TU/e EINDHOVEN UNIVERSITY OF TECHNOLOGY

Symposium : problems in the design of joint replacements

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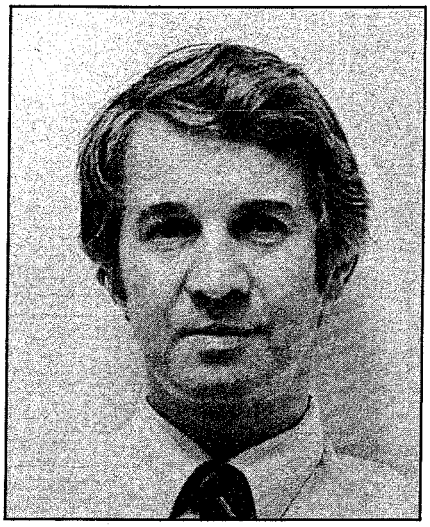
Category 1 CME Material

SYMPOSIUM: Problems in the Design of Joint Replacements



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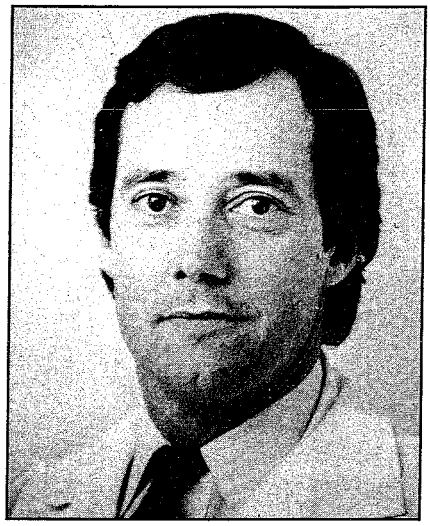

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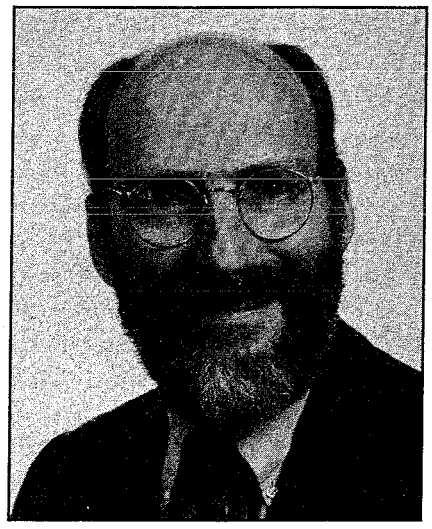

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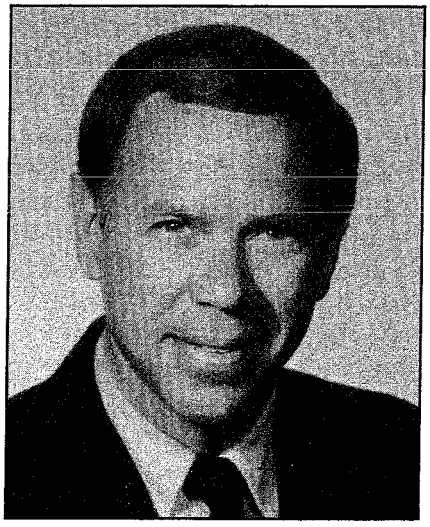

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INSTRUCTIONS TO CME ENROLLEES

The closed-book, multiple-choice examination that follows this symposium is designed to test your understanding of the content according to the educational objectives listed below. For CME enrollment information, see Table of Contents.

EDUCATIONAL OBJECTIVES

Based on the content of the symposium, enrollee should be able to:

1. Describe aspects of biomechanics and biomaterials as they relate to design considerations of total joint replacement prostheses.
2. Recall the clinical aspects of total knee and total hip replacement.

THE EXPERIENCE OF THE 1970s

WALKER: Before discussing today's issues, it is appropriate to put into perspective how we have reached the present status in joint replacement design. In this country, the main thrust in this field occurred during the 1970s. Dr. Volz, please begin our discussion by describing what you consider to be the most significant advances made in total joints during that time.

VOLZ: It is my perception that we learned a great deal about joint design from Mother Nature. A very efficient system had developed through the evolutionary process, and we learned that we needed to offer designs that replicated the normal biomechanics of the joint. One of the great advances was in the improvement of the interface design. During the 1970s, we also learned a great deal about the failure of implants, particularly metallic implants, and we saw the development of super strong metal alloys. I think we all would agree that the manufacturing techniques have been immeasurably enhanced during the past few years.

WALKER: Dr. Huiskes, what contributions were made in Europe?

HUISKES: Acrylic cement and low friction arthroplasty are two of the major European contributions (Fig. 1). I agree with Dr. Volz that progress has been made in the United States through a better understanding of the biomechanics of joints.

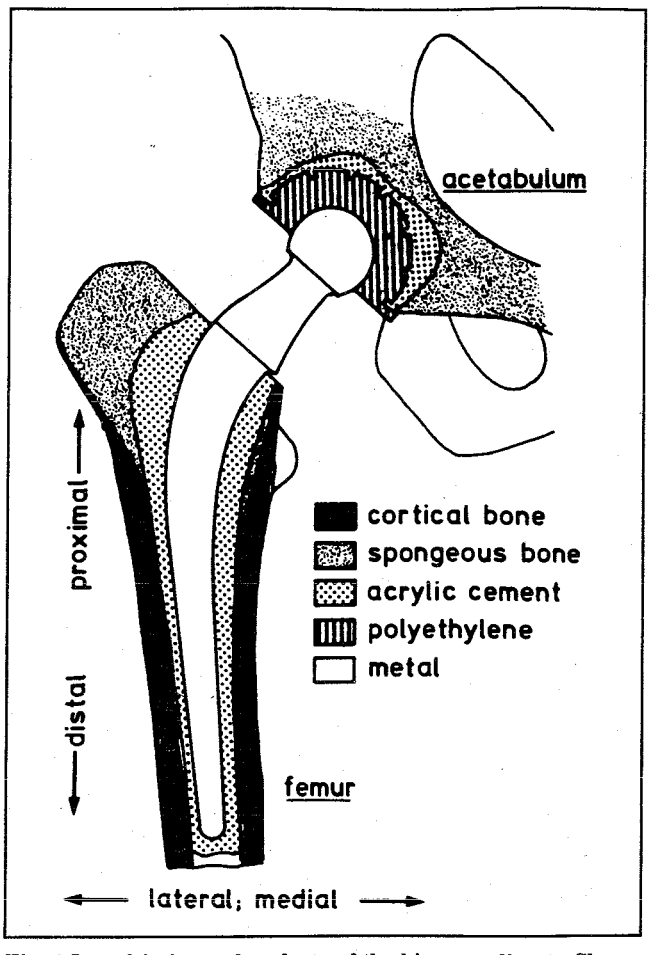

Fig. 1 Low-friction arthroplasty of the hip according to Charnley, using acrylic cement fixation.

JASTY: During the past decade, there has been considerable progress in incorporating scientific principles into the practice of orthopaedic surgery. The development of newer and stronger materials and improvements in the design of the implants and surgical techniques have led to substantial improvements in the success rates of total joint replacement procedures.

WALKER: What is your response to this question, Dr. Lotke?

LOTKE: One thing we began to appreciate about

total joints during the 1970s was that less constraint is preferable. In the mid-1970s we began using the Guepar knee prosthesis, a joint that is hinged and was doomed to fail. We have now learned that less constraint is better.

During the 1970s, there was a tremendous spread of optimism when we suddenly were presented the possibility of performing a low friction arthroplasty using cement. This procedure significantly improved the results of total knee joint replacements compared to noncemented joint replacements performed in the 1960s. However, as the decade went on, the enthusiasm became more circumspect. By the end of the 1970s, the limitations of this procedure were appreciated as some failures were seen.

The joining of forces by orthopaedic surgeons and bioengineers has been an exciting advance, resulting in improved designs of joint replacements. But that is a natural progression. More importantly, the appreciation of biology and the biological response has become more finely tuned. More energy is being expended on understanding the response of bone and tissue and a better appreciation of the biological response that occurs in bone. It is remarkable that there have been such advances in these areas in a ten-year period of time. Usually, such advances take much longer, but this has occurred with remarkable speed. The 1970s were a checkerboard that began with optimism and ended with a better appreciation of the problems. That decade was a very exciting period of time, but now we are in an even more exciting era.

WALKER: A large number of total knees were designed in the 1970s, but most of them lasted only a few years. What were the reasons for this? Were the surgeons and designers not sufficiently careful or thoughtful?

VOLZ: Several factors were involved. First, the designs were inferior. They did not match the mechanics of the normal knee. The soft tissue envelope and the interface that was being used were not in harmony. Second, performing a total knee replacement requires a great deal more finesse in handling soft tissues and alignment than is required at the hip. In the hip, the alignment of the components can be off by many degrees without creating problems that are seen in the knee with the same degree of malalignment.

LOTKE: Actually, the start-up time for hips and knees was about the same. Charnley worked on the hip for several years before he developed an acceptable design. The start-up time for Gunston, who introduced an acceptable condylar design in the mid to early 1970s, was about the same. That timespan to achieve a functional knee was not so great, considering that one of the designs introduced in the mid-1970s is still quite popular.

WALKER: Before moving away from the 1970s, let's briefly discuss the other joints. Although there was also an explosion of designs during that time for almost every joint including the wrist, elbow, and shoulder, there have not been many advances in design since then. It seems to me that for these other joints, the designs of the mid-1970s more or less represent the current state-of-the-art. Is this because the designers in general did such a good job on these joints?

VOLZ: These joints should not all be lumped together. For instance, the shoulder is similar to the hip. Both are basically a ball and socket, and the way such a joint works is somewhat simplistic. The early design by Dr. Neer has withstood the test of time because it is a good design. There isn't much more that can be done to change the interface except perhaps to add a bit more constraint if the rotator cuff is compromised.

In contrast, replacement of the elbow is still an unsolved biomechanical problem. Today, very few surgeons are performing total elbow replacements. I began doing total elbows in the mid-1970s, but I finally gave up on them. There is too much stress at the interface, creating a problem either of loosening or dislocation. There is a tremendous need for further refinement of designs for use in the elbow, particularly with regard to fixation.

At the wrist, the option of using silastic material is a practical and easy solution that has caught the

continued

attention of most surgeons who work in that area. We have designed an articulated wrist joint that has withstood the test of time. It is going to be modified, but it still is a reasonably good prosthesis.

The ankle is a joint that often does very well with arthrodesis, but the indications for that appear to be rather narrow.

Perhaps in part the answer to this question is that not enough effort has been put into developing these joints.

HEDLEY: I agree. The frequency of implantation of different joints should be compared to the frequency of implantation of hips and knees. More than 100,000 hip replacements and 50,000 knee replacements have been performed annually, compared to only several thousand of all the other joints combined. Unfortunately, we must get back to the basics, which in this case is a matter of economics. There is less incentive for spending time and effort on an area in which there isn't a high demand.

VOLZ: That is how the manufacturers look at it. However, a patient who has a very painful elbow has quite a different perception. I would make the plea that we need to continue to refine these joint designs, particularly those with complex planes of motion, and try to come up with better solutions.

LOTKE: Great progress has been made with the elbow joint during the last five years. I have been using an unconstrained elbow from Boston that is very satisfactory. That particular design has made great inroads into helping to solve the elbow problem. The use of hinges and various types of constrained elbows had been a problem in the past, but now several successful designs are available.

WALKER: Dr. Volz has said that a thorough understanding of normal mechanics and normal anatomy are required in order to design successful joint replacements. Dr. Huiskes, if that is correct, did bioengineers do a good job in the 1970s of elucidating the biomechanics of the more complex joints such as the elbow and wrist or did they pay too much attention to the hip and the knee?

HUISKES: The work is becoming more sophisticated as the years go by. There is no doubt that the emphasis has been on the knee and hip. Recently, more work has been done on other joints. However, we don't yet completely understand the more complicated biomechanics of joints such as the wrist. Based on the number of published papers concerning these problems, I agree with Dr. Volz that the manufacturers are less interested in encouraging research in areas in which there is less potential use. More research should be done in these areas in which there is still not much emphasis today.

WALKER: Given the fact that there now have been 15 years of evolution of joints, it seems that there ought to be a general consensus on the basic mechanical design of joints. Dr. Jasty, do you believe that the problem of the mechanical design of the implant is more or less solved? To turn the question around, are the major problems today how to interface the implant with the bone rather than the mechanical design?

JASTY: There is always room for improvement, especially when the procedures are performed in younger, more active patients. We have learned many important lessons from our collective experience of the past decade regarding implant designs. For example, we now know that it is important to have a metal backing on the acetabular component, which decreases the stresses in the surrounding cement and bone and increases the longevity of the prosthesis.[1] As another example, we found that femoral components should be made of high strength superalloy metals with smooth and rounded contours to minimize cement fractures.[2]

With the introduction of cementless components, however, a whole new set of problems emerged. With these devices, interfacing the implant to bone is critically dependent upon implant designs, as bone ingrowth and remodeling around these implants is influenced by the implant design, fit, and stability. While most of the currently avail-

continued on page 103

able cemented devices have similar overall shapes, the current designs of cementless devices are more variable. We are only now beginning to determine the parameters that govern bone ingrowth into these cementless devices. The real challenge now is to learn more about these parameters and design implants that promote healthy bone remodeling around them.

THE VALUE OF CLINICAL FOLLOW-UP STUDIES

WALKER: Concerning the issue of bone remodeling around an implant, what can surgeons and designers learn from long-term clinical follow-ups?

VOLZ: In the clinical follow-up we are seeking the response to the implant that has been inserted into a human being as a replacement for the original equipment. We must realize that even in this day and age, there is no perfect prosthesis. We are not capable of making an implant that can be inserted so that it will indeed offer some degree of permanency for the remainder of the patient's life, particularly if he is young and active.

We have been too superficial in the categorical assessment of patients, particularly as far as activity levels. Asking whether or not the patient uses a walking cane is not quite on the mark. We need to know what the upper level of activity is for these various designs. More importantly, there has been a tremendous lack of concern about the radiologic criteria for success. We are just beginning to see the development of rating systems in which the x-ray is considered in the overall score. The x-ray holds the key to what will happen in the future as far as the life of the prosthesis. That area needs to be developed and refined.

LOTKE: The training obtained in the laboratory is very important for furthering clinical studies; some of the best clinical studies have come from orthopaedists who have worked in the laboratory. The most important factor in a clinical study is to ask the appropriate questions. When a clinical study is initiated, it should be directed to solve a well-identified problem. The concept of asking specific questions in clinical research is something that has not always been well-established in the clinician's mind, yet this is essential in order to learn from long-term follow-ups.

HUISKES: This question about the value of the long-term clinical studies to solve clinical problems is probably the most important one that could be asked. We seem to accept the difficulties associated with conducting adequate clinical trials as being prohibitive. More should be done about improving the procedures for significant clinical research. The success of the designs must be investigated by good prospective clinical studies. Prostheses are much better than they were, but there is a great deal of room for study, analysis, and improvement.

JASTY: Without question, clinical studies are extremely important. We have learned a great deal from the clinical studies of the past decade. For example, cement fracture has been identified as being a significant problem that we hadn't considered during our earlier experience with hips. In addition, the clinical studies have shown that the cement-stem interface presents a significant problem that had not previously been identified.[3] Thus, clinical studies not only provided a good understanding of how we have done over the past ten years, they also indicate the direction we should be heading in the next ten years.

HEDLEY: We probably could conduct an entire symposium about clinical studies. The members of this panel represent a cross-section of investigators who are interested and participate in research, both clinical and otherwise. If we had available a fraction, even 10%, of the information that is available in the community concerning currently used prostheses, our learning curve would experience such a tremendous upswing that it would be difficult to believe what could happen.

I have had some experience with trying to retrieve clinical information from the community. Among the procedures I perform, 40% are revisions. Every x-ray of a revision provides a learning experience. An absolute wealth of material is available. Unfortunately, our experimental animal is not in the laboratory. We must recog-

nize the fact that our experimental animal is man. We try to fine tune things in the laboratory, then we take the big step of trying the procedure in man. All of the modifications have occurred because of failures in man, not in animals. As Dr. Volz suggested, the clinical information, particularly x-rays, is exciting and stimulating. As far as bone remodeling is concerned, it tells nearly the whole story.

We must bear in mind that the majority of implants are not done in the big centers but rather in the community at large. If we had a fraction of the information from that experience, we could take a giant step forward. We need to look at ways of acquiring that information. A good example of having come reasonably close to this is in Sweden. Generally speaking, the studies from Sweden are accurate, and they have contributed a great deal. However, there the population doesn't migrate across the country as it does in the United States. We need a way of doing this, but I don't know how it could be done.

LOTKE: That would be an excellent method of identifying the problem, but it wouldn't help to solve it. This relates to my initial comment on clinical research. The problems must be identified and then the questions asked in order to find ways to solve the problems. The community data would be a source of learning where the problems are and it would give us direction about the appropriate questions to ask.

HUISKES: I agree that all of these questions are very important. As Dr. Hedley indicated, there should be more emphasis on documentation. It is not so much a matter of seeing what the problems are at a certain point in time but rather of accumulating data. All too often, when a scientist who is doing research on a prosthesis attempts to investigate a certain hypothesis about the cause of a failure, the clinician who performed the implantation procedure indicates that all the documentation, including the x-rays, has disappeared. I am exaggerating a bit, but not much.

WALKER: Are you recommending that the major centers and individuals who are particularly interested in investigating a specific design should conduct these clinical studies or are you suggesting that this should be done on a global scale?

HEDLEY: It should be done on a global scale, but with a two-tiered system. On one level, the major centers could look for the kind of details that require research facilities to which the average clinician doesn't have access. Should a problem be identified in a given prosthesis, or in a given procedure, that center should be in a position to draw from the community's experience, and they should be able to trace those patients.

When we hear statistics presented at medical meetings stating that the success rate with a procedure is 80% or 90%, I would absolutely guarantee that is not the percentage experienced across the board in the community. Those data are reported from centers that specialize in the procedure, but the majority of procedures are not done in the major centers. Therefore, I don't believe the statistics necessarily present a true reflection of the situation.

HUISKES: An example of proof of that observation is that we have failures with surface replacement procedures, but those who developed them still have good results.

VOLZ: Although it would be ideal to retrieve data from all prosthetic implants, that may not be a realistic goal. However, it may be realistic to insist that data from experimental and new devices be made public. The concept of devices being put in and then pulled from the market place without the data having been published and made public knowledge means there is a wealth of information about failure modes that is not available to provide insight. A realistic accumulation of data might be possible if we insist that if a prosthesis is used, a public report must be made available so that we will know how those prostheses fail. That would be an excellent learning experience.

WALKER: I suggest all that would be learned from such a study would be that, in general, many who work in the big centers are more specialized,

continued on page 106

more experienced, more aware of the pitfalls of the designs, while many of those who work in the community are less aware of these things. Therefore, the success or failure is totally technique-related rather than design-related. The techniques have to be developed so that they become more foolproof.

VOLZ: But some of the problem is design-related. We probably could all agree that in the past there were prostheses that failed because of design, and I certainly believe that many of the systems that are evolving today may fail because of design. In fact, I am appalled at the lack of good reporting in the literature of some of the porous-coated devices that have a nearly hysterical degree of usage without good documentation. I don't understand how some people can abandon the gold standard of devices used with cement and use porous-coated prostheses when there is very little information in the literature documenting how these are doing.

WALKER: Concerning this issue of the importance of clinical studies, Dr. Lotke indicated that it is preferable to conduct a prospective study, determining in advance what question is to be answered. But I would suggest that in a clinical setting, as opposed to a laboratory setting, it is not possible to adequately measure many of the important parameters. For example, there is no method of measuring at surgery how precisely a hip stem fits into the canal. With a knee prosthesis, it is not possible to determine exactly how tight the knee ligaments are when the implant is put into the patient in order to predict how the loosening and stability would be affected. Since many of these things cannot be measured clinically, they must be measured in a laboratory somehow.

JASTY: Another aspect of this issue is that essentially we must wait for ten or 12 years before we get enough information from clinical studies, whereas in the laboratory some of the information can be gained much sooner, which can give some indications of the potential problems that may arise. One example is the use of canine total joint replacement models to evaluate some of the design features that may affect the bone ingrowth into the porous-coated implants.[4] From these studies we found that implants with pore sizes less than 150μm were not optimal for bone ingrowth. We also found that uniform bone-implant apposition and rigid initial fixation were critical for bone ingrowth and that gaps as small as 0.5mm between the bone and the implant were detrimental to bone ingrowth.

While the laboratory studies have been critical in the development of optimal implant designs, they cannot predict the clinical outcome in patients with certainty. Long-term human follow-up studies and retrieved implant studies are needed to accomplish this.

VOLZ: Actually, there are two different considerations in prosthetic design. One relates to the mechanical properties, stress distribution, and so on. Those parameters can be measured in the laboratory. However, the true essence of what we hope to achieve is measured against time. Mother Nature will tell us whether or not a particular device is biologically acceptable. The only way to develop the data is to study a sizable group of patients over a long period of time, hoping that the other variables are not so great that the end result is skewed.

LOTKE: It is possible to be more precise in obtaining clinical information than in the past, but we must adjust our thought processes in order to do so. I am not so pessimistic about the problems of answering some of these questions clinically. To use the example of the importance of ligament balance, it is possible to evaluate this, but the question would have to be asked at the operating table, with the tension measured in essentially the same manner in each of the patients in the series being reviewed. Then down the line, it could be determined whether or not the ligament tension is important. But the correct question must be asked first and the data collected prospectively. When the data are analyzed, the question will be answered. Unless a specific question is asked prospectively and the pertinent parameters are measured, there will be no answers.

TODAY'S APPROACHES TO IMPLANT DESIGN

WALKER: While we are still talking about research studies, what is the role of biomechanical laboratory research in these considerations of design, follow-up, and longevity, Dr. Huiskes? What should bioengineers be doing in this area?

HUISKES: Biomechanics is a field of basic science. We are trying to give a scientific basis for the procedures. For example, the bioengineer can answer in a laboratory study the specific question of how strong a material is. In the laboratory, parameters can be interrelated and hypotheses developed that can be tested in reality.

WALKER: Are engineers sufficiently involved in the actual design of implants? It's all very well to do theoretical and testing studies in the laboratory. But are surgeons generally doing the vast majority of the designing, and should the engineer play a bigger role?

HUISKES: We have come a long way from the time when a surgeon suddenly came up with an idea and a new joint was born. Although there are some exceptions, I would not say that at the present time the role of the engineer in the design of implants is too small. Overall, there is a great deal of cooperation in this area.

WALKER: Dr. Volz, you have designed a number of implants. Have you found that it is necessary or desirable to work in direct collaboration with engineers, or do you find that the biomechanical literature is of sufficent help in developing a design?

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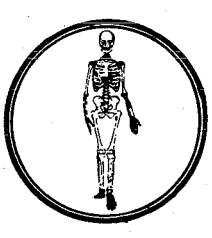

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VOLZ: I have found that it is absolutely essential to collaborate with good engineering talent. The joints have reached such a state of complexity that the design requires a multidisciplinary approach, and this is what I see happening in the industry. It is fortunate that the companies are skeptical about new designs. They are not willing to accept every design that is presented without careful analysis and discussion at many levels. I don't see that as a deficiency in the system. There are other areas that represent much greater deficiencies as far as what we are trying to achieve for the patient.

WALKER: What are some of those deficiencies?

VOLZ: One of the greatest problems that we need to face deals with the materials, the modulus of elasticity, the durability of materials under frictional forces. For instance, I think that putting a stiff metallic stem down the femoral canal is analogous to putting a steel rod down a garden hose. Of course, that is an exaggeration, but there is such a mismatching of moduli of elasticity that there are numerous problems with excessive stresses in some areas and stress-shielding in others. An implant is supposed to last for an indefinite period of time, but we can't expect that with devices fabricated of the presently available materials.

The future of total joint replacement lies either in the use of allografts, a better appreciation of how to arrest the mechanical deterioration of articular cartilage, or the development of sophisticated composites that more closely resemble what takes place with the bone under repeated loads.

HUISKES: I believe this idea about material stiffness is a misconception. The search for isoelastic materials has been going on for some time, and there is nothing in the literature that proves that isoelastic material is any good. Part of the problem is a result of a misunderstanding about structural rigidity, which in fact is partly a product of the geometry of the design. For example, in the hip joint, intramedullary canal fixation with isoelastic materials is potentially disastrous. On the contrary, the clinical experience indicates that quite often we rely on inherent rigidity in the prosthesis, for example, the metal backing in the knee joint and the acetabular component.

VOLZ: I agree that with the present state of knowledge, it would be a disaster to use the isoelastic materials that currently are available because of potential fatigue problems. However, that doesn't mean that we shouldn't be trying to search out better materials that more closely replicate the flexural patterns of the host.

LOTKE: The biggest single problem in implant surgery is related to the materials. We use allografts because we don't have a synthetic material that can do what an allograft can do, which is to behave like bone. We are using allograft as another material; it just happens to be of human origin. If we had the technology to duplicate that allograft, we would be using that particular material. Whatever the parameters turn out to be for making an ideal prosthesis, the answer will be related to the material. The future lies in designing and developing materials that simulate the body's own material.

VOLZ: If you see this as a biological problem, you are right. If you see it from a purely mechanical point of view, you are wrong. As long as there is an interface between a stiffer artificial material and living bone, problems of stress distribution will exist.

LOTKE: I see it as a purely biological problem. Bone is very dynamic; approximately 10% of it is replaced every year. There is a turnover of bone at the junction between the prosthesis and the bone. Where once there was a stable interface, it suddenly is unstable as bone remodels or is stress-shielded. In part, it relates to the materials that are being placed adjacent to the bone.

WALKER: Let's separate the issues. Although there are other types of bonding, let's suggest for the moment that there is a rigid bonding between the material and the bone. Dr. Huiskes, can you expand on why you disagree with Dr. Volz and

continued on page 112

others in the group that an isoelastic type of material is desirable? Many reported studies have indicated that the more rigid the stem, the more problems there are with the bone. For example, proximal bone resorption seems to be a function of excessive rigidity of the stem. Therefore, how can you say that the search for a lower modulus material is not a good goal?

HUISKES: The rigidity of the stem is a relative thing. The stem has a certain flexibility. The thicker it is, the more rigid it becomes. If a material has half the modulus of elasticity, the stem has half the rigidity. If the thickness of the stem is decreased by 16%, the stem also has half the rigidity. The elastic modulus of the material cannot be uncoupled from the geometry when considering structural rigidity. A flexible stem provides an increase in proximal load, which is good from the viewpoint of stress protection, but which is bad from the viewpoint of interface stress.

The experience suggests that a general statement cannot be made about the desired rigidity of the material. For instance, if a metal-backed acetabular cup is changed to ceramic, there will be no change in the load transfer. The metal-backed cup already is so stiff that a further increase in stiffness doesn't change anything as far as the bone is concerned.

The rigidity of the femoral stem, however, is another matter. The stiffer it becomes, the more stress protection occurs in the diaphysis. The more flexible the stem, the higher the proximal interface stresses and the potential for interface motion. The optimal rigidity is in between, where the degree of stress protection does not result in disastrous osteopenia, and the amount of interface stress does not cause loosening. In principle, it is feasible to determine the optimum. For instance, with regard to the problem of stress protection, there probably is a threshold stem rigidity beyond which the bone cannot remodel towards its natural stress level. The optimal rigidity obviously is below that threshold, but, in view of proximal interface stresses, is as high possible. Our research is aimed at determining the optimal rigidity of both the material and the structural components.

VOLZ: Have we reached that optimum as far as the mating of the materials that we are using with the biological properties of the bone?

HUISKES: No, not at all.

VOLZ: That is precisely my point. We have come to a point of agreement from different positions.

THE FIXATION METHOD IN THE HIP JOINT

WALKER: Most of this discussion has been about the hip and the design of hip stems. Dr. Jasty, if it is a given that there are shear stresses between a stem and the endosteal surfaces of a bone, what is the appropriate goal for that interface? Is it appropriate to try to rigidly fix the entire interface or is it appropriate to allow a certain amount of shearing motion to occur? With rigid fixation, there are shear stresses that ultimately can destroy the interface. Dr. Huiskes has pointed out that if more isoelastic materials are introduced, the shear stresses could increase, therefore the situation might be worse as far as the interface is concerned.

JASTY: I believe that the comments Dr. Huiskes has made are very appropriate. The important issues in this area are: 1) How rigid is rigidly fixed? and 2) How pliable is the adjacent bone? A certain amount of slip or motion occurs at the interface regardless of whether the implant is cemented or not. This is due partly to the pliability or compliance of bone and partly to the fact that bone is almost never chemically bonded to the implant material. The questions then are: What is the critical limit of this slip at the interface that can be tolerated prior to interface breakdown, and is it actually possible to totally impede the slip in the clinical situation?

The function of the bone cement is to minimize the amount of slip at the interface to levels that can be tolerated by the bone that interdigitates into the cement. If the implant is allowed to slip more, these interdigitations may break off and the implant may migrate grossly. The more isoelastic materials may increase the amount of this slip,

leading to implant migration.

On the other end of the spectrum, if the slip at the interface is prevented completely, there would be concern about high local stresses at the interface, stress-shielding, and adverse bone remodeling. This was a concern with fully porous-coated cementless femoral components. In the clinical setting, however, this problem may not occur with partially porous-coated components since the bone does not chemically bond to the implant and a thin layer of fibrous tissue develops over parts of the interface, especially around the nonporous regions. I believe that currently the problem is having too much slip at the interface rather than too little since there is no rigid chemical bond between the bone and the entire implant surface.

WALKER: Dr. Hedley, do the porous-coated devices provide the optimum compromise solution? Most of the porous-coated devices have a proximal porous coating to achieve proximal bone ingrowth, but the distal portion of the stem allows pistoning. Where there are shearing motions in the distal portion of the stem, no attempt is made to resist them.

HEDLEY: I don't know the answer to that question. We all are beginning to appreciate that on x-ray analysis there is a significant difference in how the bone reacts with a proximally porous-coated stem versus a fully porous-coated stem. A fully porous-coated stem provides proximal stress-shielding, whereas the reaction with a stem coated more proximally is totally different. I have x-rays of several patients who have a proximally porous-coated stem on one side and a stem that is two-thirds porous-coated on the other side, and they are totally different. From that point of view, my experience has been most illuminating.

I have been interested to hear the comments Dr. Huiskes has made because I believe we should not depart from the design in using stiff materials in different ways to impart load to the bone where it is desired. I think we can do that, whether with a porous-coating or a collar. We know that it is possible to load the calcar with a collar. However, if it is loaded at the top end through use of a porous-coating, the collar becomes superfluous.

My answer to your question is that there is a significant difference depending on where the porous coating is applied. In some of the experimental work in which we are involved, there may be an opportunity to put a porous coating with pores of different sizes on different areas, encouraging fibrous ingrowth at one place and bone ingrowth at another, to create a composite. Dr. Huiskes mentioned tapering of the stem. It may be possible to taper the stresses, going from solid bone to fibrous tissue to nothing.

We have only scratched the surface in the area of implant design. We have a lot to learn, and I am looking forward to the next several years.

LOTKE: As I interpret the comments that have been made, you all are saying that the general concept is to simulate normal physiologic loading of bone. With the designs used in the past, a stem cannot do that by itself, and it will not be able to unless there are significant design modifications because a stem is by itself unphysiological. Dr. Hedley is saying that normal physiologic loading in the proximal femur must be simulated in order to prevent stress resorption and the problems we have seen in the past. This will be achieved by a combination of modifications in both design and material properties.

HEDLEY: At the risk of sounding like a dissident, I must point out that you have used the words normal loading. However, that is not even in the back of my mind. I don't believe we will ever achieve that. I tell my patients that I cannot give them a normal joint, period. The limitations are so great that I am certain this is a true statement. We are trying to get within 50% of normal. We are so far away from that right now with the majority of designs that even 50% would be an improvement.

DESIGN OF TOTAL KNEES

WALKER: There has been a great deal of controversy regarding design considerations in the knee, particularly concerning whether or not the posterior cruciate ligament should be resected. Designs of both types are reported to be doing very

continued on page 116

Reference:
1. Panati C: *The Browser's Book of Beginnings: Origins of Everything Under (and Including) the Sun.* Boston, Houghton Mifflin Co, 1984, p 10.

Brief Summary
CEFOBID® (cefoperazone sodium) *For Intravenous or Intramuscular Use*
CONTRAINDICATIONS: CEFOBID (cefoperazone sodium) is contraindicated in patients with known allergy to the cephalosporin-class of antibiotics. **WARNINGS:** BEFORE THERAPY WITH CEFOBID IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.
PSEUDOMEMBRANOUS COLITIS HAS BEEN REPORTED WITH THE USE OF CEPHALOSPORINS (AND OTHER BROAD-SPECTRUM ANTIBIOTICS); THEREFORE, IT IS IMPORTANT TO CONSIDER ITS DIAGNOSIS IN PATIENTS WHO DEVELOP DIARRHEA IN ASSOCIATION WITH ANTIBIOTIC USE. **PRECAUTIONS:** Although transient elevations of the BUN and serum creatinine have been observed, CEFOBID alone does not appear to cause significant nephrotoxicity. However, concomitant administration of aminoglycosides and other cephalosporins has caused nephrotoxicity.
CEFOBID is extensively excreted in bile. The serum half-life of CEFOBID is increased 2–4 fold in patients with hepatic disease and/or biliary obstruction. In general, total daily dosage above 4 g should not be necessary in such patients. If higher dosages are used, serum concentrations should be monitored.
Because renal excretion is not the main route of elimination of CEFOBID, patients with renal failure require no adjustment in dosage when usual doses are administered. When high doses of CEFOBID are used, concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.
The half-life of CEFOBID is reduced slightly during hemodialysis. Thus, dosing should be scheduled to follow a dialysis period. In patients with both hepatic dysfunction and significant renal disease, CEFOBID dosage should not exceed 1–2 g daily without close monitoring of serum concentrations.
As with other antibiotics, vitamin K deficiency has occurred rarely in patients treated with CEFOBID. Those at risk include patients with a poor nutritional status, malabsorption states (e.g., cystic fibrosis), alcoholism, and patients on prolonged hyper-alimentation regimens (administered either intravenously or via a naso-gastric tube). Prothrombin time should be monitored in these patients and exogenous vitamin K administered as indicated.
A disulfiram-like reaction characterized by flushing, sweating, headache, and tachycardia has been reported when alcohol (beer, wine) was ingested within 72 hours after CEFOBID administration. Patients should be cautioned about the ingestion of alcoholic beverages following the administration of CEFOBID. A similar reaction has been reported with other cephalosporins.
Prolonged use of CEFOBID may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential.
CEFOBID should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. **Drug Laboratory Test Interactions:** A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** The maximum duration of CEFOBID animal toxicity studies is six months. In none of the *in vivo* or *in vitro* genetic toxicology studies did CEFOBID show any mutagenic potential at either the chromosomal or subchromosomal level. CEFOBID produced no impairment of fertility and had no effects on general reproductive performance or fetal development when administered subcutaneously at daily doses up to 500 to 1000 mg/kg prior to and during mating, and to pregnant female rats during gestation. These doses are 10 to 20 times the estimated usual single clinical dose. Cefoperazone had adverse effects on the testes of prepubertal rats at all doses tested. Subcutaneous administration of 1000 mg/kg per day (approximately 16 times the average adult human dose) resulted in reduced germinal cell population and vacuolation of Sertoli cell cytoplasm. The severity of lesions was dose dependent in the 100 to 1000 mg/kg per day range; the low dose caused a minor decrease in spermatocytes. This effect has not been observed in adult rats. Histologically the lesions were reversible at all but the highest dosage levels. However, these studies did not evaluate subsequent development of reproductive function in the rats. The relationship of these findings to humans is unknown. **Usage in Pregnancy: Pregnancy Category B:** Reproduction studies have been performed in mice, rats, and monkeys at doses up to 10 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to CEFOBID. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Usage in Nursing Mothers:** Only low concentrations of CEFOBID are excreted in human milk. Although CEFOBID passes poorly into breast milk of nursing mothers, caution should be exercised when CEFOBID is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in children have not been established. For information concerning testicular changes in pre-pubertal rats see Carcinogenesis, Mutagenesis, Impairment of Fertility. **ADVERSE REACTIONS:** In clinical studies the following adverse effects were observed and were considered to be related to CEFOBID therapy or uncertain etiology: **Hypersensitivity:** As with all cephalosporins, hypersensitivity manifested by skin reactions (1 patient in 45), drug fever (1 in 260), or a change in Coombs' test (1 in 60) has been reported. These reactions are more likely to occur in patients with a history of allergies, particularly to penicillin. **Hematology:** As with other beta-lactam antibiotics, reversible neutropenia may occur with prolonged administration. Slight decreases in neutrophil count (1 patient in 50) have been reported. Decreased hemoglobins (1 in 20) or hematocrits (1 in 20) have been reported, which is consistent with published literature on other cephalosporins. Transient eosinophilia has occurred in 1 patient in 10. **Hepatic:** Of 1285 patients treated with cefoperazone in clinical trials one patient with a history of liver disease developed significantly elevated liver function enzymes during CEFOBID therapy. Clinical signs and symptoms of nonspecific hepatitis accompanied these increases. After CEFOBID therapy was discontinued, the patient's enzymes returned to pre-treatment levels and the symptomatology resolved. As with other antibiotics that achieve high bile levels, mild transient elevations of liver function enzymes have been observed in 5–10% of the patients receiving CEFOBID therapy. The relevance of these findings, which were not accompanied by overt signs or symptoms of hepatic dysfunction, has not been established. **Gastrointestinal:** Diarrhea or loose stools has been reported in 1 in 30 patients. Most of these experiences have been mild or moderate in severity and self-limiting in nature. In all cases, these symptoms responded to symptomatic therapy or ceased when cefoperazone therapy was stopped. Nausea and vomiting have been reported rarely.
Symptoms of pseudomembranous colitis can appear during or for several weeks subsequent to antibiotic therapy (see WARNINGS). **Renal Function Tests:** Transient elevations of the BUN (1 in 16) and serum creatinine (1 in 48) have been noted. **Local Reactions:** CEFOBID is well tolerated following intramuscular administration. Occasionally, transient pain (1 in 140) may follow administration by this route. When CEFOBID is administered by intravenous infusion some patients may develop phlebitis (1 in 120) at the infusion site.

CEFOBID IM/IV q12h

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well in the clinical follow-ups so far. We have seen designs with a wide variation in laxity that have performed very well. Dr. Lotke, how much freedom of design is there, or is there an optimum kind of design?

LOTKE: The answer to your question about the design of the knee is quite complicated because it is actually multifactorial. In the general concept, the knees available today are remarkably similar in their overall contours and design, including the shape of the condyles and the tibial planes. The differences that are beginning to be seen are subtle, and it will be difficult to determine whether or not they are important without well-controlled studies.

The posterior cruciate is an example of one of these differences. Two prostheses, one saving the posterior cruciate and the other sacrificing it, are both functioning quite satisfactorily, and the overall appearance is that they are both successful. Only in the long term will it be possible to determine whether or not the posterior cruciate should be saved. Based on the present state-of-the-art, I don't know the answer to this question. I sacrifice the posterior cruciate, but others whose work I respect save it.

One major design consideration that can be modified from what is seen today, excluding the bone-prosthesis interface, is the meniscal-bearing concept. In the long run, the meniscal-bearing surfaces may provide a solution for the problems that would be apparent with knees that are going to survive for as long as 30 years because it would eliminate some wear problems on the metal-plastic bearing surfaces. The meniscal-bearing devices have not yet demonstrated long-term benefits, but I believe that is the area in which the next major design advance will be made.

WALKER: It seems that designs requiring resection of both cruciate ligaments would be subjected to higher shear stresses and rotational torque, and therefore the loosening would be much greater with such designs. Is there any evidence that this is the case?

LOTKE: According to the data, the total condy-

lar prostheses do not appear to loosen with time. Some have been in for as long as 12 years, and the late studies show that the knees continue to function well and that loosening is not a major factor. When the posterior cruciate is retained, it may be a constraining force that is not compatible with the design of the particular knee. In other words, the axis of rotation in the posterior cruciate may be different than in the prosthesis. Therefore, retaining the ligament may actually put increased constraint into the prosthesis, and it may loosen.

WALKER: Do you have any views on this question, Dr. Volz?

VOLZ: It is a multifactorial question that is difficult to answer. At this point, we need more clinical studies to look at the issue carefully. How the device will perform also relates to the insertion technique. Intuitively, I would say that sacrificing the posterior cruciate will lead to greater stress on the bone-cement interface, therefore resulting in a higher failure rate. However, there are no data to support that prejudice.

WALKER: What about the amount of inherent laxity in the design of a total knee replacement? How much is too much, and how much is too little? It seems that a device that allows an immense freedom of motion, providing no inherent stability, would overstress the remaining structures of the knee.

VOLZ: I have not seen that with unicompartmental replacement, which has absolutely no inherent constraint. I have not seen a progression of deformity, or even a progression of breakdown of cartilage on the opposite side. If we use that as a model, I would have to say that a lack of any constraint at the interface doesn't appear to be a problem.

LOTKE: With the present generation of total knees, the alignment is more important than absolute ligament tension and stability. The patient walks with an essentially stiff knee gait. The knee is locked, then the patient plants it and walks over it. The static alignment is key in that particular situation. If the ligament stability was perfect, perhaps it would not be necessary for the patient to stiffen the knee so much.

HEDLEY: This brings up an important question because we do not operate on normal knees, we operate on "sick" knees. It is fundamentally important to keep this in mind in order to understand why patients don't do well clinically, why they don't get the anticipated range of motion. In the laboratory, we simulate normal knees; the ligaments are normal and there are no complications such as scarring or capsular contracture. We simulate normal knees, and we develop a generation of anatomically correct knees. The question is, when we operate on a sick knee, should we let it do what it wants to do? In other words, should there be total lack of constraint and direction, or should the device dictate to a certain extent where rotation does and does not occur, whether the condyle is allowed to roll back or is kept in position? This is a fundamental question, and I don't know the answer. If we had the answer, we would know what to do in total knee replacement.

HUISKES: What Dr. Hedley has said is true. We have been studying normal joints. One difference between the United States and Europe is that the approach in Europe is much more conservative. The amount of joint deformity prior to the eventual operation is more extensive and the results are not as good. From a research point of view, I believe that we will head in that direction once these knee joint models are in the stage that they can be used clinically. It is very important for us in our research that in the coming years years we are able to obtain postmortem material with documented deficiencies in order to try to categorize the deformities.

LOTKE: Dr. Hedley is assuming that there is one normal knee motion. The fact is that every normal knee has a tremendous amount of variation and there is not one fixed motion path. Secondly, every knee has a different kind of laxity. Trying to dictate one particular kind of motion would violate the normal function of an individual knee.

continued on page 121

HEDLEY: Again, you are using the word normal. I prefaced my comments by saying that we don't operate on a normal knee. I am not certain that a normal knee does have that total lack of constraint. Sick knees don't. They form osteophytes, the cartilage disappears, eburnation of the bone is seen, and a track often is seen because they are unidirectional knees. The knees I operate on don't have that laxity. It is correct to say that if a total knee replacement is put into a normal knee, the result will be great. The knees with deformity are the biggest problem when we are trying to recreate an acceptable range of motion and maintain stability. Looking at normal knees is terribly misleading when we are designing total knee replacements. No currently available knee replacement provides routinely and uniformly restored normal flexion. The average is 105° of flexion. The question is whether or not that is acceptable. I don't know that it is.

LOTKE: At present, it is not possible to reconstruct a knee to normal. There is a biological spectrum of size, shape, configuration, laxity, etc., yet there are only three or four fixed sizes available to replicate this biological spectrum. It is difficult to reproduce the normal anatomy of the knee by using a prosthesis from the shelf, therefore there always will be some compromise in function.

HEDLEY: We are trying to reproduce function, and then we get into the whole issue of whether or not to retain the posterior cruciate. Intuitively, I agree with Dr. Volz that it should be retained. Historically, the results with the total condylar knee have been excellent. That prosthesis dictates to the knee where it will go, not vice versa. We have introduced complications by designing anatomical knees, some of which don't perform as well as a total condylar. We have complicated the issue, and we need to clarify it by looking at the fundamental principles we are attempting to pursue.

VOLZ: Part of the issue is how the surgeon out in the field can match the patient's deformity and the changes in the soft tissue envelope with the degree of constraint required to maximize function of that knee. One area that is very deficient in the present state of total knee replacement is the need for coding of the degree of constraint at the interface. For instance, if there was a grading of one to five, with one being the least constrained, we would know a grade four would offer a given degree of constraint, and this would be comparable with other manufacturers. We would have at least some idea of how much constraint is being put into the knee and how much soft tissue stability is being relied upon. Such a system would be a great help to the average surgeon.

JASTY: There is no question that converting the kinematics to the normal situation is inexact. While it is possible to establish a set of parameters to define the normal kinematics, the question is whether we can actually replicate that with our designs or with our techniques. For example, if the posterior cruciate is preserved, should the anterior cruciate also be preserved? If the answer to that is yes, the question is whether that actually can be done in the surgical setting. Given current technology, I don't think we can.

HEDLEY: Approximately 50-75% of the patients we operate on don't have an anterior cruciate ligament.

WALKER: One final issue in knee design that was mentioned previously is the wear of the material. The underlying issue in the concept of a meniscal-bearing knee is that it would reduce wear. I believe long-term wear may well be a problem with the knees of present designs. The evidence is there on retrieved implants. Many retrievals at ten years have an alarming amount of surface destruction. My question is, does that matter? What role is it going to play in reaction to the tissue? Is it going to be a factor in loosening of the implant over the long term?

JASTY: Wear debris is an important problem. Many implants have small radiolucencies over portions of their interfaces, but function quite well for a time. Benign fibrous tissue occupies these areas of radiolucencies. However, particulate debris, whether fragmented methylmethacrylate

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or wear debris from the polyethylene liberated into the tissue, changes this to an aggressive biological tissue response that may cause resorption of the adjacent bone.[5]

We looked at the tissue obtained at retrieval surgery from patients with well-fixed components and from patients with loose components.[6] The membrane at the bone-cement interface obtained from patients with well-fixed components was composed of benign fibrous tissue without macrophages or particulate debris. The membranes obtained from patients with clinically loose components contained large amounts of polyethylene wear debris and particulate methylmethacrylate and was richly infiltrated with macrophages and giant cells. These data suggested that particulate debris due either to wear of polyethylene or fragmentation of methylmethacrylate plays a critical role in the pathogenesis of bone lysis and may play a role in implant loosening.

THE ROLE OF DESIGN AND FIXATION IN TODAY'S PRACTICE

WALKER: Getting back to fixation, what should the current role of cemented hips and knees be in the routine practice of the orthopaedic surgeon?

VOLZ: For the orthopaedic surgeon in private practice, cement could be the gold standard. Unless he has exceptional talents and has had special training, he should continue to use acrylic cement until we know precisely what the role of some of these other techniques is going to be. In fact, there is only one porous-coated device that has been approved by the FDA. The surgeon who chooses to use an implant that has not been approved puts himself at risk, and also perhaps the patient. The techniques for inserting the porous-coated devices are more demanding, the fit must be very precise, there probably will be more intraoperative complications, particularly insertional fractures. In addition, there are no hard data to indicate that a noncemented device consistently measures up to a cemented device within the first few years following the surgery.

LOTKE: As Dr. Volz indicated, cement fixation is the gold standard. At this time, we should continue to use cement except under experimental investigational circumstances. Although I have some reservations about the porous coatings, I believe that the future of implants is in porous surfaces. However, it is almost like dynamite, which is a great tool when it is used correctly, but is destructive when it is used incorrectly. At this time, we do not know what is going to be destructive and what is going to be advantageous five or ten years from now. During the next decade there is going to be a learning curve as we gain more experience in this very exciting area. However, we don't have the answer yet. The orthopaedic surgeon working in a private practice should continue to use cemented implants while research centers work for the next few years to develop the use of porous materials.

Because I am from Philadelphia, where it is a major subject of debate, I would like to make a comment about toxicity of porous material. We have often talked about the surface area and potential toxicity of the metal ions, which we tend to think of in terms of systemic toxicity. However, we lose sight of the fact that there also is local toxicity. The question is whether the ingrown bone that is seen at one to two years is going to continue to remain ingrown in the site of high concentrations of heavy metal ions or whether there are going to be local toxic effects with local bone necrosis. Obviously, I don't know the answer to this question, but time will tell. Toxicity is an area that makes the porous coating a little dangerous until we have had more experience with it.

JASTY: We must separate what we already know from what we think will happen. We know that with current cementing techniques the cemented total hips function well in the vast majority of patients. Our minimum five-year results with cemented femoral components done with plugging of the femoral canal using a cement gun showed a 1.7% incidence of loosening, which is satisfactory for elderly patients.[7] The problem, however, lies with the younger, more active patients in whom the porous-surfaced, uncemented implants that provide biological fixation by bone ingrowth are at-

continued on page 124

tractive for improving long-term fixation.

I do not believe that the mechanisms by which long-term implant anchorage is obtained are different in the cemented and cementless implants. However, there are several advantages in using each. With cement, the accuracy of the initial fit is not a major problem because cement fills in the gaps. Rigid initial stability is easily obtained using cement and the procedures are easier technically for the surgeon. On the negative side, there are concerns about the strength of the cement mantle, the strength of the interface, and the biological consequences of cement fragmentation. On a theoretical basis, the concept of bone ingrowth and biological fixation are more attractive. There is no cement to fragment and excellent interface tensile strength with bone can be obtained. However, there are new sets of problems with cementless implants that we have not anticipated, just as there were problems with cement that we did not anticipate in the early 1970s.

One of the problems with cementless devices involves getting an accurate fit of the implant in the bone. We know that gaps as small as 0.5mm can inhibit bone ingrowth. Precise instrumentation, surgical skills, and implant manufacturing skills are needed to achieve such precision. The cementless implants also need rigid initial stability to obtain bone ingrowth. In some situations, such as that with our acetabular component, rigid initial stability is easily obtained by inserting the component into a precisely reamed hemispherical cavity and by using ancillary fixation devices such as screws placed through the component into bone. However, the stemmed femoral components and the pegged tibial components rely on interference fitting within a slightly smaller hole machined into bone for initial stability. The tolerances for interference fitting of a metal component into bone are very small. There is a high risk of fracturing the adjacent bone and losing the initial stability with interference fitting.[8] We also don't know how much porous surface is needed for long-term implant stability. An additional problem that Dr. Huiskes mentioned is that we don't know the mechanisms of stress transfer around the porous surfaced implants.

I currently use cementless femoral stems only in very young patients. In the vast majority of elderly patients, I prefer to cement the femoral components using contemporary cementing techniques. On the acetabular side, however, it is more difficult to do a good job with cementing, and I use cementless acetabular components regardless of the patient's age. In time, as we learn more about the design parameters important for cementless components, I suspect that our indications for these devices will broaden.

WALKER: Dr. Hedley, you give the impression of being more enthusiastic about the clinical use of cementless implants. What is your recommendation concerning the use of cemented versus cementless implants in the general orthopaedic practice?

HEDLEY: In principle, I agree with Dr. Volz. However, I take a slightly different tack because I do a great number of revisions. I perceive that in clinical practice right now there is an urgency to come up with a solution for younger patients. Either that or the clinician must stop doing cemented total joint replacements in patients under 65 years of age, as John Charnley suggested, because younger patients are having enormous problems.

Based on all the reported series, we know that revisions probably don't do as well as primary procedures. We are seeing young patients who come into the office with a failed procedure. The down side to failed total joint replacement is irretrievable bone loss unless something extraordinary is resorted to in an attempt to replace the bone. We don't know how the cementless primary procedure is going to fare in the long term, yet we are beginning to perform cementless revisions in an attempt to regain lost ground.

I look at cemented total joint replacements with a very jaundiced eye because I see a large number of patients requiring revisions. In an elderly patient, a cemented stem is quite acceptable. I cannot intellectually, however, ignore the fact that there is a biological response to that cement regardless of how old the patient is. Regardless of how well the cement column looks in five years,

continued on page 126

Dilaudid® C II
hydromorphone HCl
Warning: May be habit forming

INDICATIONS AND USAGE: For the relief of moderate to severe pain.
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WARNINGS
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Respiratory Depression: DILAUDID produces dose-related respiratory depression by acting directly on brain stem respiratory centers. DILAUDID also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.
Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce effects which may obscure the clinical course of patients with head injuries.
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Drug Interactions: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, tranquilizers, sedative-hypnotics, tricyclic antidepressants or other CNS depressants (including alcohol) concomitantly with DILAUDID may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.
Parenteral Administration: The parenteral form of DILAUDID may be given intravenously, but the injection should be given very slowly. Rapid intravenous injection increases the possibility of side effects such as hypotension and respiratory depression.
Pregnancy: *Pregnancy Category C.* Teratogenicity shown in hamsters at 600 times the human dose. There are no adequate and well-controlled studies in pregnant women. DILAUDID should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.
Labor and Delivery: Administration of DILAUDID to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.
Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: Safety and effectiveness in children have not been established.
FD&C Yellow No. 5: DILAUDID 1 mg, 2 mg and 4 mg color-coded tablets contain (tartrazine) dye which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. It is frequently seen in patients who also have aspirin hypersensitivity.
ADVERSE REACTIONS
Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, pyschic dependence, mood changes.
Gastrointestinal System: Nausea and vomiting occur infrequently; they are more frequent in ambulatory than in recumbent patients.
Cardiovascular System: Circulatory depression, peripheral circulatory collapse and cardiac arrest have occurred after rapid intravenous injection. Orthostatic hypotension and fainting may occur if a patient stands up suddenly after receiving an injection of DILAUDID.
Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.
Respiratory Depression: See WARNINGS.
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it may not endure, and the biological response will be the same.

What is the down side of a failed cementless joint replacement? I can't answer that, but I believe we should look at the down side. Is the down side the same as osteolysis, bone loss, a difficult revision? We have a population of patients who are not even in middle age yet who are in serious trouble.

Dr. Lotke mentioned ions. I am concerned about ions, but I am more concerned about limbs that are lost due to irretrievable bone stock loss. I know of several amputations that have been necessitated by irretrievable failure, not because of malignancy, but because the cement ate away the bone.

WALKER: In all fairness, you may be talking about patients whose procedures were performed five or ten years ago in an era when the experience level was far lower. The fact is that the better series of cemented total knees and hips report very low incidences of failure.

HEDLEY: The total knee is a different matter that should be separated out. I don't feel the same concern if a conservative cemented total knee is used. But I am really concerned about hips. I am beginning to form the opinion that a cemented acetabulum should not be used because the cementless ones do well. We really must defer to Europe where they have a long experience with this. I have seen some eight-, nine-, and ten-year results from Dr. Lord in Paris that are outstanding. There is no other way to describe them. Although it is a significant problem, we should not look at an uncemented joint with the same kind of pessimism as when we are looking at failures. At the present time, the revision rate for total hips is 10%. That is 10,000 patients per annum. It is a significant problem. The foundations that we have built with cement are weak. We are facing a new industry, which is called revision surgery. What do we do with the massive bone loss?

JASTY: Dr. Hedley, why do you think there is an adverse biological response to cement?

HEDLEY: The body doesn't like cement, period.

It is a foreign substance and there is a foreign substance response to it.

VOLZ: Is it the cement or the stem?

HEDLEY: The body dislikes fragmented cement. To date, mechanics about the stem have not been able to maintain the integrity of the cement column which has cracked, fragmented, and led to eventual failure due to loosening.

VOLZ: I think there is more to it than that. The Swedish investigators have done some interesting studies in which they implanted chambers into the tibias of rabbits [Personal communication: Albrektsson T: Department of Anatomy, University of Göteborg, Göteborg, Sweden.]. Various materials were placed in these chambers, which were then looked into using optics. When methylmethacrylate was put in these chambers, it was not fragmented. There was a slower ingrowth of bone than when the methylmethacrylate was not present. This suggests that there is something offensive about the presence of methylmethracylate. I don't know why this is, but intuitively many of us feel that the body finds it biologically unacceptable. Again, I would say that cement is still the gold standard. Its use should not be totally abandoned, but it is normal that we look for alternate means of fixation of these devices.

JASTY: I do not see in our own studies or in reviewing the literature any strong evidence that the body does not like bulk cement. While fragmented cement induces a strong foreign body response, there is evidence that bulk cement is relatively inert.[9]

HUISKES: We have been involved in an analysis of the research conducted in Sweden on heat conduction. It is interesting to see that in Sweden there is considerable interest in what heat does to bone, but in the rest of the world they don't worry about it. I believe that heat is a potential problem, but I also believe it can be solved. There is a great history in orthopaedics of throwing away good concepts just because minor problems are involved that may be solved. According to some animal experimental work we have conducted and also retrieved joint replacements, it is amazing what modern cementing techniques can do for implant fixation.

CUSTOM-MADE IMPLANTS

WALKER: In this era of cost containment, are the present implants becoming increasingly more expensive? If that is the case, is the goal of customizing an implant for each individual patient unrealistic and unnecessary?

VOLZ: The use of a custom-designed implant for each individual is unnecessary, and it is fiscally irresponsible in today's world.

HEDLEY: Imposing fiscal restraints on the quality of medicine is unethical.

LOTKE: I agree.

JASTY: Cost can be prohibitive now, but with advances in manufacturing technologies, it may come down. I also am concerned about the instrumentation required to accurately fit the complex shapes of the custom prostheses.

LOTKE: Foresightful planning and design are essential. Then there will be less compromise between the ideal perfect fit and reality. Cost must always be considered as well as the practicality of stocking huge quantities of devices to meet every individual need. Somewhere in the middle is the real world.

WALKER: I would like to thank each of you for your contributions to this discussion.

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continued on page 130

Surgical Simplex® P Bone Cement*

*Also available as Surgical Simplex® P Radiopaque Bone Cement with Barium Sulfate.
(Methyl methacrylate; mixture of Polymethyl methacrylate, Methyl methacrylate-Styrene-copolymer with Barium Sulfate).

Indications

Surgical Simplex® P Bone Cement (Methyl methacrylate; mixture of Polymethyl methacrylate, Methyl methacrylate-Styrene-copolymer) is indicated for the fixation of prostheses to living bone in orthopaedic musculo-skeletal surgical procedures for osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, sickle cell anemia, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty procedures. The drug is also indicated for the fixation of pathological fractures where loss of bone substance or recalcitrance of the fracture renders more conventional procedures ineffective.

Contraindications

The use of the drug is contraindicated in infectious arthritis and in active infection of the joint or joints to be replaced or if there is a history of such infection. It is also contraindicated where loss of musculature or neuromuscular compromise in the affected limb would render the procedure unjustifiable.

Warnings

For safe and efficacious use of Surgical Simplex® P Bone Cement (Methyl methacrylate; mixture of Polymethyl methacrylate, Methyl methacrylate-Styrene-copolymer) the surgeon should have specific training and experience to be thoroughly familiar with the properties, handling characteristics, and application of the drug.

Because of a lack of adequate information, the use of the drug is not recommended in younger patients.

AS THE LIQUID MONOMER IS HIGHLY VOLATILE AND FLAMMABLE, THE OPERATING ROOM SHOULD BE PROVIDED WITH ADEQUATE VENTILATION SO AS TO ELIMINATE THE MAXIMUM AMOUNT OF MONOMER VAPOR. CAUTION SHOULD BE EXERCISED DURING THE MIXING OF THE TWO COMPONENTS TO PREVENT EXCESSIVE EXPOSURE TO THE CONCENTRATED VAPORS OF THE MONOMER WHICH MAY PRODUCE IRRITATION OF THE RESPIRATORY TRACT, EYES, AND POSSIBLY THE LIVER.

The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The component should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

Long-term durability, wearability, and stability of the hard polymerized cement *in situ* is unknown; therefore, long-term follow-up is advised for all patients on a regularly scheduled basis.

A carcinogenic study in rats did not show any cancer formation attributable to the drug. However, until long-term well controlled clinical studies are available, the carcinogenic potential of the drug in humans is unknown.

It has been recommended by manufacturers of soft contact lenses that such lenses should be removed "in the presence of noxious and irritating vapors." Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

Precautions

Data from clinical trials dictate the absolute necessity of strict adherence to good surgical principles and technique. Deep wound infection is a serious postoperative complication and may require total removal of the prostheses and embedded drug. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Care should be taken in the mixing of the liquid and powder components that the entire contents of the ampul and pouch be utilized. The mixing of the liquid monomer and the powder component should be thorough and vigorous. Data from *in vitro* studies have shown that monomer loss is related primarily to the frequency of stirring and secondarily to the duration of stirring.

Caution, however, should be taken to avoid kneading of the drug too long to avoid progression of the polymerization process to the point that the drug is not adequately soft and pliable to obtain good filling of the bone cavities and fitting to the prostheses.

After application, during the completion of the polymerization process of the drug *in situ*, positioning of the prostheses should be maintained securely without movement to obtain proper fixation.

Special precautions should be taken to detect and correct the transitory fall in blood pressure that may occur when the drug is implanted into the bone.

The completion of polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat. Temperatures occurring during the polymerization have been reported as high at 110° Centigrade. The long term effect of the heat produced along with the resulting tissue damage is not known.

Use in pregnancy: Although the results of animal teratology studies were negative, the use of the drug in pregnancy or by women of childbearing potential requires that potential benefits be weighed against the possible hazards to the mother or fetus.

Adverse Reactions

The most serious adverse reactions, some with fatal outcome, reported with the use of acrylic bone cements are:
- Cardiac arrest
- Myocardial infarction
- Pulmonary embolism
- Cerebrovascular accident
- Sudden death

Other adverse reactions reported are:
- Heterotopic new bone
- Short-term irregularities in cardiac conduction

The most frequent adverse reactions reported are:
- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematome
- Loosening or displacement of the prosthesis
- Surgical wound infection
- Deep wound infection
- Trochanteric bursitis
- Trochanteric separation

IMPORTANT PHYSICIAN INFORMATION

ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM HAVE BEEN ATTRIBUTED TO LEAKAGE OF UNPOLYMERIZED LIQUID MONOMER INTO THE CIRCULATORY SYSTEM. MORE RECENT DATA INDICATE THAT THE MONOMER UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID, AND THAT A SIGNIFICANT FRACTION OF THE CIRCULATING METHACRYLATE IS IN THE FORM OF THE FREE ACID RATHER THAN THE METHYL ESTER. CORRELATION BETWEEN CHANGES IN CIRCULATING CONCENTRATIONS OF METHYL METHACRYLATE/METHACRYLIC ACID AND CHANGES IN BLOOD PRESSURE HAS NOT BEEN ESTABLISHED.

HYPOTENSIVE EPISODES REPORTED APPEAR TO OCCUR PRIMARILY IN PATIENTS WITH ELEVATED OR HIGH NORMAL BLOOD PRESSURE, IN HYPOVOLEMIA, AND IN INDIVIDUALS WITH PRE-EXISTING CARDIOVASCULAR ABNORMALITIES. IF A HYPOTENSIVE REACTION OCCURS, THE ONSET MAY APPEAR 10 – 165 SECONDS FOLLOWING APPLICATION OF THE BONE CEMENT. ITS DURATION MAY LAST FROM 30 SECONDS TO 5 – 6 MINUTES.

ALTHOUGH THE ETIOLOGY OF CARDIAC ARREST IS UNCLEAR, IT MAY WELL BE EITHER DIRECT EMBOLIC EFFECTS OR SECONDARY TO HYPOXIA PRODUCED BY PULMONARY EMBOLIC PHENOMENA. CLINICAL EXPERIENCE HAS SHOWN THAT FAT, BONE MARROW AND AIR EMBOLI CAN BE SIGNIFICANTLY REDUCED BY SCRUPULOUS CLEANING OF THE MEDULLARY CAVITY PRIOR TO INSERTING THE CEMENT.

INTRODUCTION OF LIQUID CEMENT UNDER PRESSURE INTO A CLEAN MEDULLARY CANAL HAS BEEN SHOWN TO APPRECIABLY ENHANCE THE FILLING OF THE BONE CAVITIES WITH MARKED IMPROVEMENT IN THE SECURITY OF THE BONE CEMENT INTERFACE. CARE MUST BE EXERCISED IN INTRODUCING THE CEMENT CONTINUOUSLY FROM DISTAL TO PROXIMAL TO AVOID LAMINATIONS IN THE CEMENT.

How Supplied

Individual unit or ten-unit dispenser carton, each unit containing:
1 STERILE PACKET CONTAINING 40 g. — full dose (20 g. — 1/2 dose) of sterile powder polymer.
1 STERILE AMPUL CONTAINING 20 ml. — full dose (10 ml. — 1/2 dose) of sterile liquid monomer.

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