

The First International Society for Fracture Repair and International Osteoporosis Foundation “Osteoporosis: from Evidence to Action” Combined Symposium & Working Groups

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On December 4–5, 2009, in Monte Carlo, Monaco, the International Society for Fracture Repair (ISFR) held its first 2-day combined event, “Osteoporosis: from Evidence to Action”, endorsed by the International Osteoporosis Foundation (IOF). The initiative united research and educational fronts, comprising working groups followed by symposia. The Osteoporotic Fracture Campaign (OFC) was launched by Professor Antonio Moroni (Bologna University, Bologna, Italy) in 2002 at the “Fracture Treatment in Elderly and Osteoporotic Patients” symposium (Rizzoli Orthopaedic Institute, Bologna, Italy, May 16–18), and was subsequently officially adopted by the umbrella organization of the ISFR. The OFC has evolved rapidly over the 7 years since its inception, beginning with workshops and brainstorming think-tanks gathering together experts to discuss “burning issues” in the field, and progressing to working groups seeking to improve outcomes [1,2]. Osteoporosis: from Evidence to Action was the product of synthesis of research stemming from previously held workshops, with international faculty presenting on >50 topics covering all aspects of osteoporosis, from patient management strategies to surgical treatments and outcome assessment. The success of the innovative working groups pivoted around the skills and multispecialty expertise evident in the osteoporosis network, ranging from geriatricians to engineers, working in a collaborative fashion with industry partners on the fundamentals of science and methodology of trial designs. The primary goals of the event were as follows:

- To draw together OFC members in order to elucidate how they have advanced in their various spheres since 2002, and to demonstrate how their association with the OFC has helped in this process.

- To paint a vision of the next 5 years, identifying key areas in which we would like to influence global health concerns, such as surgical issues and patient-oriented assessment.
- To advance the current understanding of functional outcomes from the patient perspective using both quantitative and qualitative research.

Evidence-based orthopaedics

Before and after the working groups convened, lectures on evidence-based orthopaedics and trial design methodology were presented. Faced with the multitude of new diagnostic and therapeutic interventions, busy surgeons need clear guidance on the best approaches to use for their patients. This need has led to a more or less uncontrolled outpouring of practice guidelines. Among these guidelines, there is much conflicting guidance, and the literature displays extensive variation in approaches to formulating recommendations. Therefore, there is an international move towards standardizing guideline methodology so that recommendations are conceived through a systematic and transparent process and so that the link between the evidence and the strength of recommendations is explicitly documented.

Anders Jönsson (Osteosynthesis and Trauma Care Foundation, Nice, France) provided a brief overview of the GRADE (Grades of Recommendation Assessment, Development and Evaluation) working group. This group has formulated a system for assessing the strength of evidence and the challenges guideline developers face in formulating graded treatment recommendations. Bruce Mitlak (Lilly Corp, Indianapolis, IN, USA) explored important design techniques for avoiding bias in clinical trials, such as blinding and randomization. Amy Hoang-Kim (University of Toronto, Toronto, ON, Canada) argued that the current quality of reporting in the orthopaedic surgical literature

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is poor [2,3]. Several checklists have been developed for various study designs to guide authors and researchers conducting systematic reviews and meta-analyses of the literature in order to evaluate the quality of the evidence [4,5].

In terms of outcome measurement, Dorcas Beaton (University of Toronto) argued that the best place to start when deciding on an outcome measure is to be specific about your target [6]. She recommended asking a series of specific questions. What do you want to be able to measure (be specific – what would “function” look like?). In whom do you want to measure it (patient group and potential needs for that particular group). How do you want to use it – to describe people at one point in time as in describing burden of disease, to predict a future state such as revision or return to work, or to evaluate change over time such as in a clinical trial? Once these matters are decided, it is critical to look at the available tools and focus on those that can provide evidence that will address your measurement need and that have adequate reliability and validity. Dr Beaton stressed that it is important not to become attracted to a popular index or outcome without first defining your measurement need. It may be that a popular tool would miss your target. It is better to define the needs of the study design and then research the literature to identify useful measures. Clinical experience and any published critique of existing measures are invaluable, and there are guidelines that can help decipher how to appraise more specific measurement properties [7].

Hip fracture outcomes working group

Physical function, health status, and perceived quality of life (QoL) are important indicators of the success of medical and surgical interventions. Instruments (questionnaires and scales) assessing these elements must be derived from the patient's perspective in order for the results to be relevant. Unfortunately, not all QoL instruments have been systematically developed with regard to quality or the ability to reflect the patient's perspective. The objective of the hip fracture outcomes working group, chaired by Dr Hoang-Kim and Jason Busse (McMaster University, Hamilton, ON, Canada), was to gain a rich understanding of patient, proxy responder, and expert opinions on patient care following hip fracture using a mixed methods approach. The in-depth qualitative analysis will be used to evaluate the current evidence on outcome tools used in hip fracture clinical trials in order to determine which are valid and reliable for the measurement of patient responsiveness and changes in health status or health-related QoL.

The group of 20 experts consisted of four surgeons, seven clinical researchers, one geriatrician, two osteoporosis falls specialist nurses, two internists, two outcome scientists, and one cardiologist, as well as industry representatives. Nine participants came from the US and Canada, nine from Europe, and two from Asia. Data on age, gender, position, years of research, and clinical

experience in dealing with hip fracture patients were collected. The group felt that proxy responders can and often do play a role in decisions regarding treatment and patient care. Measures of self-assessment such as the Short Form-36 (SF-36) were felt to be useful in healthy individuals, but elderly patients with more than one comorbidity were thought likely to find the SF-36 burdensome and many questions either redundant or irrelevant. Establishing baseline characteristics such as mental status and pre-fracture ambulation was also argued to be important for stratifying patients in order to collect relevant data following treatment of a hip fracture. In the second half of the session, the working group filled out questionnaires for quantitative analysis on topics such as the impact of severity versus frequency of comorbidities affecting the target population, and on useful items tailored to hip fracture management and rehabilitation.

Hip fracture surgical treatment working group

In preparation for the hip fracture surgical treatment working group, individuals were asked to provide the chairs Professor Moroni and Burkhard Wippermann (Klinikum Hildesheim, Hildesheim, Germany) and the facilitator Gary di Giovanni (Synthes, West Chester, PA, USA) with what they considered the “top ten” burning questions concerning femoral neck treatment. The participants (eight orthopaedic surgeons, six industry representatives, and one research scientist) were asked to consider some of the following thought-provoking questions prior to the event. Do we really know our patients' feelings? Do patients tolerate more to avoid further surgery? What are the biggest patient complaints? Are there other alternative treatments we have not considered? What can we do better? How are we dealing with end-of-life issues and how do they relate to decisions surgeons make in treating these patients?

At the meeting, 12 questions were posed: six relating to femoral neck fractures and six relating to trochanteric and subtrochanteric fractures. These questions were discussed in a round robin fashion until consensus was reached. While there were many specific issues discussed relating to techniques of fracture fixation and so forth, general consensus with regard to the management of hip fractures was reached in several important areas, including the following:

- Fractures should be treated surgically within 24–48 h of admission to hospital if the patient is medically fit for surgery.
- Patients with three or more significant comorbidities that could be improved by focused medical management should be optimized for surgery by specific treatment for those comorbidities. Comorbidities that could not be improved by focused medical management should not impede the patient being taken to the operating room in a timely fashion.

- Ongoing medical management of hip fracture patients is probably better supervised by a physician with a specific interest in these patients, such as a geriatrician, a physiatrist, or trained hospitalist.
- The concept of orthogeriatric centers is popular in some countries but does not exist in other health systems. The advantages of such centers should be explored further.

Distal radius fracture working group

The distal radius fracture working group applied the nominal methodology to establish a minimal core set of measures for wrist fracture trials. The moderators Jörg Goldhahn (Schulthess Clinic, Zurich, Switzerland) and Amy Ladd (Stanford University, Palo Alto, CA, USA) and the facilitator Francesco Pegreffì (Cervesi Hospital, Cattolica, Italy) guided the group, which comprised three orthopaedic surgeons, one academic research scientist, one academic basic scientist, two science coordinators, one businessman from a medical device company, and one endocrinologist from the industry. Seven participants were from Europe and three were from the US or Canada. The participants were asked to present five measures that a good trial should have and then the session involved prioritizing the measures. Structured presentations included “Evidence vs Observation” by Dr Ladd, “Conceptual Frameworks” by Dr Beaton, “An Example of a Good Study: Rheumatoid Arthritis” by Dr Goldhahn, and “A Review of Radius Fracture Trials” by Dr Pegreffì.

Subsequently, the group tackled two questions: what is an ideal trial and what does it take? The participants included Sylvie Pennaforte (Institut de Recherches Internationales Servier, Courbevoie, France), who briefed the group on the setting up of a fracture model study currently taking place, with measures of patient self-assessment as well as radiological analysis. Nadine Hollevoet (Ghent University Hospital, Ghent, Belgium) showcased a study using mixed treatment methods demonstrating a correlation between increased ulnar variance and outcome in patients aged <65 years [8]. J Edward Puzas (University of Rochester, New York, NY, USA) outlined current trials and discussed the limitations of the measures selected to assess fracture healing in osteoporotic bone.

Vertebral compression fracture working group

The topic of study design methodology was discussed in the vertebral compression fracture working group of 18 participants, chaired by David Marsh (Institute of Orthopaedics & Musculoskeletal Science, Stanmore, UK) and Henry Ahn (University of Toronto). In particular, the controversy surrounding the recently published studies by Buchbinder et al. and Kallmes et al. was summarized and evaluated [9,10]. Buchbinder et al.’s study was a multicenter, randomized, double-blinded,

placebo-controlled trial in which participants with one or two painful osteoporotic vertebral fractures that were of <12 months duration and unhealed were allocated to undergo either vertebroplasty or a sham procedure [9]. The group discussed the validity of allocating patients to a sham procedure and whether it supported the authors’ concluding remarks that there was no beneficial effect of vertebroplasty compared with a sham procedure in patients with painful osteoporotic vertebral fractures at 1 week or 1, 3, or 6 months after treatment.

Hip, wrist, and spine: do we have an answer?

Under the title, “Hip, wrist, and spine: do we have an answer?”, 11 sessions ran concurrently including satellite symposia on the current evidence on complication reporting in trials, the achievements of the AO Foundation Clinical Priority Program, and femoral neck held by the Active Implants Corporation (Memphis, TN, USA) in conjunction with Joint Replacement Instrumentation Ltd. (London, UK) and vertebral compression fractures held by Medtronic (Minneapolis, MN, USA). Finally, three free paper sessions included presentations on the biomechanics of the osteoporotic bone, clinical outcomes, and prevention strategies.

He argued that a new definition of osteoporosis is needed and that future directions should seek to review current diagnostic and therapeutic approaches

Gerold Holzer (Medical University of Vienna, Vienna, Austria) stated that his group found that in terms of the different functions of the two bone types, cortical bone is primarily responsible for load-bearing and transmitting forces, whereas trabecular bone seems to build a framework supplying large surfaces to rapidly provide minerals and different cell types and their progenitors [11]. He argued that a new definition of osteoporosis is needed and that future directions should seek to review current diagnostic and therapeutic approaches.

In the morning session on osteoporosis strategies and patient management, Suthorn Bavonratavech (Bumrungrad Hospital, Bangkok, Thailand) showed evidence confirming that hip fracture will be a major health challenge in Asia in the coming decades [12]. However, in the West, the incidence of hip fracture is showing some signs of stabilization, and in Hong Kong the incidence of hip fracture has not increased between 2001 and 2006 [13]. The reasons for the secular decline in the incidence of hip fractures in these areas are unknown but could be related to socioeconomic changes, such as increases in body mass indexes, or the fact that more patients with osteoporosis

are being diagnosed and treated. Dual-energy X-ray technology, considered the gold standard for measurement of bone mineral density, is relatively expensive and not widely available or easily accessible in most developing Asian countries. Some positive trends show that governments are beginning to recognize osteoporosis as a major health problem. Successful education and awareness initiatives are being organized by non-profit organizations with industry support.

In terms of vertebral fractures, spontaneous reduction has not been taken into account in recently published series of balloon kyphoplasty but must be considered when performing vertebral augmentation and when reporting vertebral height restoration. Gregor Voggenreiter (Klinik Eichstätt, Eichstätt, Germany) presented data on the treatment of 30 patients with 39 osteoporotic vertebral compression fractures [14]. The Cobb angle, measured postoperatively using standing radiographs, demonstrated a 3.1° significant loss of reduction compared with intraoperative measurements after cement application. Cement leaks occurred in nine vertebral fractures. All patients reported immediate relief of pain with a significantly improved visual analogue scale score of 2.3±0.9 compared with 8.7±1.4 preoperatively. The investigators concluded that the restoration of height was attributed to dynamic fracture mobility as well as to the expansion of the inserted balloon tamp.

In the satellite symposium on femoral neck fractures, Raghu Raman (Hull Royal Infirmary, Hull, UK) reported clinical outcomes of hip hemiarthroplasties using hydroxyapatite (HA)-coated femoral components and evaluated the cost implications of this procedure [15]. The clinical outcomes of 239 patients recorded a mean Harris Hip Score and Oxford Hip Score of 73 (range 49–86) and 28.4 (range 18–40), respectively. Dislocation occurred in 11 patients. Three stem revisions were performed for aseptic loosening, infected periprosthetic fractures, and recurrent dislocation. The cost–benefit ratio was 0.61 for the HA prosthesis compared with the Austin Moore implant.

In the free paper session, James Waddell (University of Toronto) presented the Ontario provincial integrated model to improve care for patients following hip fracture [16]. The primary objectives were that all surgical procedures should be performed within 48 h of patient admission, that the surgical treatment of hip fractures must permit unrestricted weight-bearing, and that a structured acute care postoperative course should be followed from admission to progressive rehabilitation. The number of patients with hip fractures returned to their pre-injury residence post-fracture increased significantly from approximately 35% to 70% over a 3-month period following surgery.

Conclusion

While this brief meeting report only highlights a small portion of the data presented in the sessions and working groups, many of the topics will be explored in more depth in future newsletters

of the society and will be highlighted in sessions of the upcoming biennial ISFR conference to be held in London, UK, this year on September 26–29, with local organizers Dr Marsh and Allen Goodship (Insitute of Orthopaedics & Musculoskeletal Science), and the help of the program committee chair Takashi Matsushita (Teikyo University, Tokyo, Japan) and the committee members David Hak (Denver Health, Denver, CO, USA), Nick Fazzalari (Institute of Medical and Veterinary Science, Adelaide, SA, Australia), and Dr Hoang-Kim. A call for abstracts with a submission deadline of March 31st can be found on the ISFR website www.fractures.com.

You can submit comments or questions on this article, and find links to suggested reading and similar educational programs at www.advancesinorthopaedics.com

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