The Canadian Orthopedic Trauma Society (COTS)
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Chapter 2

The Canadian Orthopaedic Trauma Society: A model for success in Orthopaedic research

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Abstract

The Canadian Orthopaedic Trauma Society has been a promoter of multi-centre research studies for more than a decade. From its modest beginnings, the group has grown to over 50 members who meet twice a year. The following article is a review of how the group developed to become a leader in level-one Orthopaedic research. The success of the group stems from the respect and collaboration amongst the surgeons and research coordinators. This is most evident in the design of new studies. Surgeons and coordinators both have input into new protocols and this has been essential in designing protocols that are followed to completion. The group has completed a number of prospective randomised trials over the years and has received numerous awards. These awards are highlighted along with recent publications by the group. These accomplishments have led to recognition as a leader in successful randomised orthopaedic trials and have helped us to obtain funding for our ongoing and future research.

Introduction

The Canadian Orthopaedic Trauma Society (COTS) is a group of Canadian Orthopaedic Association members who have banded together to perform randomised prospective multi-centre trauma research studies. Over the past decade, COTS research has received some of the highest praise and presentation acceptance associated with orthopaedic outcomes research.

The Development of COTS

The COTS began in 1990 in true orthopaedic fashion: three friends meeting over a beer to discuss a clinical problem. The orthopaedic surgeons were Robert McCormack (New Westminster, BC), David Petrie (Halifax, NS) and Ross Leighton (Halifax, NS). While nothing was solved that night, cross-country discussions continued and eventually led to the initiation of a 2-year study regarding “CT
classification of Proximal Humeral fractures” involving both sites. It was a modest study looking at the benefits of CT scans in assisting in the classification of proximal humeral fractures. The study did not find any benefit related to treatment or outcome so no publication or presentation occurred; however, it did initiate communication between centres.

The original meetings for a study on calcaneal fractures (Operative versus Nonoperative Treatment of Displaced Intra-Articular Calcaneal Fractures) really formed the basis of the COTS group. Richard Buckley championed the study and the meetings of this randomised trial. That first meeting included Robert Meek, David Petrie, Robert McCormack, Richard Buckley (Principal Investigator), and Ross Leighton. We laid the groundwork for the calcaneal study with all of our names on the study (except Robert Meek at his request). We met in 1992 and Dr. Buckley obtained partial funding in 1992 from the Workers Compensation Board of Alberta. Further peer-reviewed funding (our first as a group) was received from the Orthopaedic Trauma Association (OTA) in 1993. The study had follow-up for 7 years from 1992 to 1999. We decided to invite our colleagues from other Canadian academic centres to join us in discussing clinical issues and debate the virtues and practicalities of creating a prospective randomised trial group.

The first step in the development of the group was to approach the Canadian Orthopaedic Association (COA) and decide whether we should do this as part of their organisation or should form a new association in conjunction with the Orthopaedic Trauma Association (OTA). Legally and from a funding perspective it appeared more direct and better for COTS to stay with the COA and use the Canadian Orthopaedic Foundation as our research fund depot. It was already in place, its mandate supported our objectives, and it was prepared for the funding of research projects. This allowed us to pursue grants and research funding from various sources: peer reviewed, OTA, COA, local Hip Hip Hooray events, and industry funding. We did this aggressively and have been successful in obtaining peer-reviewed funding on most of our multi-centred studies to date.

The next step was to have some long-term and intermediate-term studies on topics important to orthopaedic trauma in order to attract surgeons and centres to our group. The second COTS study originated from another surgeon in Calgary, Alberta. Following the lead from Dr. Buckley, James Powell came forward with a reamed versus unreamed intramedullary femoral nailing study in isolated femoral shaft fractures. A second arm of this study was to recruit multitrauma patients with femoral shaft fractures. At this time reamed versus unreamed nailing of femoral shaft fractures was a huge clinical debate.

With one study complete and two underway, we adopted a more inclusive set of bylaws that mirrored the bylaws of the Orthopaedic Trauma Association. This allowed us to discuss the funding mechanisms that would need to be in place to complete these two studies. We then continued to meet and set up a method of research funding that would allow us to begin a series of prospective randomised multi-centre trials. Through perseverance and hard work, each of our principal investigators has been successful in attaining local, regional, Canadian Orthopaedic Association, AO North America, and/or Orthopaedic Trauma Association grants. This is a tribute to the excellent work performed by the group and also the tenacity of the individual clinical researchers in their bid for funding from all sources.
One of the main premises of the Canadian Orthopaedic Trauma Society was to have every surgeon in the group engaged and involved with each protocol. This would provide the best possible input to each and every protocol and provide better transparency for those involved in the study. It also allows centres which are not able to participate for various reasons to give feedback on proposals. This “buy in” proved to be an excellent motivator (a) to engage everyone in each suggested study and (b) to provide motivation for each institution to become involved in every study possible. Everyone (both surgeons and coordinators) involved in COTS could profess the hard work, the background of the basic science and clinical work that inspired the study, and the ingenuity that went into each protocol. Therefore, despite the requirement that every project had a surgeon champion, each protocol had significant discussions (sometimes for years) and huge input from all in the COTS group. So much so that some in the group felt our acronym (COTS) should stand for “Compromising Orthopaedic Trauma Surgeons”!

There is no question that compromises in individual protocols are necessary to accomplish the society’s goals.

Fortunately each surgeon and research coordinator respected each other and the group as a whole. Our ability to ultimately agree on a protocol for “all of our centres” and stick to that protocol for the sometimes significant length of each study (over 5 years for the calcaneal study) has really been the cornerstone of the success of the COTS group. This “stick to the protocol” attitude is particularly hard when “technological advances” seem to be going by. However, it has been extremely rare that these “advances” have made a significant difference in a short period of time. On the other hand our randomised studies have served to alter our practice and the practice of orthopaedic surgeons throughout North America and Europe over the last 10 years.

The Role of Research Coordinators

Early on the COTS investigators recognised the importance of having Research Coordinators participate in meetings. Research Coordinators are involved in one or more aspects of research, including, but not limited to data collection, analysis, and monitoring; recruitment and enrolment of study subjects; protection of subjects and their rights in conjunction with institutional review boards (ethics review boards); development of informed consents; reporting of adverse events; 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 study results.

Research Coordinators are recognised as associate members of COTS. As contributing members of the organisation, the coordinators remain enthusiastic and committed to completing trials. The research coordinators connectivity has become so important to COTS that we now support travel for one coordinator from each centre to meet with us at each of the two formal meetings each year. In addition, in 2006 they initiated their own Trauma Coordinator meetings to discuss their issues. The COTS Coordinators Group (CCG) meets twice a year (COA in June and OTA in October). Their issues tend
to be the ones that need to be solved to maintain ongoing studies. Issues include: how to improve enrolment, design of data forms, data acquisition and control, web site information and updates. The meetings also provide a forum for trauma and study-specific training for coordinators involved in COTS studies. Areas of education include: overview of anatomy/physiology for area of study, description and demonstrations of study devices, and training in study measurements and/or administration of questionnaires.

The coordinator meetings proved so successful that four COTS coordinators joined to form the executive of a national group for orthopaedic research coordinators. The idea had been discussed for several years by coordinators in various orthopaedic specialty areas, but the closeness and camaraderie of the CCG was the catalyst that made it a reality. Through the hard work of Kelly Trask (Halifax, NS), President; Mauri Zomar (New Westminster, BC), Vice-President; Lynn Vicente (Toronto, Ont.), Secretary; and Gwen Dobbin (Halifax, NS), Treasurer, in June 2007 the Orthopaedic Clinical Coordinators Group (OCCG) held their first annual meeting in Halifax, NS at the COA annual meeting. The meeting brought together coordinators from all orthopaedic specialties including trauma, arthroplasty, sports medicine, and paediatrics. Similar to COTS, the OCCG seeks funding from outside sources and uses the Canadian Orthopaedic Foundation as its funding depot. The requirements of multicentred studies necessitate a familiarity, surgeon-to-surgeon and coordinator-to-coordinator, so early contact can be achieved regarding initial REB approvals, consent forms, follow-up visit times, forms, data acquisition, statistical power and web-based projects. The coordinators’ ability to solve day to day issues quickly and amongst themselves truly makes a seamless environment in which to run these multicentred studies. The creation of a web site (http://cots.medicine.dal.ca) for the group with both public information and member-only data areas has been useful to communicate our work to the public and share study files amongst members. Ongoing research studies and a list of COTS members can be found on the site.

The investigator meetings (two per year) are spent on protocol adjustment and new protocols. We have been able to achieve funding via COTS to allow each centre to send a surgeon and a coordinator to each meeting. This was an important step in team building, protocol initiating, and sustainability of the long-term protocols (i.e. calcaneal study >5 years). The meetings for these long-term projects are akin to a pep rally where we renew our enthusiasm to continue and complete the medium and long term studies; pledging yet again our desire to complete, present, and publish each study. Our goals have always been modest but the results have been outstanding with the COTS group initiating and completing many randomised prospective trials that have had a practice-changing impact on the global orthopaedic family.
Development of a COTS Protocol

As discussed above, the development of a study protocol is a collaborative effort. Protocols may be presented to the group at any stage in their development. Some begin as an idea or question, sometimes in the form of an informal survey of COTS members (“How do you treat this at your site?”), which leads to a study question. Others are based on preliminary laboratory work or a literature review. And still others come fully prepared—some even have a pilot study completed and are ready for a multi-site study. What they all have in common is a study “champion” who is open to feedback from the group. Regardless of how developed the protocol or idea is, the process of getting to a final protocol that the majority of the group can agree upon can be a lengthy process. In some cases, it has taken years of debate, and even then we all usually have to agree to compromise somewhat to get a reasonable protocol.

A study is presented as a clinical question that needs an answer. Often the first step is to ask our colleagues if they feel it is worth answering. Is there a controversy or a debate in treatment options? Are the surgeons interested enough to participate? Is the study population in our centres large enough to complete a study? Do we need a prospective randomised trial to answer the question, or would a different study design be better? If the “question” incites interest, the study’s “champion” begins the process of developing the protocol. This includes the background literature search, the design of the study, inclusion and exclusion criteria, the outcomes to be measured (and how they are to be measured), the power analysis, and an estimation of the length of time it will take to complete the trial. After achieving great input from the individuals from the group the “principal investigator” presents a proposal to the group for further input prior to putting the finishing touches on the protocol. As mentioned previously, all COTS members and associate members are invited to give feedback on the proposal.

Common items up for debate include:

- **Study design**: How many arms of the study? How should we randomise?

- **The primary outcome**: Is this the best option to answer the question? i.e. Should we look at time to healing or functional outcome?

- **Outcome measures**: Are the questionnaires validated? Available in French and English? Are they sensitive enough to give us an answer?

- **Subject selection**: What age limits? What fracture classifications? Do we include smokers? Diabetics? How will each inclusion/exclusion affect enrolment or results?

- **Follow-up schedule**: How many time points do we need? What information do we need to collect at each visit? How long do we need to follow subjects?

- **Standardisation**: How much can we standardise? Operative technique? Surgical approach? Rehabilitation schedule? Device manufacturers?
- **Budget:** Is the study feasible? How much will it cost to run? Do sites have the devices already available? Enough staff (coordinators) to follow the subjects? Where can we get funding?

Often a lengthy but stimulating process, this discussion amongst members is what leads to a study in which everyone is comfortable in participating. Members are able to debate each point to determine which is ‘the best’ approach. As a result, even if the resulting protocol is not what all members would have preferred to do at their own site, they understand and have agreed to the accepted protocol and will continue it until the end of the trial. Once the major points in the design of the study have been agreed upon, the study ‘principal investigator’ prepares the protocol in a standard format and with the assistance of the research coordinator at his/her site, develops the accompanying documentation, i.e. informed consent form, and case report forms. The applications for peer-reviewed funding and industry funding then begins!

### Awards

COTS has received a number of awards over the years:

#### Charles S. Neer Award for outstanding clinical investigation

This award is presented annually in recognition for outstanding clinical investigation contributing to the understanding, care or prevention of injuries to the shoulder and elbow.

**2007:** A Multicenter Prospective Randomized Controlled Trial of Open Reduction Internal Fixation versus Total Elbow Arthroplasty for Displaced Intra-articular Distal Humeral Fractures in Elderly Patients. Michael McKee, MD; Christian JH Veillette, MSc, MD; Emil H. Schemitsch, MD; Lisa M. Wild, BScN; Jeremy Hall, MD; Robert McCormack, MD; Bertrand Perey, MD; Mauri Zomar; Pierre Guy, MD; Scott Mandel, MD; Thomas Goetz, MD; Karyn Moon; Shirley Petit, RN; Irene Leung, RN

#### Edwin G. Bovill Award

This award is presented annually to the author of the most outstanding OTA Annual Meeting scientific paper. The Canadian Orthopaedic Trauma Society or its members have received this award seven of the past 8 years.

**2007:** A Randomized Trial of Reamed versus Non-Reamed Intra-medullary Nail Insertion on Rates of Reoperation in Patients with Fractures of the Tibia. The Study to Prospectively evaluate Reamed Intramedullary Nails in Tibial Fractures (SPRINT) Trial. Mohit Bhandari; Gordon Guyatt; David W. Sanders; Emil H. Schemitsch; Marc Swiontkowski; Paul Tornetta III; Stephen Walter
2006: A Multicenter Prospective Randomized Controlled Trial of Open Reduction and Internal Fixation versus Total Elbow Arthroplasty for Displaced Intra-articular Distal Humeral Fractures in Elderly Patients. Michael D. McKee, MD, FRCS(C); Canadian Orthopaedic Trauma Society; (all authors a-OTA/Zimmer Grant) Christian J. J. Veillette, MD, FRCS(C), MSc; St. Michael’s Hospital, University of Toronto, Toronto, Ontario, Canada

2005: A Multicenter Randomized Control Trial of Non-Operative and Operative Treatment of Displaced Clavicle Shaft Fractures Michael D. McKee, MD, FRCS(C); Jeremy A. Hall, MD, FRCS(C); and the Canadian Orthopaedic Trauma Association: Hans S. Kreder, MD; Robert McCormack, MD; David M.W. Pugh, MD; David Sanders, MD; Richard Buckley, MD; Emil H. Schemitsch, MD; Lisa M. Wild, RN; Scott Mandel, MD; Rudolph Reindl, MD; Edward J. Harvey, MD; Milena V. Santos, RN; Christian J. Veillette, MD; Daniel B. Whelan, MD; James P. Waddell, MD; David J.G. Stephen, MD; Terrence Axelrod, MD; Gregory Berry, MD; Bertrand Perey, MD; Kostas Panagiotopolus, MD; Beverly Bulmer, Mauri Zomar; Karyn Moon, Elizabeth Kimmel, Carla Erho, Elena Lakoub; Patricia Leclair; Bonnie Sobachak; Trevor Stone, MD; Lynn A. Crosby, MD; Carl J. Basamania, MD; (all authors a-OTA/DePuy Grant; Zimmer, Inc. Grant) St. Michael’s Hospital, University of Toronto, Toronto, Ontario, Canada (OTA Administered Research Grant)

2004: The Gold Standard in Tibial Plateau Fractures? A Prospective Multicentre Randomized Study of AIBG vs. Alpha-BSM. Thomas A. Russell, MD; Ross K. Leighton, MD; Robert W. Bucholz, MD; Charles N. Cornell, MD; Sam Agnew, MD; Robert F. Ostrum, MD; James A. Goulet, MD; B.H. Berrey, MD; Brian Davison, MD; Thomas Gruen, MS; Mark S. Vrahas, MD; Alan L. Jones, MD; Andrew Pollak, MD; Peter O’Brien, MD; Thomas F. Varecka, MD

2003: Previously Unrecognized Deficits after Nonoperative Treatment of Displaced, Mid-Shaft Fracture of the Clavicle Detected by Patient-Based Outcome Measures and Objective Muscle Strength Testing. Michael D. McKee, MD, FRCS; Elizabeth M. Pedersen, MD; Lisa M. Wild, BScN, Emil H. Schemitsch, MD, FRCS; Hans J. Kreder, MD; David J.G. Stephen, MD, FRCS

2002: A Randomized Controlled Trial of Closed Reduction and Casting versus Closed Reduction and External Fixation for Distal Radius Fractures with Metaphyseal Displacement but without Joint Incongruity. Hans J. Kreder, MD; Douglas P. Hanel, MD; Julie Agel, MA; Michael D. McKee, MD, Thomas E. Trumble, MD. Harborview Medical Centre, Seattle, WA

2000: Prospective Randomized Clinical Multi-Center Trial: Operative versus Nonoperative Treatment of Displaced Intra-Articular Calcaneal Fractures. Richard E. Buckley, MD; Robert G. McCormack, MD; Ross K. Leighton, MD; Graham C. Pate, MD; David P. Petrie, MD; Robert D. Galpin, MD

J. Edouard Samson Award

The premier award for orthopaedic surgery and research in Canada, the J. Edouard Samson Award, is offered annually to recognize the best orthopaedic research over a 5-year period at a Canadian Centre. In 2001, Rick Buckley received this award for a COTS study.
Conclusion

Presentations to date have included all peer reviewed meetings with multiple papers and posters at the OTA, COA, AAOS, SICOT and many national and international educational meetings around the globe. These have been accomplished with all authors and coordinators working hard to make sure the data is clean and well presented. These accomplishments have enhanced our ability to attract industry and peer reviewed funding. We have become a “go to” group for anyone wishing to get really good credible numbers and achieve a study that will provide level one evidence with a well-powered study. This reputation has enhanced the group’s activities and allowed us to choose the topics we consider to be of academic and clinical interest.

We have been very fortunate to achieve a level of financial endowment at this the point where we now give out our own research grant to young investigators of the group. It is a $10,000 seed money grant for investigators in the group under the age of forty. Preference is given to a well-designed prospective randomised multicentre trial. We believe by fostering the young investigators of the group we will indeed ensure the success of the COTS clinical investigators for years to come. We would encourage any interested readers or those who feel they may wish to duplicate or enhance our efforts to visit our website and obtain more information regarding our activities or contact Kelly Trask via the website. Our group, although 98% Canadian in site participation, welcomes any site who feels they can participate in a meaningful way for the duration of any of our studies. We would like to thank the editors for the opportunity to feature our group as a model of success in the world of orthopaedic research. We feel our contributions of “level one information” using prospective randomised trials have been helpful to us, as a group, and to the clinical practice of all orthopaedic surgeons. Many studies have had the desired effect of affecting significant changes in clinical practice. I would personally like to publicly thank our entire COTS group: the surgeons for the ingenuity of the questions and the quality of the protocols, and the Research Coordinators without whom virtually nothing would ever get completed. The dedication of the whole team to the common goal at hand has really driven the process to the success it has achieved to date.
Lessons Learnt

1. **Data** - To initiate a randomized trial center requires dedicated staff to administer the life quality measures and limb specific testing. It also requires a digital tool where all sites may upload their data for central evaluation (*Example* – ‘RedCap’). Note that this will usually require a license for each specific study center. The data tool itself must be deemed safe for storing national and international data. It is essential that the data is unattached to the patient (*Example* – ‘patient AC2’ as opposed to Mrs. Susan Johnson). This will ensure all privacy laws and limitations are met for sites involved in the study.

2. **Funding** - It is best to have infrastructure for funding available prior to initiating a study (although we at COTS were not always so fortunate). Where possible, obtain industry grants or institutional funding for a research coordinator. Even if only available on a part-time basis, such research coordinators can be extremely helpful and help accelerate the funding process. As happened with COTS, it is possible to first obtain funding for individual studies and then use that funding to hire a part-time research coordinator. Eventually, funding can then be gradually increased to allow for at least one full-time research coordinator to be hired. This becomes more relevant as the number of funded studies starts to increase. All of our COTS sites presently have at least one full-time research coordinator to allow us to participate in numerous studies simultaneously and ensure we remain on track with protocol. There are a variety of funding methods, although most are highly institutionally-based. Sharing of this information between sites can then help gain support in additional sites. As a randomized trials group gains momentum, it is an absolute “must” that data is recruited and collected in a predictable fashion. Without permanent research coordinators, there is just too great a chance of individual sites not participating in a consistent fashion. Unfortunately, this can often lead to missing data, which severely cripples the efforts of the overall group.

3. **Recognition** - The goal of a randomized trials group should be “*a collaborative working group within your own country*”. The group should identify itself as being a collection of individual successful sites—each with common overarching goals and a positive track record of past papers and presentations at peer-reviewed meetings. The next step is, of course, publishing the data in a peer-reviewed journal with the caveat that all authors involved should have the ability to use this as an academic publication on their Curriculum Vitae. This notion has seen COTS studies appear in many very high impact journals such as the Journal of Bone and Joint Surgery (JBJS), Injury and Journal of Trauma (JOT).
Part 2

Landmark RCTs
& the ‘Lessons Learnt’