■ ANNOTATION

# The Canadian Orthopaedic Trauma Society

R. Buckley,
R. Leighton,
K. Trask

*From the University of Calgary, Calgary, Alberta, Canada*

**The Canadian Orthopaedic Trauma Society was started in an endeavour to answer the difficult problem of obtaining enough patients to perform top-quality research into fractures. By maintaining a high standard, including randomised study design, inclusivity, open discussion among surgeons and excellent long-term follow-up, this group has become a leader in the orthopaedic research community. This annotation describes the short history, important components and spirit necessary to build a research community or team which will function well despite the difficult research environment facing individual surgeons.**

All surgeons wish to read about relevant and possibly 'practice-changing' clinical research in their favourite journals. In order to accomplish that task, the authors of clinical research must produce work of quality that demonstrates strength of protocol, randomised design, a large numbers of patients and excellent long-term follow-up. Individual surgeons and clinics can struggle to thrive in the research environment when faced with these challenges, but research teams and clinical groups with common aims and goals can help accomplish these tasks. Surgeons have been late to arrive onto the clinical research scene when it comes to developing teams to perform high-quality clinical research studies.

## The history of the Canadian Orthopaedic Trauma Society

The Canadian Orthopaedic Trauma Society (COTS) began in 1990, when three friends met to discuss a clinical problem. Although nothing in particular was solved that night, discussions continued which eventually led to the initiation of a two-year research project. It was a modest study which looked at whether CT scans were of assistance in the classification of fractures of the proximal humerus. It found no specific benefit related to treatment or outcome, so it was never reported, but it did open channels of communication between trauma centres in Canada.

In 1992, more surgeons were graduating with training in evidence-based medicine, and randomised controlled trials were relatively easy to devise and fund, whereas previously, surgical trials with prospective data collection were almost unknown. That year the first meeting for a study on calcaneal fractures (operative *versus* non-operative treatment of displaced intra-articular fractures) was attended by those who formed the basis of the COTS group. In order to collect enough study centres, an invitation to participate was extended to ten different centres across Canada and four in the United States. Within a year it was evident that a solid group of four centres – Calgary; Halifax; London, Ontario; and New Westminster, British Columbia – could accrue enough patients and achieve good long-term follow-up. In 1993, local funding from Calgary was increased by funding from the Orthopaedic Trauma Association (OTA). The study required clinical follow-up for seven years between 1992 and 1999.[1] We decided to invite colleagues from other Canadian academic trauma centres to join us to discuss clinical issues and debate the virtues and practicalities of creating a prospective randomised trial group.[2]

The first step was to approach the Canadian Orthopaedic Association and decide whether we should do this as part of their organisation or form a new association in conjunction with the OTA. Legally and financially, it seemed more sensible for COTS to stay with the Canadian Orthopaedic Association and to hold our research fund within the Canadian Orthopaedic Foundation, as it was already in existence; its mandate supported our objectives, and it was prepared for the funding of research projects. It also allowed us to pursue research funding from various sources, such as the OTA, the Canadian Orthopaedic Association, local and national

■ R. Buckley, MD, FRCS(C), Professor and Head of Orthopaedic Trauma
University of Calgary, Foothills Medical Center, AC 144A, 1403-29 Street NW, Calgary, Alberta, Canada T2N 2T9.

■ R. Leighton, MD, FRCS(C), Professor
■ K. Trask, BEng, MSc, Research Associate
QEII Health Science Center, Halifax Infirmary, Room 810, 796 Summer Street, Halifax, Nova Scotia, Canada B3H 3A7.

Correspondence should be sent to Dr R. Buckley; e-mail: buckclin@ucalgary.ca


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initiatives and events, and industry. We did this energetically and have been successful in obtaining peer-reviewed funding for most of our multi-centred studies to date.

The next step was to establish intermediate and long-term studies on topics relevant to trauma in Canada. After the Displaced Intra-articular Calcaneal Fracture Study, we initiated a study on reamed *versus* unreamed intramedullary femoral nailing.[3] With one study complete and another underway, we adopted a more inclusive set of bylaws that mirrored those of the OTA. This allowed us to discuss the funding mechanisms that would need to be in place to complete the studies. We continued to meet twice yearly at our own Canadian Orthopaedic Association meeting and at the OTA meeting and set up a system of research funding that would allow us to begin a series of prospective randomised multi-centre trials.

After considerable effort, each of our principal investigators has been successful in obtaining local, regional, Canadian Orthopaedic Association, AO North America and/or OTA grants.

One of the main aims of COTS was to have every surgeon in the group involved with each protocol. It also allowed centres who were not able to participate for various reasons to give feedback on proposals. This commitment proved to be an excellent motivation to engage everyone in each study and for each institution to become involved in every study. Despite the requirement for every project to be led by a single surgeon, each protocol was discussed, sometimes for years, and reviewed by all of the COTS group, so much so that some of the group felt our acronym (COTS) should stand for 'Compromising Orthopaedic Trauma Surgeons'! There is no question that compromise in individual protocols was necessary to accomplish the goals of the society. Soon other studies followed, including prospective randomised and multi-centre trials comparing the rate of acute respiratory distress syndrome in patients undergoing reamed and unreamed femoral nailing;[4] open reduction and internal fixation compared with circular external fixation for bi-condylar tibial plateau fractures;[5] non-operative treatment compared with plate fixation of displaced midshaft clavicle fractures;[6,7] ORIF *versus* total elbow arthroplasty for displaced humeral fractures;[8] and nail *versus* plate fixation for humeral shaft fractures.[9] Other studies about ankle fractures,[10] distal femoral fractures[11] and others are in the final stages of preparation.

The inspiration of COTS has helped to establish a larger international group led by Dr Mohit Bhandari, who initiated and published the SPRINT Trial.[12] This was a randomised trial of reamed *versus* unreamed tibial intramedullary fixation locking at rates of re-operation. Other international efforts, led by the McMaster Clinical Trials Group, are studying femoral neck fractures in the FAITH[13] and HEALTH trials,[14] PRAISE[15] (Intimate Partner Violence), TRUST[16] (tibial fractures with ultrasound treatment), and FLOW[17] (fluid lavage of open wounds). Other randomised controlled trials include a study of bone graft substitutes: a prospective multi-centre trial of autogenous bone graft *versus* bone substitute,[18] outcome trials on distal radial fractures, acromioclavicular injuries, isolated ulnar shaft fractures, and extramedullary *versus* intramedullary fixation for proximal femoral fractures.

## The role of research coordinators

When the first protocols were established, COTS investigators recognised the importance of having research coordinators participate in meetings and actively being a part of the team. Research coordinators are involved in one or more aspects of the studies, including but not limited to data collection, analysis and monitoring; recruitment and enrolment of patients; the protection of patients and their rights in relation to institutional review boards; the development of informed consent; reporting of adverse events; the development of case report forms; grant and budget development; report preparation; education of other health-care professionals, patients or families about research studies and protocol requirements; and dissemination of the results of the study. Research coordinators are recognised as associate members of COTS. As contributing members of the organisation, they remain enthusiastic and committed to completing trials. The importance of including research coordinators as team members within COTS cannot be understated. Face to face meetings, commonality of purpose, assigning individuals to locations and understanding local and national idiosyncrasies has allowed the position of the research coordinator to be of the utmost importance. Communication between the coordinators has become so important that their travel to the two large meetings that take place every year (Canadian Orthopaedic Association in June and OTA in October) is supported. The issues they have addressed include how to improve enrolment; the design of data forms; data acquisition and control; website information and updates. The meetings also provide a forum for study.

Multi-centred studies need to be familiar to all the participants, so that Ethics Board approvals, consent forms, follow-up visit times, data acquisition forms, statistical power and web-based projects become automatic. The coordinator's ability to solve day-to-day issues quickly and among themselves engenders a seamless environment in which to run these studies. The creation of a website[19] (COTS) for the group with both public information and member-only data areas has enabled us to communicate our work to the public and share the details of studies with all our members. Ongoing studies and a list of COTS members can be found on this site.

## Development of a COTS protocol

The development of a protocol for each study is a collaborative effort. Protocols are presented to the larger group at any stage in their development, as some begin as an idea or question, whereas others are started with an informal survey of COTS members. Others come fully prepared as a

pilot study or completed protocol. Each study is led by a single surgeon, who receives feedback from the group. Regardless of the stage of development of the protocol or idea, the process of reading a final protocol that everyone can agree upon can be lengthy.

Often the first step is to pose a question that colleagues feel is worth answering. Is there controversy or debate about treatment options? Are the surgeons interested enough to participate? Is the study population in our centres large enough to complete such a study? Do we need a prospective randomised trial to answer the question?

If the answer is yes, then the study's lead investigator begins the process of developing a protocol and estimates the length of time needed to complete the trial. All COTS members and associate members are invited to give feedback on the proposal and items of budget, standardisation of patients, follow-up scheduling, patient selection, and primary and secondary outcomes.

Often a lengthy but stimulating process with discussion among members is what leads to a study with which everyone is comfortable. Members are able to debate each point to determine the best approach. Even if the resulting protocol is not what all members would have preferred for their own sites, they understand and have agreed to the accepted protocol and will usually continue with it until the end of the trial. The lead investigator will prepare the protocol in a standard format and, with the assistance of the local research coordinator, will develop the accompanying documentation, informed consent and case report forms. The applications for funding from industry and other sources then begins.

## Keys to success

There are several reasons for COTS' success.

1. The Canadian healthcare system is a completely public system with no, or little option, for private medicine. The main drawback to this is the real and perceived potential for a long wait to access care. This is true for elective consultations, but fracture care is consistent, relatively well-funded and with good access coast to coast. This has enabled us to bring together many surgeons and coordinators to create consensus-based protocols that can be completed even in the face of market pressures.

2. The academic centres in Canada have all been able to obtain excellent coordinators to enable them to design and complete the clinical studies. They have come together as a group to create a channel of communication through which information can be shared. This has allowed COTS to concentrate on the studies and complete most within a reasonable amount of time.

3. We have been fortunate to have extremely cooperative colleagues at all the centres who have been able to direct the patients toward individual studies. Many have participated actively as co-investigators. This has allowed us to recruit as many patients as possible. We cannot overemphasise the need to communicate the protocol designs to colleagues and to ask for their input. If they accept the importance of the question and the need for an answer, the chance of their participation increases exponentially.

4. The patient population across the country is relatively stable. This allows for long-term follow-up in most studies. Trauma centres are widely separated, which ensures that patients have little alternative but to return to their own centre for follow-up care, and they are not easily lost, with long-term follow-up (two years) often reaching 85%.

5. The support of the Canadian Orthopaedic Association has allowed the COTS group to use the annual meeting as a place to meet and present their academic work. This has proved to be a positive situation for both the organisation and the COTS group. The guidance and support from the Canadian Orthopaedic Association in the early years has allowed us to take complete control of academic trauma education in the country. The individual members of the group still participate in other educational courses and remain core members of many other educational groups.

6. The Canadian Orthopaedic Foundation offered to administer our grants and support from industry over the years. Without this it would have been difficult to maintain our biannual meetings. These face-to-face biannual meetings held in conjunction with the Canadian Orthopaedic Association in June and OTA in October remain the stabilising structure of the organisation. We have been able to offer a COTS young investigator research grant of $10 000 to our younger members as seed money to get their projects started.

7. Our partners in industry have also supported us with unrestricted educational grants. This was particularly helpful in our initial years. However, peer-reviewed funding at local, national and international levels has sustained the group. The initiative of all members of COTS has allowed us to keep our momentum going as we move from older to younger orthopaedic trauma surgeons. All members treat fractures on a day-to-day basis, and everyone recruits and follow-up patients.

8. Finally, one of the issues that threatened to be divisive in the group was solved at an early stage by group discussion. The concern was the issue of authorship and the ability to include these large studies in one's curriculum vitae. The ruling on the number of authors that one can include was thought reasonable in these large studies, as there are always many authors who contribute to the protocol, the recruitment, evaluation, follow-up and final manuscript. We were able to solve this dilemma by submitting the papers for publication under the name of the COTS group, and the journals allowed us to name all significant authors and to add acknowledgements. The named authors could then include these papers when they were published on their CVs. This took a year of hard work, but it was essential that all those who put a great deal of work into the study should have credit for their contribution. Publishing as "COTS" has proven to be acceptable to many journals and has become the standard.

Research has grown to be big business, and the days of individual surgical trials for simple problems are probably over. Historically, surgeons have not been involved with teams or, if they were, they were the leader. The approach taken by COTS has been one of placing local leaders in positions of responsibility and trying to ask an important clinical question. The key to all of this has been the development of teams working with coordinators and colleagues to provide an environment for top-quality research into all aspects of trauma.

## Supplementary material

Complete lists of the Canadian Orthopaedic Trauma Society surgeons and coordinators are available with the electronic version of this article on our website at www.jbjs.org.uk

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