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Innovation in prosthetics and orthotics

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Introduction

As I look back over my 35 years in the field of prosthetics and orthotics research, and consider those years from the point of view of the innovations I have witnessed and participated in, certain insights and influences stand out. They cluster around specific people and projects. Two years in Toronto with Fred Hampton and Colin McLaurin led to the establishment of the Canadian Plastic Syme's Prosthesis, the Canadian Hip Disarticulation Prosthesis, plastic reinforcement of wooden prostheses and conception of the SACH Foot.

The products of ten years at Berkeley with Chuck Radcliffe, Leigh Wilson, Bill Hoskinson, Frank Todd, Jim McKinnon and others, included design of the SACH Foot, the Quadrilateral above-knee (A.K.) socket, the Patellar Tendon Bearing below-knee (B.K.) prosthesis; conception of socket standardization, studies of prosthesis alignment and experiences with modular prosthetics.

Introduction of modular prosthetics to the clinic, development of the electrical alignment unit, use of semiflexible sockets and work on standard sockets and standard cosmetic restorations were experiences of my 8 years in Winnipeg with Ian Cochrane, Doug Hobson and Reinhard Daher.

Invention of Shapeable Matrices, development of Tubular orthotics, development of Computer Aided Socket Design and design of the valgus varus resist knee orthosis are milestones of my Vancouver experiences with colleagues Steve Cousins, Richard Hannah, David Cooper, Carl Saunders and Margaret Bannon over the past 15 years.

I have appreciated experiences in projects outside my work environment too. The most recent was the cooperation that developed around Computer Aided Socket Design and Computer Aided Manufacturing between the group at UBC and the groups at University College London and West Park Research, Toronto. I am pleased that cooperation is being extended by new initiatives developing between the original groups and others. I speak of these things to convey to you the team basis for developments and the positive effect cooperation between people has on advances in our field.

Those of us who have worked together on various projects functioned best when we recognized and used each others qualities. Among the qualities I am thinking of are drive, curiosity, imagination, persistence, patience, trust, confidence and the ability to share.

To keep sweet reasonableness alive between people, participants have had to review their motives and consider the needs of their associates. How these associates functioned varied.

Some were definite and decisive. Some pondered things over and came to considered views. Some were very competent at the things they were trained to do. Some inspired new ideas on

how to solve the problems we worked on. Some were able to take risks easily. Assertiveness born of clarity of view could sometimes be mistaken for arrogance. While human relations are never without their problems, all of these people enlarged my capabilities and enriched my work life. There have been things I loved doing. Other things I have compelled myself to do. My attachment has been to what I believe were keystone projects, projects that had the potential to generate multiple solutions. In addition, they were projects that suited my natural rhythms, abilities and needs, and were championed by colleagues who could fill the gaps in my own abilities. For the most part, the means used to solve problems were traditional engineering coupled to vigorous artisanship. A great deal of self education was involved. Now we are at a new intersection of events. Many of the problems have been defined but new means for problem solving are at hand. Although engineering and artisan skills are still required, there is a need to reassess our methods in light of the new means so that smooth and effective advances can be made. Re-education and new education are involved. Factors affecting innovation, on the other hand, will not change. Some already alluded to are:

1. A suitable field for inventing.
2. Colleagues who cooperate, lead and support.
3. A mix of skills and temperaments in the team.
4. People willing to take risks.
5. An environment conducive to study and experimentation.
6. A speculative attitude.
7. Tools and techniques for problem solving.
8. A willingness to reassess methods and means periodically.
9. Appreciation of accumulated skills and knowledge.

In order to develop the theme of innovation in prosthetics and orthotics, I will use a review of the problem of shaping structures that fit against the body for control of forces and movements. Although the emphasis will be prosthetic, the problem is common to both prosthetics and orthotics.

I have organized the presentation around eight propositions which have a bearing on shape management. Factors I have observed as conducive to innovation are interspersed among them.

First proposition: Tissue density is non-homogeneous (1955)

Clinical studies of the quadrilateral socket for trans femoral amputees taught us that the residuum cannot be treated as a homogeneous mass. I believe that an examination of derivation of this proposition in relation to design of the quadrilateral socket will help us to identify some factors associated with innovation and indicate the need for further innovation.

The quadrilateral socket

The quadrilateral socket for AK amputees was brought to the Biomechanics Laboratory, University of California, USA from Germany by Eberhart and his team in 1949. It was assumed to be a suitable solution to prosthetic socket design for the above-knee amputee.

The plan was to examine its characteristics and to test it clinically at the Laboratory. It was studied throughout the 1950s for rational factors that could help to define it. Simultaneously,

suction suspension was used, a factor that imposed greater demands on socket design, thereby highlighting problems with the quadrilateral socket.

Difficulties:

Common difficulties encountered included (a) cysts on the residual limbs in areas contacting the medial and anterior brims; (b) formation of horny nodules, or keratin plugs in the ischial-gluteal weight-bearing regions and (c) distal residuum oedema.

Shear forces on tissues where they extended over socket edges were identified as contributing to cyst formation. Oedema was due to proximal wedging effects and to insufficient support of distal tissues. Nodules, or keratin plugs, were traced to high compressive forces which drove small corns inward, building them into pain-producing nail-like structures.

It was assumed by Radcliffe that if the ischium was stabilized on the seat of the quadrilateral socket by means of more positive anterior forces, these difficulties would be overcome. To achieve this, he proposed that soft tissues over Scarpa's Triangle be compressed more positively as compared to harder muscular regions laterally. This led to the inward bulge over Scarpa's Triangle characteristic of present day quadrilateral sockets.

The differential displacement of tissues to effect even loading on the front of the residuum was a new idea that could be applied to any part of the body for force transfer and movement control.

In order to convey the requirements, he depicted the concept in biomechanical terms that practitioners might understand. Thereafter it became common practice to illustrate biomechanical events in this way, encouraging a more systematic analysis of fit and alignment. Innovative factors illustrated in this include:

10. A person able to derive and champion a new concept.
11. Use of engineering principles for socket design.
12. Confident application of the hypothesized solution.
13. Using a clinical environment for testing it.

The solution helped to reduce the incidence of cysts, keratin plugs and oedema when applied to clinical study amputees.

Practitioners trying to follow the clinical study procedures however, found the information difficult to interpret because it was essentially descriptive. Their difficulties were thought to be due to their failure to abide by the principles. Measurements were made of successful and unsuccessful sockets in order to identify differences that might be responsible. From these might come a more definitive set of instructions for socket design. It was soon apparent however that the dimensions being measured could be the same for sockets that were obviously different. At the same time, successful sockets were observed to appear very similar to one another. This led Bill Hoskinson and I to speculate that it might be possible to standardize quadrilateral sockets.

This is the next proposition:

Second proposition: Socket shapes can be standardized (1957)

Calculations based on hazy ideas and gross assumptions to test the hypothesis that quadrilateral sockets could be standardized indicated that it might require approximately 11,000 one piece AK sockets (5,500 for each side of the body) to provide the range of sizes needed for a system that could be used with no more than small shape adjustments.

At that time, with no computers, storage, selection and distribution would be major problems in practical application.

To arrive at a more favourable format, the hypothetical socket was divided into sections. Attention finally focussed on the brim area alone. If the brims were one-piece, only 150 would be required for each side of the body. If all four sides of each brim were adjustable, the number

of brims required could be reduced to 3 for each side of the body.

The innovative impulse in this can be seen to follow out of:

14. A problem in strong focus.
15. The search for objective data.
16. A willingness to make assumptions in the absence of facts.
17. A practical objective.

The results of this hypothesis included:

- a) establishment of jigs for fitting quadrilateral sockets, notably the Berkeley Adjustable Brims,
- b) prefabricated temporary sockets,
- c) adjustable sockets for the study of socket design parameters.

The jig fitting method facilitated acceptance of quadrilateral sockets by making the design principles more obvious and the design methods more simple.

Factors that influenced acceptance of jig fitting methods included:

- a) the desire for total contact sockets, which could be made easily by this method
- c) difficulties experienced in defining the quadrilateral socket shape,
- c) the desire to substitute plastic laminates for wood in socket construction, a feature of the brim fitting method.

In this we see how:

18. Converging ideas and overlapping experiences bring innovation to focus.
19. Simplification of methods enhances acceptance.

In spite of these meaningful consequences, the hypothesis on standardization received a hostile response in general. I doubt if many of you will appreciate how heretical it was during the 1960s (and perhaps still is) to suggest that sockets can be standardized. I remember sending a paper based on standardization to an American journal approximately 20 years ago. The provocative title was "Instant Prostheses for Thigh Level Amputees." The editors reply was that there was no space for the article in the journal at the time, and it could not be foreseen that there ever would be! My comment is this:

20. Negative attitudes toward innovations can either hamper their development or prolong their demise!

While I consider the proposition on socket standardization valid, it may be that every successful shape will be computer banked and standardization will be bypassed. Banking all shapes overcomes obstacles to acceptance of standardization which include:

- a) the shape preferences and prejudices that people hold,
- b) concern for the population that might be excluded from coverage (i.e. congenital amputees),
- c) the lack of objective data.

Adjustable sockets constructed to study design parameters gave information on sensitivity of residual limbs to changes in socket dimensions (1962). There is a need to continue this work

in the light of what we now know and need to know.

The adjustable sockets were suggestive of socket modularization, but did not lead to it. New fabrication techniques, an appreciation of the value of socket flexibility as exemplified in the Icelandic Socket and modular shapes in computer aided socket design systems may foster socket modularization.

Data for design could be derived from computer banked shapes and this in turn could lead to the impedance matching of sockets to residual limbs proposed by Ben Wilson and Eugene Murphy once the required data on tissue qualities is available.

Without objective data on tissue qualities to use in design work, modularization will require that intelligent, workable assumptions be made. Following out of that, however, adjustable modular sockets could help refine these assumptions and ultimately be the basis for defining tissue qualities. Finally, with sufficient data available, standardization could be reconsidered. The computer would be used for shape storage and numerically controlled machines for production of the shapes.

I can add other innovation factors:

21. Advances may reduce the need for information, reduce its importance, or facilitate its acquisition.
22. New options precipitate new speculations.
23. Oscillation between various options indicates that we have insufficient data.

So far, I have indicated how the North American version of the quadrilateral socket evolved out of the original German design through clinical studies and how these developments established propositions which I now summarize:

- (1) Residual limb tissue density is variable.
- (2) Socket shapes can be standardized An appreciation of the role of the skeletal frame in determining the shape of the quadrilateral socket led to the third proposition.

Third proposition: The bony frame is the basis for socket design (1965)

For example, the triangle defined by the tendon of adductor longus, the ischial tuberosity and the trochanter is the bony frame round which the proximal shape of the AK socket is designed. Deviations from the triangular shape come about because of the need to accommodate the tissue-muscle masses adjacent to the sides of the triangle in a biomechanically compatible way.

The facts of this are most clearly exemplified in sockets derived from hand cast impressions. Lean residual limbs tend to give a shape that resembles the plug fit type of socket. Heavily tissueed residual limbs yield a more quadrilateral shape.

This proposition explains deviations from stereotyped socket shapes for any level of amputation. It can be taken into account in standardizing shapes and in adapting standard shapes for shape customization in the computer. It is relevant also in making biomechanical shapes from sensed topographical data. It indicates:

- a) why there are limitations in the Berkeley jig fitting method, which utilizes jigs of a single standard form,
- b) limitations of standard sockets currently used,
- c) what might be done to improve the biomechanical result,
- d) why computer aided socket design programs include means for customizing the standard reference shape
- e) why reference shape processing of bone geometry is significant for socket design
- f) and why we need information on tissue qualities.

The patellar-tendon-bearing BK prosthesis

In my opinion, development of the PTB prosthesis is a good model for this discussion of innovation in prosthetics and orthotics. I will stress the process rather than design in order to emphasize the mechanism of study and motivating factors involved.

Up until the late 1950's at Berkeley, so much time and effort had gone into development of AK prosthetics that there was an uneasy feeling that BK prosthetics had been neglected.

To deal with this, Radcliffe called together a group of knowledgeable practitioners and educators to lay out a plan of attack on BK prosthetics with the researchers. It was agreed that in the studies the researchers would systematize prosthesis design and the educators would disseminate the information. They would also help format the information to be disseminated. The Veterans Administration would require prosthetists to take the courses as a condition for servicing VA clients.

This was a very potent format — one I would recommend for solving other problems, one I wish was being followed in the development and dissemination of CAD/CAM for prosthetics and orthotics.

No formal evaluation component was included. Each group made its contribution. That which would normally be done by evaluators was done directly by the prosthetists who applied the system. In retrospect, I would say that it was a satisfactory way to do it. In fact, considering the rate at which knowledge and means now develop, existing scenarios for evaluation seem more like seaweed around the propeller than a jib full of wind.

I will make another comment. The fascination with statistics on the part of our major funding agency, Health and Welfare Canada, is restricting Canadian prosthetics and orthotics research. In Berkeley, and elsewhere where innovations have advanced our field to a remarkable degree, the sample sizes used in the studies were sub-statistical. Results leading to commitment to adopt the PTB prosthesis rested on multiple fittings on no more than a dozen amputees, each different in various ways.

The results were not expressed objectively so much as procedurally. We knew that our methods were better than existing ones, a fact confirmed by the rate of dissemination and application of the new information.

Competent judgement was substituted for evaluation — and I would add, at no loss.

The PTB prosthesis was essentially assembled from information modules.

A modified form of the German practice of using the patellar tendon as a weight-bearing surface introduced at the original workshop, was adopted. Total contact was already acceptable at the research level in socket design for oedema control and was adopted for use in the BK system. At the same time, Shindler's technique for making Kemblo inserts to line sockets made of hard blocked leather set in wood was adopted. Blocked leather and wood for the socket were replaced by plastic laminates. The SACH foot, now entering clinical application, was incorporated.

Simultaneously, Blevins was making prostheses which he suspended by means of multiple socks with rubber buns stuffed between them and a knee strap. Galdick in San Francisco was making BK prostheses suspended by suction. Woodall was trying condylar suspension by 1962.

This gives you an idea of the many influences at work to give rise to the PTB prosthesis and to stimulate innovation. Much of this information was present in the field but unintegrated.

Summarizing,

24. Innovation is enhanced by coordinated efforts based on shared motives.
25. Informed judgement can be equivalent to evaluation.

26. Information density affects innovation.
27. Accomplishments in one area affect events in another.
28. Practical hypotheses are quickly accepted.
29. Accident also plays a part.

Alignment of trial prostheses at the biomechanics laboratory during checkout of procedures outlined by the review group was done in two steps. The socket-foot complex was aligned without the side joint and corset system in place, and then, upon completion of dynamic alignment of the foot-socket complex, the joint and corset system was added and aligned.

At that time, it was considered hazardous for an amputee to walk for prolonged periods on a prosthesis without the corset and side joints in place to protect the knee. No explanation was given as to why some people were able to wear jointless Muley prostheses. When one of our test amputees rebelled at having the corset-joint system added to his prosthesis following successful trials without, the switch was made to what is now the PTB below-knee prosthesis. Controversy surrounded the PTB initially. Concerns remained that the knee would be damaged. Some critics said that only a few people could be successful PTB users, the majority would require side joints and corset.

Examination of the role of alignment on forces at the knee and application of normal locomotion data led researchers to abandon the myth against jointless prostheses and led to emphasizing the flexed knee gait as an insurance against knee damage.

Factors pertinent to success of the PTB prosthesis seem to have been:

- a) a better understanding of how to shape and construct a socket;
- b) a better appreciation of the biomechanics of the prosthesis as exemplified by the improved definition of alignment;
- c) relating fundamental gait data to the practical situation;
- d) the experiences of successful wearers of Muley prostheses,
- e) development of the SACH foot;
- f) a switch to new prosthesis construction methods;
- g) significant simplification of the BK system.

Factors favouring innovation were;

30. The existence of the "Muley" type of prosthesis.
31. Available fundamental information on locomotion.
32. An engineering-artisan approach to solving the problem.
33. Cooperative effort directed toward its implementation.
34. Including the amputees on the team.
35. Using accumulated information.

With regard to the last spur to innovation, I would comment that technologists who are about to do fundamental design work for the production of orthopaedic shoes using computer aided design methods would be wise to take into account what the practitioners can teach them! Much of the information that designers will need resides in the shoe lasts and methods of measurement and last modification used by the practitioners.

Innovations spawned by development of the PTB prosthesis included the air cushion socket, adjustable sockets, transparent sockets, adjustable spring loaded end-bearing sockets, sockets fabricated directly on residual limbs, foam-in-place end pads, suspension from the patellar and femoral condyles and inflatable bladders in sockets.

36. New innovations spawn innovation of variants.

Modular prosthetics

During the 1960s, a major problem, and still a problem to quite an extent in North American prosthetics, was the degree of immutability in prostheses. When there were difficulties, the socket was usually the problem. To replace the socket required major modifications to the prosthesis, even replacement of the entire prosthesis.

In experimental modular-like prostheses however, the option for quick exchange of components existed.

The need and the obvious solution led to the next proposition:

Fourth proposition: Modular structures optimize prosthetic management (1955 —)

The modular-like designs in the research laboratories that foreshadowed modern modular systems did not seem attractive to prosthetists; the Northwestern University BK pylon with alignment and length adjustability built-in and the University of California Polycentric Knee for above-knee amputees are examples.

It was apparent that a comprehensive modular system that overcame whatever obstacles were inhibiting development was needed if the potential advantages were to be exploited. This realisation influenced me to adopt modular prosthetics for clinical use when I went to Winnipeg, Manitoba in 1963. My conviction was that modularizing prosthetics would speed up access of amputees to prosthetic care. It would also help people learn prosthetic practices and would lead to economies.

The emphasis in Winnipeg was on physical rehabilitation in a newly established hospital designed for that purpose. However, the prosthetics clinic was bogged down in wooden leg making practices of the times. Geographic isolation and absence of modern technical resources in prosthetics inhibited change.

I came as an expert. What I proposed for clinical application in fact was experimental. I had worked in an environment linked to innovating and wished to bring the attitudes associated with innovating into the clinic. The aim was to have a comprehensive and adaptable modular system that included as many prefabricated elements as possible. The system would be used to manage patients with any level of amputation through their full spectrum of care from immediately post surgery to return to community life.

The design process would be evolutionary with the designed system used for what it was good for at every stage of development. A system with the least number of parts would be designed and common parts and tools would be used as far as possible.

A key feature would be rapid assembly-disassembly and reassembly for quick adjustment and socket exchange.

Only a few basic elements had to be designed to manage BK, AK and HD prostheses. All other parts were available or could be adapted.

We tried to make the system suit a basically rural environment so that a person who was distant from services might be able to manage repairs using community resources, including the local hardware store.

This experience illustrates:

37. Integrating what exists in new ways is innovating.
38. Experimentation can be a part of a service system.
39. Problems can be tackled from the users point of view.

The risks that might be involved in adopting a modular system for clinical use seemed small compared to the advantages to be gained in overcoming the bottlenecks affecting amputee

rehabilitation.

Results were positive. No amputee had to postpone rehabilitation because of the prosthesis. In fact, it became common for a training prosthesis to be delivered on the day prescribed.

The evolutionary design approach allowed defects in design to be overcome as a means of extending usefulness of the system while it was used for what it would permit. At first, the objective was to keep people walking until the definitive prostheses were delivered. Stage by stage, the system was improved until finally it could be used definitively.

Evaluation proceeded in tandem with design. This circumvented the possibility of incorporating unsatisfactory features into the final design. In my view reaching objectives in this manner must be one option to consider in the interest of economizing on time, costs and effort (I must admit that I would always choose this approach).

Shaped components were a source of problems, especially with the BK amputees. Although standard cosmetic covers had been designed, and also standard socket receptacles to link the sockets to distal components, the sockets themselves were all custom made. This was reasonable for definitive prostheses, but training prostheses require frequent socket changes.

Successes with the AK prefabricated sockets motivated us to develop prefabricated BK sockets in response to the bottleneck experienced.

Nineteen sockets were made for each side of the body.

Use of these sockets taught us that five sizes for each side of the body were sufficient to fit all of the new amputees managed in this way and that one size alone met 50% of the needs. This illustrates other factors in innovating:

40. Previously successful patterns are followed.
41. Every experience is treated as an information source.

We were acutely aware of limitations imposed by standardization. Standardizing can mean that someone is left out unless the standardized item is adaptable. Such implications for the client need to be kept clearly in mind during innovating. That is:

42. A sense of responsibility must influence what is done.

Shape sensing

At that time, obtaining limb shapes by means of a shape sensing method, subject of the next proposition, seemed like a possible solution to the limitations imposed by standardizing.

Fifth proposition: Shape sensing gives data for interface design (1961)

When the idea of automating shape management for the fitting of sockets and cosmetic restorations was first raised in 1960, there was no sympathy for it at Berkeley. In fact there was strong scepticism toward it in the research community when I raised it as a proposal at a meeting of the Subcommittee on Socket Design of CPRD in 1965. Although I was chairman of the subcommittee, the proposition did not even win a place in the minutes.

43. An innovative idea in its first stages is fragile.

I had discussed shape management by automated means in a letter to Colin McLaurin in June 1961. In practical terms, Frank Todd and I constructed a left side shank model from a right side shank model by means of photographic silhouetting in 1962 and that was all that was attempted until I returned to the idea in 1969.

When the gap between conception and initiation of work is considered, one can appreciate

that:

44. Innovators must be patient and persistent.
45. A concept has to be suited to its times for acceptance.

Our first formal attempt to sense shape for prosthetic applications involved use of the shadow moire phenomenon. These studies spanned the period 1972 to 1980. A prosthesis replicated in Vancouver, using the moire technique for sensing the shape and a numerical controlled carver for producing the models, was worn by the recipient for three years.

We were introduced to the shadow moire technique by Dr. Duncan, then Head of Mechanical Engineering at UBC. He was actively engaged in shape processing for ocean bottom survey, boat hull design and machine design purposes.

Using a system that he had built to obtain multiple view photographic contour maps around objects, Steve Cousins and I produced a number of maps and models of residual and intact limbs.

On the basis of this work, Tony Staros established a contract with us to quantify shoe last shapes for the USA Veterans Administration, a forward looking project which we completed in December 1980.

We set up design criteria and had fabricated on principles demonstrated by Dr. Vickers and Doug Dean at UBC Mechanical Engineering Department, a machine that gave a single continuous moire shoe last map.

Saunders forced the system to work by putting the data into the computer point by point. He soon appreciated that quick input of data was necessary if sensing was to be a part of automating prosthetic procedures.

In later studies of what was being done in Japan where considerable expertise in shape processing had developed, he identified the flying spot technique as significant. It offered direct, rapid deposit of data into the computer at an affordable cost.

These experiences taught us to:

46. Look outside our field for information.
47. Go for information where the information density is greatest.

The light streak technique has been adopted at West Park Research Centre, Toronto, Canada, where, by agreement between us, sensing shape has become a central project while we concentrate on manipulating shape.

Because sensed shape is topographical, it must be used in conjunction with tissue quality data or be subjected to manipulation to derive the required biomechanical shape. This weakness in topographic mapping methods for derivation of biomechanical shapes has yet to be overcome.

On the other hand, biomechanical data are inherent in standard shapes and this fact can be the basis for deriving custom shapes. I proposed this concept first during the ISPO course in AK prosthetics held here in Denmark in 1978. (You may recall, that in Winnipeg 50% of new BK amputees were found to fit into a single standard socket size).

This leads us to the general hypothesis of the next proposition.

Sixth proposition: The shapes of all examples of any given anatomical feature or its biomechanically matched representation are sufficiently similar to permit shape matching on a mathematical basis using a standard shape as the reference (1978) and Strathclyde Paper #1, 1984.

That is, you can make a standard shape bigger, make it smaller, make it longer or shorter,

make it differentially flatter or deeper in any direction and add or subtract from a particular point any required amount starting with a preconceived shape that serves as a biomechanically relevant core or reference shape.

My UBC colleagues have designed the current CASD (Computer Aided Socket Design) system on the basis of this proposition. Colleague Dave Cooper has extended its application to derive the shape of bones in vivo using external bony landmark measurements.

The hypothesis stems from attempts to standardize sockets and from attempts to adapt sensed shapes to socket design.

The hypothesis does not discount the significance of shape sensing. Shape sensing can be used:

- a) to deposit shapes in the computer for further processing; and
- b) for defining how a shape should be processed.

Reference shape modelling has elegance. It can be used for internal as well as external anatomical structures and has no adverse effects on the person for whom the shape is being developed. It can be used for other than anatomical features. It can be used in conjunction with other techniques, such as shape sensing. It is, in fact, a concept of general significance.

The next gap to leap is that of constructing the interface with a degree of elegance comparable to that offered for designing it.

This leads to the next proposition:

Seventh proposition: Shapeable matrices can be used to construct biomechanical structures directly (1977)

A shapeable matrix is a structure made up of nodes and links in a format that permits it to be contoured to match a required shape. You may liken it to a flexible lattice that can be made rigid once shaped and be returned to flexibility for re-shaping.

The new emphasis could be on structures that can be assembled in the shape format required and remain amendable for post fitting adjustment. The seating systems developed at the Bioengineering Centre University College London and at MERU are the only examples of shapeable matrices so far.

Design of shapeable matrices grew out of brainstorming sessions led by Steve Cousins when he worked with the team at the Medical Engineering Resource Unit, Vancouver in 1977.

With advent of the Shapeable Matrix, shape management is targeted from two directions:

- a) On the one hand, computer graphic techniques for shape management can be used to define the shape.
- b) On the other, mechanical matrices can be used to build up the shaped structures directly.

Yet to be achieved is the mating of computer and matrix to allow configuration of the matrix by computer.

The aim should be to develop universal matrix building blocks from which any shape can be constructed. This may lead to modularization of interfaces, or modularization may circumvent development of matrices. If the matrix approach is circumvented, there may be some gains but there will also be losses. The matrix approach is much more fundamental even though design is difficult. Hybrid modular-matrix systems, as proposed by Cousins, may develop as stepping stones to either matrix or modular structures.

This illustrates other factors in innovating:

47. The path to choose is the more fundamental one if an innovation is to be far reaching.

48. Concepts can be combined.

Difficulties experienced with hand assembly and adjustment of miniature shapeable matrices which we have attempted to design for direct use against the body have led us to the eighth proposition:

Eighth proposition: Shape dependent components will be produced by robot constructors

To produce sockets directly by computer controlled robots, while difficult, would set the stage for a manufacturing method that precludes the need for moulds. Such an approach is infinitely compatible with computer aided design.

It is also compatible with the needs in prosthetics and orthotics which are now so heavily dependent on custom made moulds for production of shape determined components.

This view is shared by our colleagues in Toronto at the West Park Research Center where it is proposed to use a robot constructor to make seats.

The dream is that CAD and CAM will become so intimately meshed that the design and fabrication of shaped objects will proceed simultaneously. Also, it will be possible to have raw material managed in a way that will deliver an interface that varies in stiffness according to the way in which materials are delivered from the nozzles held by the robot constructor.

Establishment of computer controlled robot constructors would be as revolutionary in production technology as was the introduction of mass production.

Intermediate steps might include (a) the design of programmable moulds, or (b) design of matrix elements that can be assembled by computer controlled robots.

When all of this is put together, we can say:

- a) Biomechanical shape is determined by bone geometry and tissue quality.
- b) Biomechanical shapes can be standardized.
- c) Standard shapes can be customized.
- d) Shape sensing can capture and classify shapes.
- e) Interfaces can be constructed from matrices.
- f) Matrices can be constructed by robots.

You may well consider the long and arduous course of actions bringing us to these possibilities. We can mesh them easily on the basis of hindsight. What step could have been omitted, what influences of colleagues on one another done without?

The adoption of matrices, computers, shape sensing, internal and external reference shapes and robot constructors is equivalent to a new date zero for design of shaped components for use in prosthetics, orthotics, and orthopaedics. We come to this as a consequence of the technology that surrounds us or can be envisioned on the basis of what surrounds us. We have merely to take note of it, reassess our problems in the light of it and act innovatively.

An important principle to guide us is to derive solutions that have wide-spread uses. This will help make what we design available to the disabled population. Matrices are like this. They could dim the boundary between prosthetics and orthotics and the boundary between disabled and able bodied persons. Computer aided design already does this. Robotic constructors are likely to have the same affect. I urge you to this — aim for universal solutions.

Epilogue

I have tried to show how, starting with limited information, some propositions that foster solution of difficult problems have come into focus. The time and effort and innovative skills of many people, some unknown, have been involved. That there are such people with the time and resources to solve problems is a prime requirement. They need to be in environments that are conducive to original thinking. Persons within or between groups need to be linked to permit complementary problem solving paths to develop. Innovating is not the province of a person or a group but is a flower that grows out of the human garden.

Innovative impulses need to influence not only what and how we design, but how we organize to do so. The need for cooperation and joint involvement in large projects is growing. Fortunately, the technical means are available to foster this. Seemingly separate entities such as standardizing shapes, designing modular systems, sensing shape, manipulating shape, transmitting shapes over the telephone, designing matrices and constructing custom shapes by robots coalesce as lively possibilities for automation of design and production of shaped components for prostheses, orthoses and orthopaedic footwear.

I cannot help but wonder how all of these things might have fared had they been part of an overall strategy fostered by cooperation of all of us engaged in prosthetics/orthotics research over the past few decades.

The necessity is for designers to overcome indifference to colleagues, mistrust, greed and jealousy so that field-adoption of comprehensive systems that can develop from joint efforts will be realized.

I personally feel that copyrighting and patenting are impediments to the free flow of information. Researchers would not be corrupted by the impulse to protect what they innovate in order to derive gain if the social means were available for the work they wish to do. The political problem is to foster mechanisms by which such programmes can be funded and the benefits be directly applied where the needs exist.

As I see it, we must be free of attitudes that keep us bound to our particular institutions. We must discount nationalism and ideologies to become truly conscious of our roles in relation to the world's people. Every person in our field plays some part in this. Manufacturers do when they make quality the factor of significance in their competition. Designers do when they encourage the best things to be used by the various participants in the rehabilitation field regardless of origins. Practitioners do when they stay informed and use what is best in the developing armamentarium. Educators do by trying new things, selecting the best and disseminating information about them. Funding agencies do when they are sensitive to grass roots inputs that identify appropriate objectives for research in support of services. Politicians do when they transcend political boundaries in response to world-wide needs.

These are the sorts of ideals that thoughtful men have brought to us down through the years.

An innovative approach to their implementation is to be encouraged.

ISPO is the means by which we keep in touch with each other for furtherance of our common interests. They are the sorts of interests Knud Jensen held for ISPO which he saw as an important element in the evolution of a brotherhood dedicated to the well-being of physically disabled people throughout the world.

I appreciate the chance I have had to outline a course of events that illustrates the innovative process, to give you these thoughts through the Knud Jensen lecture and to wish you an inspiring 5th World Congress of the ISPO.