Computer aided design, computer aided manufacture and other computer aids in prosthetics and orthotics

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Introduction

Development in computer technology and its application is very fast. Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) have now been introduced in prosthetics. What are these new technologies? What can we expect from them for the future? There is no doubt that we can expect dramatic progress in fitting technology, including quality, speed, capacity and low costs. It is the purpose of this presentation to use problems in contemporary fitting procedures as а background for discussion.

This development in computer technology is just beginning and of course very little is known about what the future will be like. New, unexpected tools will open new, unexpected possibilities to make new, much better prostheses. The computer is a tool, but it is a tool that will take over work from our hands, as well as from our brains. We are probably in for a revolution that will be much greater than the industrial revolution. There are reasons to be worried about forthcoming changes where, among other things, traditional professional experience and skill may become obsolete or unnecessary.

We all want the best for our patients all over the world. But we also want a happy and secure professional life for our colleagues. The most important step then, in my opinion, is that we prepare the young students in our training programmes for the future, and not for the past.

The future does not accept any precise analysis. By pointing out a few facts about the current state of development, a few possibilities and a few experiences from other fields, I hope to contribute to an increased awareness of what is happening.

What is CAD

Design is a creative, intellectual process, based on things like the specification of the aim, knowledge of physics, manufacturing, components, materials, calculation of strength, etc., experience from other designs, talent, intuition, skill and hard work.

Design is art work based on science.

The design process covers many activities, some of which are:

- generation of ideas
- creation of geometrical shapes
- calculations
- experiments
- simulation
- development of manufacturing data.
- The design approach may be:
- iterative
- direct
- choice from alternatives.

In the *iterative* approach a preliminary solution is developed through intuition or experience. Then the solution is analysed with reference to the demands that were specified for the product. If the specification is not satisfied, the solution is modified, and remodified if

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necessary, until it is acceptable, or until the designer is convinced that no solution is possible.

In the *direct* approach, an analysis of the problem is used for the direct development of an acceptable solution.

If choice from alternatives is used, many alternatives, all of them satisfying the specification, may be generated. After analysing all the alternatives, the designer selects and finalises the best one.

These approaches all fall into the following general design process:

- specification
- --- selection of design strategy
- solution of the design problem
- checking of the design
- preparation for manufacture of the design.

During the 20th century manufacturing may be said to have increased in efficiency by 1,000%, but design by only 20%. The reason is that it has been possible to increase the efficiency of manufacturing dramatically by means of machines, which has not been the case for design. The most important progress in design was the introduction, about two decades ago, of the computer as an aid for fast calculation. The calculation volume in a design can be very large.

The next step, now being developed and applied, is the introduction of such descriptions of geometrical configurations that they can be stored in computer memories, along with interactive graphic terminals, where the configurations can be displayed, or imaged, and modified by the designer. This is Computer Aided Design or CAD.

CAD is only at the beginning of its development, but it is already very powerful, especially if combined, or interfaced, with calculation of strength (FEM—Finite Element Method) and simulation of the designed object in operation. Such comprehensive applications are, however, very demanding as far as computer power is concerned.

Contemporary CAD systems may not be very convenient for a unique design, but as a "library" of knowledge is accumulated, the economic efficiency increases. It may not be practical for the design of a "Mark I", but it is much more efficient in modifying Mark I to produce "Mark II", "Mark III", etc.

The philosophy is that if the best abilities of

man are combined with the best abilities of the computer, the result will be better than if man made it alone. The computer can amplify the designer's memory, support his analytical and logical ability and take over repetitive routines. The designer will then supply creativity and experience to the design process, control it and organize the information about it. The following (economic) reasons for the use of CAD are frequently mentioned:

- avoid duplication of work
- simplify studying three dimensional geometries avoiding physical models
- simplify input of data for analyses and display of results
- simplify documentation of the product
- store experience and information from previous designs.

What is CAM

CAM is Computer Aided Manufacture. Unfortunately there is no general agreement as to how much is included in CAM. In the USA, CAM covers the preparations for manufacture as well as the manufacture itself. In Sweden CAM covers the preparations only. In this presentation the US concept of CAM is applied.

One of the economic reasons for using CAD is that time consuming steps, other than the design in the process of production, can be integrated into the system. The most obvious operation is then the connection to numerically controlled production machines. Interfacing CAM to CAD is obvious and rational, but CAM can be used and has been used for a long time without CAD.

CAM has been applied for a much longer time than CAD and it is less critical than CAD as far as the introduction of Computer Aided Socket Design is concerned. In this context it is sufficient to understand CAM's potential of being connected to CAD for automatic manufacturing.

Applications to prosthetics and orthotics Reproducibility

Probably the most pressing problem in prosthetics and orthotics research, development and clinical practice is that the fitting procedure is not reproducible. The prosthetist learns how to use his hands and tools when making a cast of the stump to be fitted. The same is true for the modifications he may perform on the cast to

4

improve the function of the socket. He is working according to rules, habits or concepts that may vary from place to place or from country to country. The result depends on how the individual prosthetist interprets the rules and the concepts and how he applies forces (which is not a reproducible process) etc.

Some reference measurements are taken of the stump with calipers, but these measurements are also distorted by the individual's handling of the instruments, mostly because compression of soft tissues is involved.

When the socket is checked on the patient's stump there are two sources of information, the prosthetist's observations and the patient's reactions. The prosthetist's observations are qualitative but not quantitative, and the same is true for the patient's reactions. There is no method available to measure the result. If this repeated trial and error process leads to success, the reasons are not known.

There are two factors, of significance in this context, why so many amputees are successfully fitted. One is that there are so many skilled prosthetists. The other is of a psychological nature.

The lack of reproducibility in the procedure has some unfortunate consequences:

- the fitting procedure is sometimes, if there are many failures, a prolonged, painful, frustrating, depressing, expensive and maybe physically destructive experience for the patient
- probably many patients are left with unreasonably bad fits
- the fitting programme is more expensive than is necessary.

These comments are not insulting to prosthetists in general, most of them achieve a high average standard. Some are excellent but some must be below average standard. This is true for all professions and higher standards of fitting can therefore only be achieved through improved methods.

Lack of reproducibility is also a serious bottleneck in research and development. No prosthesis is better than the fit (the interface between the stump and the prosthesis) irrespective of the sophistication of the rest of the prosthesis. Often when a new prosthetic component is subject to evaluation, it is not possible to isolate the quality of the new component from the quality of the fit.

Resources

At the World Congress of ISPO in 1974, in Montreux, Switzerland, Dr. Einar Helander of WHO reported that there is a need to train 70,000 fitters if the rest of the world is to have access to the same capacity of fitting service as exists in Western Europe.

An ISPO workshop in Moshi, Tanzania, in 1984, states that "Recognising the size of the problems of prosthetics and orthotics services in the developing countries the traditional approaches from the industrial world have failed in solving them." (Jacobs and Murdoch, 1985).

The Swedish administration for support for developing countries, SIDA, noticed some years ago that not one of the 25 poorest countries of the world had rehabilitation of the disabled on the lists of priorities that they presented to SIDA. The money was needed for "more important tasks". Even in the industrialized countries it is already becoming apparent that less money is available for these services. On the other hand we want to continue to improve patient service. This may be accepted only if costs do not increase and this means methods must be better and cheaper.

The basic steps

The first step in current CAD/CAM projects in prosthetics is to find a way to arrive at an optimal socket shape from information about the stump. This is Computer Aided Socket Design (CASD). The second step is to find a rational way to manufacture the socket. The third step is to find a way to modify the socket if needed after checking it on the stump.

The problems in orthotics and fitting orthopaedic footwear are rather similar to those in prosthetics.

James Foort started to get interested in CASD as early as the beginning of the 1960's. His idea is that a limited amount of significant measurement on a stump is sufficient to define the shape of an adequate socket after the data has been processed to fit to a model. The model, which is a program in the computer, performs modifications in a way similar to the prosthetist's deformation of the stump when making a cast. The model actually represents experience from thousands of fittings. It is a common misunderstanding that the model is the final shape. The model is the transformation from the measured profile to the socket shape.

In Foort's current system the measurements used for the PTB prosthesis are the conventional antero-posterior and medio-lateral measurements at the knee, plus an anteroposterior measurement each inch or each quarter-inch down the stump. When these measurements are fed into the CAD computer, the shape is generated and presented on the monitor screen.

It is possible to look at selected cross-sections, modify the shape and see the new result. When the prosthetist is satisfied by the result presented on the monitor, the first CAD step is finished and the information can be used in the CAM step for automatic manufacture of the socket.

Such a system is already a reality through joint efforts between Vancouver and London, as described in papers which follow. It is fast. The CAD processing takes about 10 minutes, numerically controlled carving of a mould another 10 minutes, and making the socket in a "Rapidform" machine a further 30 minutes. The entire process, therefore, takes about 40 minutes to one hour. There is no need for a big, central computer in this system. An IBM personal computer is sufficient. The fact that it is sufficient points out a limitation of the system.

This limitation is not a criticism of the entire project. The joint project between the Medical Engineering Research Unit of the University of British Columbia. Vancouver. and the Bioengineering Centre of University College, London, is a total project-interfacing, measuring, design and manufacture. All individual steps have to be simplified as much as possible initially. When the whole process is under control, the details can be refined. The potential of the project is much more interesting than the fit of the sockets coming out of the Rapidform machine now. An evaluation of this project based upon patient trials now, would probably be an evaluation of the socket concept and not of the value of CAD/CAM. It would miss the point if not very carefully performed. The classical PTB concept has already been modified or replaced in many places.

Socket design possibilities

The James Foort concept utilizes limited profile information from the stump to generate the total shape of the socket. On the other hand, it is agreed that good surface fit is important. One example is when the medial flare of the tibia is used for weightbearing. Consequently, there is a need for a measurement technique that can feed surface information to the computer and the computer must be powerful enough to process this information. Furthermore, there may be a need to control the *volume* of the socket, at least if it is not open ended. Many doctors and prosthetists are of the opinon that the stump tolerates very little change in its original volume. Any modification of the shape has to be compensated for somewhere else in the socket. There is also, therefore, a need for a measurement technique that can feed volume information to the computer and a computer powerful enough to handle it.

This leads to the conclusion that measurement techniques constitute the most interesting area for research and development. The computer requirements, concerning hardware as well as software, are very much defined by the character of the input data.

- The three important questions are:
- 1. What is a good fit?
- 2. What information is necessary to achieve a good fit?
- 3. Which processing of the information is necessary to arrive at a good fit?

Current practice in measuring a stump is that a cast is made where as many of the modifications to achieve a good functional fit as possible are performed already during the casting. Further modifications are made at the workbench remote from the patient.

There are three basic principles available when measuring the stump:

- 1. The stump is not touched when measuring and only the surface is measured.
- 2. The stump is not touched when measuring and the surface, as well as the interior, are measured (X-ray, etc.).
- 3. The stump is deformed during measuring.

The trend right now is that scientists try to find ways of avoiding the third principle, successfully applied by prosthetists all over the world, in favour of the first and second ones. This is possible if:

1. Statistical documentation shows that the modification from the shape of the "free" stump to the shape of a good fit follows mathematically definable laws or rules.

2. The data available from measurement and other available means is adequate for the purpose.

This has led to a focusing of interest on:

- further development of James Foort's concept utilizing photographs or videodigital interpretation of silhouettes (in the sagittal plane)
- surface scanning by means of light (laser, moiré shadow, etc.)
- CAT (Computer Aided Tomography) scanning. CAT offers a possibility to actually study the bone/soft tissue distribution in the stump and use this information to determine the ideal modification of the shape.

It is, however, not impossible to combine CAD with a measurement technique that deforms the stump and actually during measurement physically creates the shape of the allowing for patient reaction. One fit. justification for this statement is the fact that automatic, computerized palpation devices are now being developed for diagnosing cancerous mammae. It is my view that soon interest will be refocused on the third principle. The reason stems from the question "What is a good fit". A good fit is not primarily defined by a particular shape of socket, but by the accommodation of the forces or pressures between the stump and the socket, to provide for comfortable and harmless weightbearing, stabilization and suspension. All forces are transmitted from the socket to the skeleton of the patient via soft tissues. Generally speaking soft tissues transmit forces in two ways, hydrostatically and elastically. The "elastic" force transmission appears to be the most critical one, as far as fit is concerned. The force chooses the "stiffest" way through the soft tissues. A uniform force or pressure distribution can be achieved even through a thin layer of soft tissues between a bone surface in the stump and the socket, but a local mismatching will change the pressure distribution, which may result in pain or damage.

The late *Gunnar Holmgren, one of the world's foremost prosthetists, known for his combined analytical capacity and manual skill, used to say that he wanted to create or simulate the working conditions for the stump when casting (and make a minimum of modifications to the cast afterwards). He applied pressures and checked the result, and the shape resulted from the application of pressure. He shared the opinion of many prosthetists that modifying a socket is not a matter of adding or shaving away a few millimetres here or there; it is rather a matter of modifying the pressure distribution when making the cast.

It is the writer's opinion, that the real break-through in CASD will take place when the system can simulate the socket on the stump, i.e. when we have an active Computer Aided Stump Measurement technique. I do not think that we will have to wait very long for this. This concept has for a long time been included in at least one development project.

CAD/CAM as a substitute

It has been realised for a long time that CAM reduces the need for qualified technicians and other blue collar employees.

One example of interest comes from a company making complicated tools, moulds, dies, etc. This company has now started to use an integrated CAD/CAM system. Three very important things have happened:

- 1. They can now design and manufacture tools in ¹/₅ of the time they needed pre CAD/CAM.
- 2. The process is controlled by engineers who know programming and manufacturing. There is literally no need for the company's skilled toolmaking craftsmen any more.
- 3. The craftsmen confess that the CAD/ CAM system can make shapes that they are not able to make.

It is natural that the labour unions organizing the craftsmen are worried when they find that the manufacturing process does not need their members. It has been agreed in this company that "workshop-floor-experience" is important when working with and controlling the system.

This may very well turn out to be an agreement for temporary comfort. Soon experience from the CAD/CAM system may be sufficient. Labour union spokesmen have confessed that the unions have no strategies to handle this new situation.

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Prosthetics/orthotics covers a lot of activities and many different appliances. It is at this point reasonable to look at possible alternative developments of the service and the future professional roles to make sure that the essence of patient care is not being lost.

It is not only a possibility but a reality that a socket, good or bad, can be made in a CAD/CAM system under the control of an operator who is able to interpret and quantify the patient's reactions in an iterative (repeated trial and error) manufacturing process. The computer can assist in performing the iterations more systematically, faster and more cheaply. It is obvious that this operator can be the orthopaedic surgeon or a completely new professional. But if he is the surgeon he will probably not be the orthopaedic surgeon with whom we are now familiar. There is every reason to believe that Computer Aided Surgery with Artificial Intelligence and Knowledge will also change surgery in the future. The most certain approach to future prosthetics/orthotics service is probably based on the assumption that no professional role is safe from change! A protectionistic approach may defend "fortresses" for a short time, but only as long as there are no alternatives available elsewhere.

It has not been possible for conservatives to avoid the development from mechanical watches to electronic ones, or to avoid computerized setting instead of cold typesetting, synthesisers instead of strings and musicians, mass produced shoes instead of invidually made ones, electronic alarm systems instead of guardsmen, and so on. It has not been possible, because the new and winning alternatives are better and/or less expensive! If there is a choice, the consumer, and not the supplier, makes the decision. We must ask then, how can we, in the light of current and future development of technology, make sure that the patient gets the best possible service at costs that can be accepted by those who pay for it? If others can do that better than our current professionals, we are simply losers!

This is by no means a new situation. Industry and the business world are used to facing substituting products and technologies. CAD/ CAM offers a technology that substitutes for the craftsmanship represented by prosthetists, orthotists, orthopaedic shoemakers and the technicians working with them. It is agreed in business and industrial management that:

- substitutes may limit profit, the more so, the stronger the buyer is
- the most "dangerous" substitutes are those which have a potential to improve costbenefit ratio....
- or those which are produced by companies in very profitable industries.

Before deciding upon a strategy for facing the threat imposed by the new substitute, it is important to consider the above factors and analyse the strength and the potential of the substitute. There is an unfortunate tendency to spend most of this analysis on the weakness or the negative factors of the new substitute. Very often this negative evaluation is based on the new substitute in a premature state of *development*, and the only result is temporary comfort and loss of time. It is not uncommon that competitors in a market join forces to act against new substitutes. Actually, one of the purposes of many professional associations is to seal the market against possible intrusions from new substitutes.

In trying to revue the strength of CAD/CAM in prosthetics/orthotics, it is necessary to analyse the "market". Most prosthetics/orthotics service is part of a political welfare programme. The service is provided by specialists (orthopaedic surgeons, prosthetists, orthotists, shoemakers, therapists, etc.), but the important economic decisions are made by the politicians or by administrative officers. The consumer and the buyer are not the same persons and the buyer has only second or third hand information about the service. As the buyer usually has no experience of his own about prosthetics/ orthotics service, he is perceptive to all kinds of information from different sources. He has the problem that costs have to be reduced and he may have to reduce the cost in contradiction of the opinion of the specialists. He may evaluate a substitute in a way that is very different from the way the specialist, representing the conventional products, evaluates the substitute.

The strength and potential of CAD/CAM and other interfaced computer aids

The following points identify the strengths of CAD/CAM, reasonable insight and an open mind would permit the identification of others.

- Although the results may be primitive, it is already possible to design and manufacture a prosthetic socket using a CAD/CAM system.
- All aspects of socket fit which have been discussed can be included if the measurement technique allows for surface and volume control, including the application of load at selected areas. This is possible with CAD using contemporary technology (although a lot of development may be required).
- CAD/CAM is reproducible.
- All modifications of a socket shape are quantitatively controlled and simply documented.
- CAD and CAM are backed up by enormously strong industries with good profit, huge research and development resources and good salesmen.
- Computer technology is a main topic area in schools and universities.
- Computer technology has such a strength in itself, that it may be easily sold to less informed politicians and other "decision makers".
- CAD/CAM interfaced with Computer Aided Production Planning offers cheap mass production of items where each unit is unique or "tailor made".

The real conflict

The computer is an instrument of great power and, for good reasons, it frightens many people. It started as a device for simple calculation, but produces an increasing challenge to human beings as it becomes better and better at storing knowledge and experience and utilizing it for intelligent decisions. It is much faster than we are, and by systems integration (CAD to CAM, etc.) it does not need us even as an interface between different systems. This is what many people feel, but computer science approaches our human and professional integrity even closer than that. Computer science now deals with analyses of the nature of knowledge, intelligence and creativity so that it will be possible to market computerized knowledge, intelligence and creativity by the end of the 90's. This is what is called the fifth generation of computers.

We in prosthetics/orthotics have good reason to look at the nature of knowledge, to be able to

understand better what is happening and to be able to communicate better. One aspect of this is the difference between apprentice education and academic education. A Swedish research team has coined the concept of silent knowledge versus articulated knowledge.

- An apprentice, following his master, learns how to do things and how to approach problems. He does not necessarily learn and understand why, so he may never be able to, or need to, explain why. He may end up being very skilled, but his knowledge is *silent*.
- In academic education everything is explained and analysed in qualitative and quantitative terms (hopefully), and consequently the knowledge is *articulated*.

computer The can only accept articulated knowledge. What will progressively happen is that the silent, sometimes secret, knowledge of the craftsmen will be, step by step, smoked out and analysed and articulated. This is the real threat and this is why contemporary and future education has to prepare the students for a world where knowledge, if it is possible, has to be articulated.

The computer, a knowledge sink!

There is an increasing awareness that computerizing routines may result in a loss of professional skill. Such observations have been reported in many areas. As adjustments of insurance claims are nowadays more frequently computerized, the traditional human communication with knowledgeable and sensible claims adjusters is, in some areas, no longer available. There is a similar situation in expropriation of land, where there may be no person with whom to discuss the value.

Another aspect is that the "golden ear" or the "professional eve" is encountered less frequently. This development started, however, before the computer was available to avoid negative "human factors", check lists have been used for a long time. The safety of an aircraft is controlled using a "check list" with as many quantifiable checks as possible. Minimum toxic outlet from a motor car is guaranteed by adjusting ignition, etc., to specific values. But there is no one who listens to the song of a perfectly tuned engine, and actually many servicers do not know the basic rules of, for example, adjusting the ignition of a car engine to the gas mixture from the carburettor. They do not know how to read out information from the colour of the spark plugs or the exhaust pipe.

Malpractice in medicine is a result of negative human factors and excellence is most frequently a result of positive human factors. People are not very often rewarded for eventual excellence, but they are frequently punished for malpractice. Consequently, there is a tendency to rely upon established routines. The better the punishment system is organized, the more true this is.

For the consumer who has not got access to the most excellent service, check lists or computerized programmes may guarantee a minimum standard, unfortunately with minimum communication.

In prosthetics/orthotics communication based on knowledge is important, and there are good reasons to look further into this aspect of development into computerization. The patient wants to be able to talk with someone who knows.

Impact on the roles of professionals and on education

There is, of course, one professional role which has to be considered first of all in this context, and that is the role of the prosthetist (and orthotist). Who is the best prosthetist? The one who is able to give the patient the best possible prosthesis, or the one who is able to convince the patient that he has got the best possible prosthesis? The answer is not obvious, as the acceptance of the handicap and the prosthesis is a subjective process, including intra-psychological and socio-psychological factors. It is my view that CAD/CAM projects develop tools for the prosthetist to enable him to improve the quality of his service. Limb fitting is very much a communication between the prosthetist and the patient. It is the prosthetist who interprets the reactions and the information from the patient and the doctor in such a way that a prosthesis can be made. I cannot see that this role will be changed, but there is no doubt that he will have to interpret in a much more precise way to be able to communicate with the computer. This is a normal development in any profession these days. I have seen people engaged in office work who refused to look at the

computer a couple of years ago but today play games with the computer and spend their evenings studying data processing. This is a matter of introduction and rather simple training programmes.

There are many problems though and there will be many conflicts. Some of the conflicts will actually be between different generations of prosthetists. There is no way to stop development and the profession will be changed, not for the first time. Those who do not realise this in time will face serious problems. Those who see this as a possibility will push the development and contribute to it.

Prosthetists and orthotists are now being trained for a career stretching forward some 40 years. It is obvious that we have to train them for the future as well as we can and accept that the profession will change. We may have to sacrifice many things that are more or less sacred now and the most obvious one is the emphasis on craftsmanship. We need good craftsmen, but the education programmes have to include more basic engineering, data processing and other sciences. We may also have to modify our criteria on how to select the students.

Although the quality of contemporary education in prosthetics and orthotics is very high, the limited application of reproducible and quantitative methods in the fitting procedure has probably delayed an understanding of the future need for basic engineering skills in the prosthetic service. For example, analysis of prosthetic alignment calls for an understanding of mechanics and the same is true when judging the strength of a structure.

It is, of course, the prosthetist/orthotist who should represent engineering competence in the clinical fitting team. This, by the way, is one of the reasons why in Sweden the professional title for prosthetist/orthotists has been changed to Orthopaedic Engineer. There is a need to back up the art of limb fitting with more science. It will not destroy the art but improve it.

In Sweden, before entering the prosthetics/ orthotics school, the students are required to have a college education in engineering. Consequently, they possess basic knowledge in physics, mathematics, mechanics, strength of materials etc. Topics that were difficult for former generations, like biomechanics, now tend to be much simpler to teach. It is interesting

CAD/CAM in prosthetics and orthotics

to note that these students are also very good in the practical parts of the education programme and that they are ready for personal responsibility in the clinical work in a very short time after graduation. Our Swedish experience is not unique!

Will this education guarantee a safe professional career? Of course not! But they are better prepared to follow developments and learn new things and they will be able to bridge between professional knowledge and experience in prosthetics/orthotics on one side and new technology on the other. The may be able to prevent development going wrong.

A piece of advice finally for those of you who want to involve yourselves in CAD/CAM in prosthetics/orthotics. Join experts. This is nothing for amateurs. You are, of course, a professional in your work. Every aspect of work has to be treated professionally and you will find experts in industry and in the universities. The experts also need your knowledge and experience to help them introduce their technology in our field.

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