicine settings. *J Rehabil Med* 2008;40:497-507.
 230. van der Leeden M, Steultjens MP, Terwee CB, et al. A systematic review of instruments measuring foot function, foot pain, and foot-related disability in patients with rheumatoid arthritis. *Arthritis Rheum* 2008;59:1257-1269.
 231. Lane NE, Nevitt MC, Genant HK, Hochberg MC. Reliability of new indices of radiographic osteoarthritis of the hand and hip and lumbar disc degeneration. *J Rheumatol* 1993;20:1911-1918.
 232. Mast NH, Impellizzeri F, Keller S, Leunig M. Reliability and agreement of measures used in radiographic evaluation of the adult hip. *Clin Orthop Relat Res* 2011;469:188-199.
 233. Martin J, Marsh JL, Nepola JV, Dirschl DR, Hurwitz S, DeCoster TA. Radiographic fracture assessments: Which ones can we reliably make? *J Orthop Trauma* 2000;14:379-385.
 234. Karanicolas PJ, Bhandari M, Walter SD, et al. Interobserver reliability of classification systems to rate the quality of femoral neck fracture reduction. *J Orthop Trauma* 2009;23:408-412.
 235. Corrales LA, Morshed S, Bhandari M, Miclau T III. Variability in the assessment of fracture-healing in orthopaedic trauma studies. *J Bone Joint Surg Am* 2008;90:1862-1868.
 236. Blokhuis TJ, de Bruine JH, Brammer JA, et al. The reliability of plain radiography in experimental fracture healing. *Skeletal Radiol* 2001;30:151-156.
 237. Bhandari M, Guyatt G, Tornetta P III, et al. Study to prospectively evaluate reamed intramedullary nails in patients with tibial fractures (S.P.R.I.N.T.): Study rationale and design. *BMC Musculoskelet Disord* 2008;9:91.
 238. Goldhahn S, Kralinger F, Rikli D, Marent M, Goldhahn J. Does osteoporosis increase complication risk in surgical fracture treatment? A protocol combining new endpoints for two prospective multicentre open cohort studies. *BMC Musculoskelet Disord* 2010;11:256.
 239. Andersen T, Christensen FB, Langdahl BL, et al. Fusion mass bone quality after uninstrumented spinal fusion in older patients. *Eur Spine J* 2010;19:2200-2208.
 240. Gallinaro P, Masse A, Leonardi F, Buratti CA, Boggio F, Piana R. Eight- to ten-year results of a variable geometry stem. *Orthopedics* 2007;30:954-958.
 241. Glassman AH, Bohn JD, Tanzer M. New femoral designs: Do they influence stress shielding? *Clin Orthop Relat Res* 2006;453:64-74.
 242. Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: A radiographic analysis of loosening. *Clin Orthop Relat Res* 1979;17-27.
 243. Blake GM. Replacing DXA scanners: Cross-calibration with phantoms may be misleading. *Calcif Tissue Int* 1996;59:1-5.
 244. Pearson J, Rueggsegger P, Dequeker J, et al. European semi-anthropomorphic phantom for the cross-calibration of peripheral bone densitometers: Assessment of precision accuracy and stability. *Bone Miner* 1994;27:109-120.
 245. Jette A. Functional disability and rehabilitation of the aged. *Top Geriatr Rehabil* 1986;1:1-7.
 246. Guyatt GH, Rennie D. *Users' guides to the medical literature: Essentials of evidence-based clinical practice*. Chicago: American Medical Association, 2002.
 247. Bhandari M, Guyatt G, Montori V. User's guide to the orthopaedic literature: How to use a systematic literature review. *J Bone Joint Surg Am* 2002;84:1672-1682.
 248. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med* 1993;118:622-629.
 249. Verbrugge LM, Jette AM. The disablement process. *Soc Sci Med* 1994;38:1-14.
 250. Lezzoni LI, Greenberg MS. Capturing and classifying functional status information in administrative databases. *Health Care Finance Rev* 2003;24:61-76.
 251. Scientific Advisory Committee of the Medical Outcomes Trust. Assessing health status and quality-of-life instruments: Attributes and review criteria. *Qual Life Res* 2002;11:193-205.
 252. Lodhia P, Slobogean GP, Noonan VK, et al. Patient-reported outcome instruments for femoroacetabular impingement and hip labral pathology: A systematic review of the clinimetric evidence. *Arthroscopy* 2011;27:279-286.
 253. Hoang-Kim A, Bhandari M, Beaton D, Kulkarni A, Schemitsch E. Functional status and disability tools in hip fracture RCTs are not pragmatic enough. P265. Presented at the American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans, LA, March 9-13, 2010.
 254. Brena SF, Sanders SH, Motoyama H. American and Japanese chronic low back pain patients: Cross-cultural similarities and differences. *Clin J Pain* 1990;6:118-124.
 255. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: Literature review and proposed guidelines [see comments]. *J Clin Epidemiol* 1993;46:1417-1432.
 256. Beaton D, Bombardier C, Guillemin F, Bosi Ferraz M. *Recommendations for the cross cultural adaptation of health status measures*. Rosemont, IL: American Academy of Orthopaedic Surgeons, 2002.
 257. Goldstein FC, Strasser DC, Woodard JL, et al. Functional outcome of cognitively impaired hip fracture patients on a geriatric rehabilitation unit. *J Am Geriatr Soc* 1997;45:35-42.
 258. Vellinga A. To know or not to be: Development of an instrument to assess decision-making capacity of cognitively impaired elderly patients. Amsterdam: Vrije University, 2006 (PhD thesis).
 259. Hoang-Kim A, Beaton D, Bhandari M, Schemitsch E. HRQOL measures are underutilized in hip fracture patients with severe cognitive impairment. P263. Presented at the American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans, LA, March 9-13, 2010.
 260. Van Spall HG, Toren A, Kiss A, Fowler RA. Eligibility criteria of randomized controlled trials published in high-impact general medical journals: A systematic sampling review. *JAMA* 2007;297:1233-1240.
 261. *ICH harmonised tripartite guideline for statistical principles for clinical trials*. Richmond, England: Brookwood Medical Publications, 1998.
 262. Goldhahn S, Sawaguchi T, Audige L, et al. Complication reporting in orthopaedic trials. A systematic review of randomized controlled trials. *J Bone Joint Surg Am* 2009;91:1847-1853.
 263. Hutchinson D, ed. *The trial investigator's GCP handbook: A practical guide to ICH requirements*. Richmond, England: Brookwood Medical Publications, 1997.
 264. Carlesso LC, MacDermid JC, Santaguida LP. Standardization of adverse event terminology and reporting in orthopaedic

- physical therapy: Application to the cervical spine. *J Orthop Sports Phys Ther* 2010;40:455-463.
265. Corrales LA, Morshed S, Bhandari M, Miclau T III. Variability in the assessment of fracture-healing in orthopaedic trauma studies. *J Bone Joint Surg Am* 2008;90:1862-1868.
266. Davis BJ, Roberts PJ, Moorcroft CI, Brown MF, Thomas PB, Wade RH. Reliability of radiographs in defining union of internally fixed fractures. *Injury* 2004;35:557-561.
267. Morshed S, Corrales L, Genant H, Miclau T III. Outcome assessment in clinical trials of fracture-healing. *J Bone Joint Surg Am* 2008;90:62-67 (Suppl 1).
268. International Organization for Standardization. ISO_14155-1. Clinical investigation of medical devices for human subjects. Part 1: General requirements. Geneva: International Organization for Standardization, 2003;22
269. USFDA. Guidance for clinical trial sponsors. Establishment and operation of clinical trial data monitoring committees. *CFR* 2006:1-34.

AUTHORS

- Laurent Audigé, D.V.M., Ph.D., AO Clinical Investigation and Documentation, AO Foundation, Dübendorf, Switzerland.
- Olufemi R. Ayeni, M.D., F.R.C.S.C., Department of Surgery, McMaster University, Hamilton, Ontario, Canada.
- Mohit Bhandari, M.D., Ph.D., F.R.C.S.C., Division of Orthopaedic Surgery, Department of Surgery, McMaster University, Hamilton, Ontario, Canada.
- Brian W. Boyle, B.A., Hospital for Special Surgery, New York, New York, U.S.A.
- Karen K. Briggs, M.P.H., Steadman Philippon Research Institute, Vail, Colorado, U.S.A.
- Kevin Chan, M.D., Division of Orthopaedic Surgery, Department of Surgery, McMaster University, Hamilton, Ontario, Canada.
- Kira Chaney-Barclay, M.P.H., Steadman Philippon Research Institute, Vail, Colorado, U.S.A.
- Huong T. Do, M.A., Epidemiology & Biostatistics Core, Hospital for Special Surgery, New York, New York, U.S.A.
- Mario Ferretti, M.D., Ph.D., Department of Orthopaedic Surgery and Traumatology, Orthopaedic Sports Medicine Division, Universidade Federal de Sao Paulo, São Paulo, Brazil.
- Freddie H. Fu, M.D., Department of Orthopaedic Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania, U.S.A.
- Jörg Goldhahn, M.D., M.A.S., Institute for Biomechanics, ETH Zurich and Schulthess Clinic, Zurich, Switzerland.
- Sabine Goldhahn, M.D., AO Clinical Investigation and Documentation, AO Foundation, Dübendorf, Switzerland.
- Chisa Hidaka, M.D., Epidemiology & Biostatistics Core, Hospital for Special Surgery, New York, New York, U.S.A.
- Amy Hoang-Kim, M.Sc., Ph.D.(cand), Department of Medical Sciences, University of Toronto, St. Michael's Hospital, Toronto, Ontario, Canada.
- Jón Karlsson, M.D., Ph.D., Department of Orthopaedic Surgery, Sahlgrenska University Hospital/Mölndal, Mölndal, Sweden.
- Aaron J. Krych, M.D., Department of Orthopaedic Surgery, Weill Cornell Medical College, Hospital for Special Surgery, New York, New York, U.S.A.
- Robert F. LaPrade, M.D., Ph.D., Steadman Philippon Research Institute, Vail, Colorado, U.S.A.
- Bruce A. Levy, M.D., Department of Orthopaedic Surgery, Mayo Clinic, Rochester, Minnesota, U.S.A.
- James H. Lubowitz, M.D., Taos Orthopaedic Institute, Taos, New Mexico, U.S.A.
- Stephen Lyman, Ph.D., Epidemiology & Biostatistics Core, Hospital for Special Surgery, New York, New York, U.S.A.
- Yan Ma, Ph.D., Epidemiology & Biostatistics Core, Hospital for Special Surgery, New York, New York, U.S.A.
- Robert G. Marx, M.D., M.Sc., F.R.C.S.C., Hospital for Special Surgery, New York, New York, U.S.A.
- Nicholas Mohtadi, M.D., M.Sc., F.R.C.S.C., University of Calgary Sport Medicine Centre, Calgary, Alberta, Canada.
- Giulio Maria Marcheggiani Muccioli, M.D., Laboratorio di Biomeccanica ed Innovazione Tecnologica, Istituto Ortopedico Rizzoli, University of Bologna, Bologna, Italy.
- Norimasa Nakamura, M.D., Ph.D., Institution for Medical Science in Sports, Osaka Health Science University, Osaka City, Osaka, Japan.
- Joseph Nguyen, M.P.H., Epidemiology & Biostatistics Core, Hospital for Special Surgery, New York, New York, U.S.A.

Gary G. Poehling, M.D., Department of Orthopaedics, Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina, U.S.A.

Lauren E. Roberts, M.Sc., Department of Orthopaedic Surgery, McMaster University, Hamilton, Ontario, Canada.

Nahum Rosenberg, M.D., Department of Orthopaedic Surgery, Rambam Medical Center and Ruth and Bruce Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel.

Kevin P. Shea, M.D., Department of Orthopaedic Surgery, University of Connecticut Health Center, Farmington, Connecticut, U.S.A.

Zahra N. Sohani, M.Sc., Department of Orthopaedics, McMaster University, Hamilton, Ontario, Canada.

Michael Soudry, M.D., Department of Orthopaedic Surgery, Rambam Medical Center and Ruth and Bruce Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel.

Sophocles Voineskos, M.D., Department of Surgery, McMaster University, Hamilton, Ontario, Canada.

Stefano Zaffagnini, M.D., Laboratorio di Biomeccanica ed Innovazione Tecnologica, Istituto Ortopedico Rizzoli, University of Bologna, Bologna, Italy.

