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Stimulus & Challenge

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Faculty Endorse Establishment of Clinical Research Unit.

Following on from the two successful workshops held last fall the faculty responded to a proposal to establish a Clinical Research Unit. The proposal was developed with the input of some 30 individuals who attended and participated in the workshop. The establishment of the CRU provides an unprecedented opportunity for any of the full and part-time faculty who wish to be involved in collaborative clinical research projects. The development of this clinical research unit is very timely, it will be able to take advantage of several developments which are taking place.

The development of an umbrella organization to interface with the drug industry to support the setting up of a clinical trial facility was initiated in November 1992. The organization is intended to bring together the Faculties of Medicine, Dentistry the College of Pharmacy and the various hospitals in the region. The organization will provide a focused approach to enhance linkages with the business community. The umbrella organization will be able to provide support, advice and

encouragement for the development of collaborative research endeavors between various units in the hospital and university sector. The Faculty of Dentistry will be playing a role in developing the organization. The advantages of such an organization are the collective strength in expertise, knowledge, facilities and patient numbers and opportunities for collaborative clinical trials and research within the group. Researchers have to be in control of the aims, objectives and direction of the organization, in the dental involvement this will be greatly facilitated by the formation of the CRU. The main objective of the umbrella organization will be to enhance the development of clinical research in Atlantic Canada. Our Dental Clinical research Unit will ensure that we have an opportunity to increase the numbers of individuals involved in the clinical research rather than just increasing the amount of research being conducted by a few.

What do we have to offer to such an organization? Our colleagues in Medicine and the local hospital community have

been reminded that we have the only Faculty of Dentistry east of Quebec. Arguably the finest Dental Clinic Facility in North America. Our dental clinic has screened well over 4,000 patients in the past five years, of which 95% were accepted for treatment. We have 25,000 patient visits a year. The clinic thus provides an ideal opportunity to conduct clinical trials. The establishment of our own Clinical Research Unit gives us a flying start. Plans have been put forward to establish a Provincial Health Research Foundation. Should this come into being in the next one or two years we will be well placed to take advantage of the opportunities. The other major timely event is the restructuring of the Medical Research Council, which is almost certain to open up increased opportunities and possibilities for clinical research and health care research. Our Clinical Research Unit is indeed timely in its inception.

Empirical Fact

"The internal validity of an experimental finding cannot be judged solely in terms of the properties of the experimental design... Internal validity of a causal claim is a complex judgment that ultimately rests on a larger number of empirical facts that necessarily extend beyond the context of a single experiment."

G. V. Glass, in *Encyclopedia of Educational Research*, 5th ed. Vol. 2 pp. 631-636. NY Free Press, 1982.

The following abstract has been accepted for presentation at the 5th Meeting of the European Association of Plastic Surgeons to be held in Geneva, Switzerland, May 1994.

The role of Muscle Imbalance in Unilateral Cleft Lip Nose Deformity During the Embryological Life. An anatomical study.

by
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It is generally accepted that a congenital labiomaxillary cleft forms about day 36 or 37 of gestation, but the earliest points of ossification in the maxilla and the premaxilla appear about the end of the sixth week, at a time when the elements of the cartilaginous nasal capsule and facial muscle precursors are already present. This means that the abnormal muscular architecture is present during the formation of the bones, virtually all of which takes place at the direction and under the influence of dissymmetric and distorted muscular forces.

The displacement of the maxillary segments and the deformity of the lower lateral cartilage are both immediate consequences of the disruption of facial muscular balance. Little has been published about gross and microscopic

anatomy of cleft lip and palate, and the rare studies are frequently limited to the muscle of the margins of the cleft, and to the cartilaginous or bony structures.

Our observations at the time of surgery, and by dissection of the face of newborn are now confirmed by the examination of the microanatomy of 31 normal and cleft lip/palate human fetuses ranging in age from 7 to 26 weeks. There were 7 cleft fetuses. Frontal, horizontal or sagittal sections, 5 microns in thickness, were made using Masson's trichrome stain. In the non cleft fetuses an organised, symmetrical arrangement of the relationships of the premaxilla, nasal septum and nasolabial muscles is noted in every case. In the cleft fetuses there is disruption of the symmetry of the relationships of the premaxilla, nasal septum, nasolabial muscles and the labioseptopremaxillary traction system in general. There is deviation of the nasal septum to the non cleft side and the premaxilla is not oriented symmetrically with respect to the midline. When compared to the non cleft side, there is deformity of the relationship of the nasal muscle complex with the lower lateral cartilage. Between the 12th to 15th weeks of embryological life the deformity of the

cleft nostril is completed and is the same as in a newborn.

Furthermore the deformity involves the network of the superficial musculoaponeurotic system itself, specially the nasal muscle complex with its transverse and mytiform heads, the levator muscles of the lip and nostril and the horizontal and oblique heads of the orbicularis oris.

Conclusion:

Meaningful correction of the cleft can only be accomplished when the surgeon is fully appreciative of both normal and pathological spatial and functional relationships.

The Research Development Office Congratulates Peter Pronych on obtaining a CIDA Grant for a Collaborative Research Project with the Government of Egypt.

Need for Educational Experiments

"How are research claims validated? What methods should be employed? What is the role of experiments? How does scientific realism compare with perspectives such as interpretivism, pragmatism, and critical theory? Many questions are unanswered, but the promise of this strikingly different conception of science and causation is such that it warrants further exploration."

Ernest R. House, Educ.Res., Aug-Sept. 1991 p 2-9.

NSERC Collaborative Grant Application

A "Notification of Intent" for a Collaborative research grant, has been forwarded to NSERC. This international collaborative project links together faculty members from Medicine, Dentistry, Science at Dalhousie, Engineering at TUNS as well as the University of Toronto and the University of Liverpool in the UK. Should this grant be successful it could have many spin-off projects which can be particularly beneficial to members of the Faculty of Medicine and Dentistry at Dalhousie. The proposed research subject area is bioactive ceramics. These materials have the capability of chemically bonding to both soft and hard tissues, this provides a tremendous opportunity for a wide range of clinical research activity.

The main cornerstone of the project will rest on two main areas:

- 1) The synthesis and development of glass biomaterials which will be conducted in the biomaterials lab at Dalhousie University.
- 2) The bone cell culture methods involving the differentiation of osteo-genic cells on ceramic biomaterials at the University of Toronto.

The hypothesis of the project is that the use of wet chemical synthesis and biological assay techniques will lead to development of improved bioactive glass and ceramic biomaterials.

Two basic methods have evolved: for synthesis of glass and ceramics:

- 1) Sol-gel polymerization of prehydrolyzed alkoxides (some soluble metal salts may be added becoming complexed into the gel).
- 2) The precipitation from colloidal suspensions by volatilization.

These methods allow very homogeneous glasses and ceramics to be formed at temperatures well below the normal temperature required to sinter high density bodies of uniform microstructure.

The objective will be to determine the mechanisms involved in wet chemical synthesis leading to the development of improved glass-ceramic biomaterials. The goal will be to optimize methods for synthesizing improved bioactive materials. The aim will be to develop formulations with optimal bioactivity by means of a biological assay. These goals will be supported through a study of the mechanism of glass synthesis and osteogenic activity. The project will seek to demonstrate the selective adsorption of specific proteins by bioactive glass surface reactive layers.

Degenerating bone disorders such as, periodontal disease, osteo- and rheumatoid arthritis, bone cancer, avascular necrosis as well as trauma together with greater use of implants have increased the need for a suitable bone substitute or a stimulant for osteogenesis. In North America we have an aging population combined with a larger proportion of the population surviving into old age, thus, application of synthetic biomaterials as substitutes for natural tissues becomes an increasingly important subject. Synthetic materials are being used progressively more frequently in biomedical applications as substitutes for natural tissues.

Outstanding opportunities are available for development of bioceramics by new wet chemical synthesis technology. These methods extend our ability to provide materials with tailored chemistry. A range of glass and ceramic compositions will be synthesized using different wet

chemical methods in order to determine which method produces the optimum bone-bonding ceramic biomaterials. Wet chemical methods produce glass and ceramic materials which are more homogeneous at the atomic level, thus producing glasses having structural compositions not attainable by conventional glass making methods. Wet chemical synthesis allows variations in formulation to be easily made with good control of composition and high chemical purity. Materials of controlled surface activity showing direct bonding to bone offer potential for long-term stabilization of implants. One of the major challenges facing the use of biomaterials is to determine the mechanisms involved in the establishment of the interface between bone tissue and a variety of different implant materials.

When used as substitutes for natural tissues, ceramics may be required to: a) restore function of surrounding tissue, b) fill a space, c) physiologically interact with body fluids, d) stimulate osteogenesis and e) provide permanent stress bearing skeletal repair. Skeletal stress bearing repair is by far the most difficult problem which must be faced when attempting to use ceramic materials.

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No Guarantee

"How is it possible for research to be relevant to practice if the researcher cannot guarantee that Event A will be followed by Result B, the bedrock of the standard view? This issue has never been successfully resolved in the standard view of research, either in theory or practice."

Ernest R. House, Educ.Res., Aug-Sept. 1991 p 2-9.

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