Joint Implant Surgery and Research Foundation

Update

N • E • W • S

April 1993

INTRODUCTION

by Timothy McTighe, Editor

This is the second edition of JISRF's Update News and we will highlight the recent Fifth Annual International Symposium on Custom Made Prostheses held in Windsor, England, October 1-3, 1992. Program Chairman was Professor Peter S. Walker from the Department of BioMechanical Engineering Institute of Orthopedics, Stanmore, England. The sponsoring body for this symposium is the International Society for the Study of Custom Made Prostheses.

This Society, (ISSCP) was created for formalizing the interaction of surgeons, design engineers, scientists, researchers, and manufacturers from around the world.

I have attended three (3) of the past five (5) symposia and have found this meeting to be highly informative with major emphasis on new developing technologies in imaging, fabrication, design shapes, radiographic analysis and robotics. Also how these technologies have become applicable to primary and revision arthroplasty of the hip, knee and other musculoskeletal deficiencies. This is an exciting new Society that has a bright future and is actively soliciting interested surgeons, engineers, manufacturers and researchers to apply for membership. You will find a membership form enclosed in this edition.

Also please note, next year's meeting is being held at Amelia Island, Florida, September 30 - October 2, 1993. Program Co-Chairmen are Louis P. Brady, M.D. 'of Orlando, Florida and Bernard N. Stulberg, M.D., Cleveland, Ohio. You will find a course registration enclosed for the Sixth Annual International Symposium on Custom Made Prostheses.

Our feature article is on HA-Coatings. As you are probably aware, this has been a hot topic for the past couple of years. Some surgeons and researchers have even gone as far as saying HA is the "'white knight" for biological fixation. JISRF feels cautiously optimistic concerning this material for use with cementless implants. We also feel HA should be looked upon as an enhancement to fixation. It is not intended to be the principal mode of stability, that role is reserved for the intrinsic design of the implant. HA will not solve the problems presented by a poorly designed implant.

Dr. John Kay, author of our feature article, is considered one of the leading researchers in this area. However, a balanced review of material is important and since Dr. Kay has a long term bias interest (President, Bio-Interfaces, Inc.), we have asked Dick Tarr, Vice President of R&D for DePuy, to critique our feature article.

Please note Dr. Kay will have an opportunity to respond to the critique in our next newsletter.

FEATURE ARTICLE

HA-COATINGS FOR NON-PRECISION IMPLANT PLACEMENTS

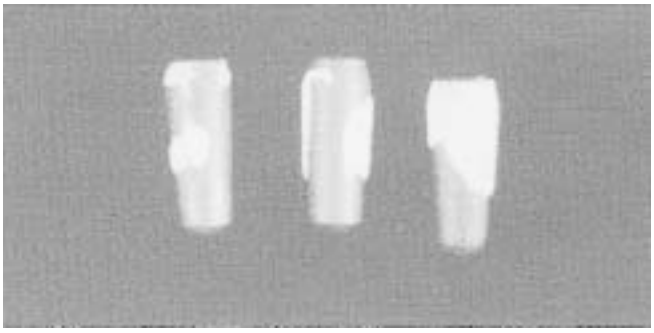
John F. Kay, Ph.D.
Bio-Interfaces, Inc., San Diego, California, U.S.A.

Introduction

Pre-clinical (in-vivo) efficacy studies show that high quality ceramic hydroxylapatite (HA) coating results in faster bony adaptation, and firmer implant-bone attachment. Properly placed in a precision fashion, dental and orthopaedic joint replacement devices coated with a high quality HA have demonstrated a clinically acceptable rate of short term success, when compared with other clinical treatment modalities. The coating of such implants with calcium phosphate materials such as hydroxylapatite can be seen as a "belt-and-suspenders" approach towards gaining an advantage of biological

fixation that can only be proven unequivocally through long-term clinical experience. Perhaps the most compelling usage of such calcium phosphate coatings today is for the placement of implants in non-precision sites where ideal bone contact and implant placement upon revision is not attained.

In oral implantology, placement of dental implants in fresh tooth extraction sites is difficult since a void of non-intimate bone contact is generally created in the superior aspect of the implanted ridge, while the apical portion of the implant may be firmly seated. Dental implants placed in the maxilla also suffer from a lack of total bone contact over the entire implant length and are generally perceived to be more difficult to place than implants in the maxilla, with historically lower percentages of overall implant success. Dental implants placed concurrently with bone grafting material, either autogenous or allografts, are also not in total direct contact with an appropriate bone receptor site and, therefore, represent a non-precision placement; the benefits of a bone conductive surface on an implant may be a benefit.



(Failed Dental Implant)

In orthopaedics, osteoporotic (type C bone) patients may not have total bony support for much of the proximal area of the implant as normally desired. Non-intimate bone contact may exist along much of the attachment area of a revision total joint component and sometimes the bone conditions available due to the localized bone pathology, compromises implant placement in primary cases. Certainly, implants placed concurrent with bone grafts, whether primary or revision in nature, represent a more challenging joint replacement procedure and again represent situations where the surface of the device designed for biological attachment or adaptation is not in direct contact with vital bleeding bone.

The in-vitro characterization of a calcium phosphate coating is very important but this characterization cannot stand alone as a predictor of in-vivo performance. In-vivo pre-clinical efficacy studies must be conducted. A high quality plasma sprayed HA-coating* was applied to smooth, grooved, and porous transcortical canine implants, smooth surface canine hip implants with a circular cross-section, and porous intermedullary implants; uncoated controls were used for all specimens. HA thickness for smooth and grooved implants were approximately 60 microns thick and 30 microns for porous implants. In all cases, the devices to be HA-coated were undersized to account for the application of a coating, except for the porous materials where the HA-coaling was thin enough and the reality of changing bead sizes to accommodate such a thin coating (approximately 30 microns) prohibited that dimensional normalization. The implants were placed using conventional and accepted techniques ensuring a snug interference-fit. Precision interference-fit placement s were obtained for transcortical implants where the model allows for direct, accurate bicortical placement; usually, an interference-fit of 0.05mm is obtained.

In-vivo evaluations, using the canine transcortical model, demonstrate the following:

TABLE I-Bone Implant Attachment (MPa)

	3 WK	6 WK	12 WK	26 WK	52WK
HA/Ti	6.04	8.75	8.17	n/a	11.06
	(3.00)	(1.99)	(1.09)		(2.22)
Grit Blast Ti	1.31	2.89	2.74	n/a	5.51
	(0,70)	(1,16)	(0145)		(1.65)
Grooved HA/Ti	9.37	11.80	13.61	18.09	19.10
	(1.67)	(2.31)	(2.86)	(3.35)	(3.77)
	4WK	6WK	8WK	26WK	52WK
Porous CoCr	6.7	10.5	10.5	22.0	18.71
	(2.17)	(2.68)	(2.26)	(3M)	(3.74)
HA/CoCr	10.1	12.8	12.8	27.1	21.21
	(4.20)	(2.30)	(2.72)	(2.36)	(3.80)

Standard deviation in () under mean value,

In an intermedullary model employing interface gaps of up to 2mm tested at times up to one-year, this HA-coating provided the following enhancements in bone deposition and attachment strengths:

*the Bio-Interface [R] brand of HA-coating

TABLE 4 – Interface Shear
Attachment Strength. MPa
Values shown are mean standard deviation in below

Implant Diameter	6mm (2mm gap)	8mm (1mm gap)	9mm (0.5mm gap)	10mm (no gap)
4 WK				
HA	0.257	0.373	0.632	1.831
	(0.411)	(0.112)	(0.556)	(0.981)
UNCOATED	0.095	0.112	0.187	0.460
	(0.034)	(0.067)	(0.143)	(0.408)
8 WK				
HA	0.373	1.388	2.061	5.738
	(0.309)	(0.822)	(1.199)	(1.532)
UNCOATED	0.112	0.339	0.816	2.759
	(0.067)	(0.328)	(0.802)	(1.795)

12 WK				
HA	0.780	1.777	4.512	9.106
	(0.811)	(1.557)	(6.635)	(5.432)
UNCOATED	0.248	0.748	1.226	3.701
	(0.179)	(0.584)	(0.800)	(1.958)
24 WK				
HA	1.016	2.072	4.038	9.249
	(1.682)	(1.520)	(2.950)	(5.350)
UNCOATED	0.3781.543	2.296	5.896	
	(0.382)	(1.420)	(2.406)	(3.377)
52 WK				
HA	0.687	2.567	4.225	11.442
	(0.517)	(2.529)	(1.776)	(5.819)
UNCOATED	0.355	0.667	1.926	4.706
	(0.253)	(0.533)	(2.013)	(2.677)

The results indicate that HA-coatings were effective in providing enhanced bone aposition and attachment strength for gaps of 1mm and less, providing the implants were initially stable. Positive attachment effects observed for HA were seen but delayed because of the gap indicating that the presence of any space, or nonprecision placement, will require additional time to resolve the intermediate defect before bony fixation can be obtained. The presence of HA, however, minimizes or eliminates the presence of any fibrous tissue seam associated with either the material placed or the presence of a gap that retards the direct adaptation of bone, to a limitation of less than I mm. This data has been presented in Seminars in Arthroplasty Vol; 268-279, 1991.

Clinical Applications

In fresh tooth extraction sites, bone has been observed to adapt to the HA-coated implant surface and is not as compromised by downgrowth of epithelial tissue. Implants must be initially stable, however, and with sufficient proportion of the apical implant body length secured in a precision-drilled site. Clinical results show that bone then will cover the implant surface, resolve the superior defect and provide biointegration of the dental implant.

For revision total joint arthroplasty, HA-coated experience with custom-coated implants generated by CADCAM programming-model generation have been designed with a grooved macrotextured surface, consistent with data obtained in animal pushout experiments presented by David Stulberg, M.D. at the 1991 ISSCP meeting in San Francisco. The preliminary clinical results over two years show higher hip scores and a decreased tendency for radiolucencies at the two-year time period. HA-coated macrotextured grooves and porous ingrowth devices provide for bone adaptation by mechanical and chemical means.

Conclusions

Based on in-vivo data from pre-clinical efficacy studies and limited, primarily anecdotal clinical experience, the presence of an HA-coating on metallic implant devices provides an enhancement of bony response over uncoated metallic components. A limited amount of controlled clinical data exists and a prospectively defined randomized clinical evaluation would be very difficult for indications involving non-precision sites. As of this writing, however, this characteristic of providing a mechanism to overcome non-precision placement is a viable approach for HA-coated metal implants. If used for such nonprecision placement, the stability of the coating must be demonstrated, as its early loss would preclude the desired bone adaptation.

Only long term clinical data will show whether the positive characteristics demonstrated in animal studies will be eventually manifested in the human clinical setting.

FEATURE ARTICLE CRITIQUE

by Dick Tarr, V.P. DePuy

Osteoconductive bioceramic materials such as hydroxyapatite and tricalcium phosphate have been investigated for over two decades as potential treatment enhancements in both dentistry and orthopaedics. It was hoped that these bioceramics would become an attractive adjunct to deal with bony loss or to improve implant fixation. However, most studies have identified device design and geometry (when these materials are coupled with implants) as a key factor in the success of this adjunctive therapy. In my opinion, I remain cautiously optimistic about the use of these bioceramic compounds as improvements to implant fixation issues. Implant design is still the most important criteria for success.

In the feature article entitled, "HA-Coatings for Nonprecision Implant Placements" by John F. Kay, Ph.D., the author summarizes work he and his co-workers have performed and published in the following articles: S.D. Cook, et. al., "Enhanced Bone Ingrowth and Fixations Strength with Hydroxyapatite- Coated Porous Implants," Seminars in Arthroplasty 2(4): 268-279,1991; and S.D. Cook, et. al., "Hydroxyapatite Coating of Porous Implants Improves Bone Ingrowth and Interface Attachment Strength," Journal of Biomedical Materials Research, 26:989-1001, 1992. Through the experimental models presented in this feature article, Dr. Kay attempts to present evidence that HA coating on implants was effective in providing enhanced bone apposition and increased attachment strengths for gaps between the bone implant interface of I mm or less. He also points out that the implants must remain stable for this fixation to occur. In general, I would agree that these osteoconductive material coatings have been shown to bond directly to bone if the implants remain stable.

However, data presented in this paper are not conclusive and only indicate a potential trend for short-term fixation enhancements with HA coated implants. Issues of the integrity of the HA substrate (implant) bond strength and relatively slow resorption rates of HA are also concerns in long-term orthopaedic applications.

In the femoral transcortical implant model, it appears only one dog was evaluated per time point. This is a major weakness of this study. Each dog had five transcortical implants spaced approximately 1.5cm apart in the mid-diaphyseal region of both femora. The text describes the precision with which implants were coated and the tight interference fit achieved in the drill holes. I would question the ability to maintain a tolerance of .002" - .003" on coating dimensions over a porous surface during manufacture of these components. Most orthopaedic manufacturers find it difficult using computer-aided, numerical-controlled turning and milling centers to achieve consistent and reproducible quality to these standards on metallic devices. I also find it hard to imagine that a hand-drilled hole can be reproducibly held to a tolerance of .002".

I would agree; however, that even with only one dog utilized per time point, the data are consistent with previous studies indicating that HA coatings of smooth devices in a non-loaded "relatively" tight, stable implant model will yield improvements in bone attachment and fixation strengths over smooth devices devoid of HA. However, the data also suggest the possibility that in the long-ten-n, the bond strength achieved between the implant and the coating may be deteriorating. There appears to be a trend in the data suggesting that between week 26 and week 52, the push-out strengths are beginning to decrease. It should also be noted that previous studies have not shown a difference in the mechanical stability of either textured or porous surfaces whether they were HA coated or uncoated. The data presented in Table 1 suggest a similar finding with the only true differences noted in the uncoated smooth, grit-blasted titanium surface versus all other component surface designs.

In the second model presented, namely that of an intramedullary rod placed bilaterally in the femora of five animals per time point, the interfacial shear strength was measured for HA coated versus uncoated rods for gaps of 2mm, I mm, 1/2mm. and no gap. It should first be noted that the data presented in Table 4 in parentheses should indicate standard errors and not standard deviations (standard error equals standard deviation divided by the square root of the sample size). Also of note are the large standard error variations for all measurement results compared to the average values.

Previous work has shown that bone will grow across and onto an HA coated rod in the presence of a gap. However, the attachment sites are far from completely gap filling. In these studies, bone bridged the gap with a spot attachment and then grew up along the HA coating forming a "neo-cortex." This may explain the trend in the data for the non-loaded intramedullary rods in which the shear strength increases for decreasing gap dimensions. Whether these data support the conclusion that gaps of 1mm or less show sufficient interfacial shear strength is a matter of opinion.

The most substantial finding from this research indicates material coating should not be a substitute for 1) appropriate pre-operative planning; 2) proper implant design; and 3) precise surgical technique. Recent clinical results presented at major orthopaedic meetings indicate the variability of resorption rates with HA coated devices, and potential beneficial effects of these bioceramic coatings in the orthopaedic arena. Appropriate selection and use of hydroxyapatite coating, which resorbs slowly, should be reserved for those applications in which the geometry of the implant would remain stable regardless of the coating technology. For porous coated products, a more rapidly resorbing, osteoconductive material such as tricalcium phosphate may be superior to HA. With tricalcium phosphate, bone would be conducted into the pores or irregular features of the implant design, and with living bone quickly replacing the tricalcium phosphate, ensure long-term stability. Many of the clinical studies under current IDE investigation will elucidate these potential beneficial effects. Until these results are in, we should carefully examine the applications and early clinical results for these osteoconductive compounds.

THE EFFECT OF FEMORAL STEM LENGTH, SHAPE AND MATERIAL PROPERTIES IN MINIMIZING PROXIMAL FEMORAL STRESS-SHIELDING

by JH FU

Stress- shielding in the proximal femur arises because the rigidity of the total hip femoral prosthesis is markedly greater than that of the cortical bone. Therefore, the possibility arises that by reducing the stem rigidity in relationship to the surrounding cortical bone, the effects of stress-shielding can be minimized.

The analysis showed that reducing the length of the femoral stem reduces the stress concentration in the femur at the stem tip, but does not alter the proximal femoral stress distribution. Unfortunately, as the femoral stem is shortened, the axial and rotational stability of the prosthesis is decreased limiting the usefulness of this design modification.

THE EFFECT OF STEM LENGTH ON TORSIONAL STABILITY OF CUSTOM PROXIMAL FEMORAL COMPONENTS

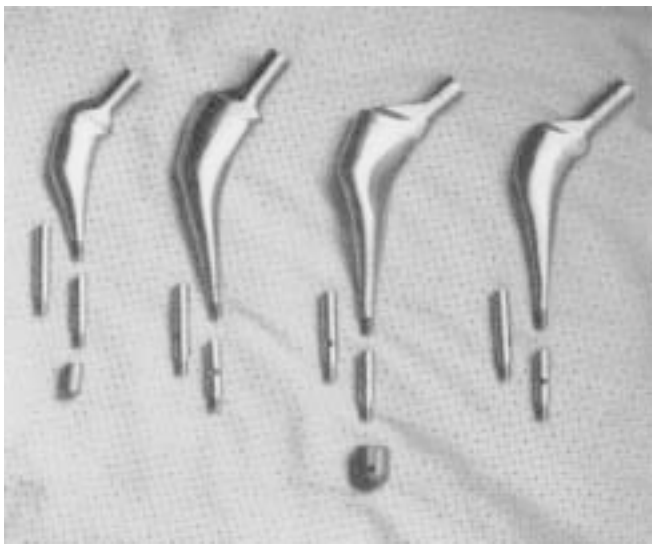
By DD Robertson, B Chan, Jr Essinger, MJ Curtis, RH Jinnah, AJ Zarnowski

Introduction

A major concern in replacement arthroplasty is the initial fixation of the implant to the bone. Motion 4 the implant at the interface can decrease or impede bone ingrowth, produce resorption, lead to subsidence or tilt, cause pain, and ultimately lead to revision. Recent work by Hayes et al (ISSCP '90) has shown increased fit and fill in the proximal femur to be correlated with decreased micromotion. We examined short and standard length symbios custom hip stems to see if there was a difference in the proximal fit and fill and in proximal torsional stability.

Results

There was no statistical difference between the proximal fit and fill of the short and standard length custom stems (paired t-test). Torsional micromotion was less than 60 microns (< 30 microns for many of the bones) during the applied torques from 3-18 N-m. Micromotion increased as the applied torques increased. There was no statistical difference in the micromotion between the short or standard length custom stems (paired t-test).



DESIGN RATIONALE FOR THE STABILITY™ CEMENTLESS TOTAL HIP SYSTEM

By T McTighe, GT Vise, S Murphy, BK Vaughn, B Shephard

Optimization of fit and fill has taken several approaches: off the shelf one piece; off the shelf modular pieces; preoperative customs, intra-op customs. The growing concern of osteolysis has led to the development of the Stability™ hip system. This system offers the versatility of modular components, however, it reduces the potential sites that can generate particulate debris.

The short term clinical results of the intra-operative custom technique of Identifit™ has had mixed results in the United States. However, the learning experience has demonstrated a number of factors. Initial focus was on fit and fill. Then the importance of shape was introduced, and recently the advent of macrotexturing and flutes.

Fit and fill, shape, and surface geometry are all important ingredients to achieve axial and torsional stability. However, fit and fill is difficult to achieve due to the varying geometry of the proximal femur. The question is: How can we improve our ability to fit and fill varying geometries? One answer is to have a large quantity of sizes, the second is customs, and the third is modular designs. All three of these answers must address the geometry considerations of proximal size and shape, distal size and shape, and stem length.

Although the cost of customs has been coming down, it still is not equivalent to standard cementless, off the shelf devices. In addition, pre-operative customs limit the intra-operative options that one is faced with and requires considerable pre-operative, precision in working with the device manufacturer.

On the other hand, in the past, a large quantity of sizes has been prohibitive because of cost involvement in standard manufacturing procedures. However, Orthogenisis technology of surface milling now makes this option cost effective. A large quantity of sizes offers many intra-operative options and reduces pre-operative precision planning. However, it still requires understanding all options (sizes) and requirements for surgical technique.

Modularity has been cost effective, offers many intraoperative options, generally has high demanding surgical technique, a high learning curve in understanding of intra-operative options and has been shown to be a site for generation of particulate debris, which can lead to osteolysis.

1. Overview - Stability™ Components
   - Initial sizes 4 diameters straight stems (12, 14, 16, 18mm)
   - Standard Stem Length (150, 155, 160, 165mm)
   - The tapered neck permits the use of a variety of head diameters and neck length in either the c.c. or ceramic.
   - Graduated Proximal Design
     There are two cone bodies for each dia. stem. Also two triangle sizes for each cone size. A total of four different proximal sizes are available for each stem dia. A third proximal triangle is being added to the large cone by mid 1993.

II. Design Features Stem

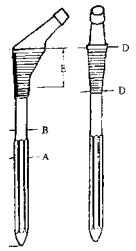
Material: Titanium Alloy

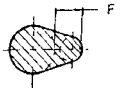
1. Taper Neck - allows for modular heads.
2. Conical Proximal body with Medial Triangle - allows for better fit and fill.
3. A Circular Distal Dia. Stem - allows for easy, precise preparation by reaming.
4. Longitudinal Flutes on Distal Stem - increases torsional resistance.
5. Non-Bead Blasting Surface - reduces surface particulate debris.
6. Forged Titanium Alloy - excellent fatigue strength, low bending modulus.
7. HA Coated - or Porous coating available.
8. Proximal Body - approximates the shape of the prepared endosteal cortex.
9. Proximal Body - 5' taper prox. to distal.
10. Proximal Steps - transfers hoop tension into compression. Helps reduce subsidence.
11. Two Triangle Sizes Per Cone - allows for better fit and fill.
12. Distal conical slot reduces distal bending modulus and reduces distal hoop stresses resulting in a more even stress transfer while facilitating ease of insertion.
13. Offers versatility of modular design for routine primary indications while reducing the need for modular sites that are known to produce particulate debris.

Summary

The fabrication process of surface milling now allows for increasing off the shelf size offerings reducing the need for modularity and customization; and, more importantly, lends itself to design evolution in a cost effective manner.

	Distal Maj. Dia.	Stem Size Prox. Dia.	Triangle	Stem Dia. mm (Minor)	Distal Reamer Dia. mm	Proximal Reamer	Proximal Triangle
1	12	20	Sm	11	11.5	20	Sm (12)
2	12	20	Med	11	11.5	20	Med (16)
3	12	22	Sm	11	11.5	22	Sm (12)
4	12	22	Med	11	11.5	22	Med (16)
5	12	22	Lg	11	11.5	22	Lg (20)
6	14	22	Sm	13	13.5	22	Sm (12)
7	14	22	Med	13	13.5	22	Med (16)
8	14	24	Sm	13	13.5	24	Sm (12)
9	14	24	Med	13	13.5	24	Sm (12)
10	14	24	Lg	13	13.5	24	Lg (20)
11	16	24	Sm	15	15.5	24	Sm (12)
12	16	24	Med	15	15.5	24	Med (16)
13	16	26	Sm	15	15.5	26	Sm (12)
14	16	26	Med	15	15.5	26	Med (16)
15	16	26	Lg	15	15.5	26	Lg (20)
16	18	26	Med	17	17.5	26	Sm (12)
17	18	26	Med	17	17.5	26	Med (16)
18	18	28	Sm	17	17.5	28	Sm (12)
19	18	28	Med	17	17.5	28	Med (16)
20	18	28	Lg	17	17.5	28	Lg (20)





Material: Ti-6AI-4V
Taper: Articul-eze
Head Diameter Available: 26, 28 & 32
Anteversion: no
Neck Shaft Angle: 130 degrees
Base Offset: 37.20 mm

Neck Lengths:

26 mm:	Metal	+4,+7,+10
	Ceramic	none
28 mm:	Metal	+1.5, +5, +8.5, +12
	Ceramic	+1.5,+5
32 mm:	Metal	+1, +5, +9, +13, +17
	Ceramic	+1,+5,+9

Broach match: Broach diameter is the same as the minor diameter of the stem

THE FIT AND FILL OF A PROSTHESIS CUSTOMIZED VIA INTRA-OPERATIVE MOULDING -A CT AND BONE SECTION ANALYSIS

By R Grelsamer, R Iorio, J Collier, N Haramati, 0 Nercessian, N Eftekhar

Significance

The ability to evaluate the fit and fill of cementless prostheses is critical: Implants featuring different designs can be objectively compared, and clinical correlation may eventually provide us with thresholds of acceptable fit and fill .

Purpose

To demonstrate that CT scan technology can be modified to evaluate the fit and fill of the femoral canal by a metallic prosthesis.

Methods

Matched pairs of cadaver femora were analyzed both with CT scans and sectioning methods after implantation of a prosthesis. The images of 10 cross sections of

the femur and the corresponding CT cuts were analyzed through an image program and compared for accuracy. The matched pairs were controlled for surgeon, technique, and type of prosthesis. Four different surgeons participated in canal preparation and prosthesis insertion. The fit and fill of the Identifit™ prosthesis was then compared with other off-the-shelf, uncemented prostheses for fit and fill. Specifically, the Identifit™ was compared with anatomic and straight stem models. Cobalt chromium prostheses were compared with the titanium Identifit™ to validate the CT scan technique with other metals.

Results

CT scanning of the femur accurately describes the fit of an uncemented femoral prosthesis with an accuracy of 97.2% when compared with cadaveric cross sections.

Conclusion

CT scan technology can be modified to evaluate 'fit and fill' with a high degree of accuracy.

SHAPE OPTIMIZATION OF INTRA-OPERATIVELY MANUFACTURED CUSTOM PROSTHESES

By V Salvi

The aim of the majority of cementless prostheses is to optimize fit and fill against good quality bone with the femoral canal.

That this aim is problematical for a range of off-the -shelf prostheses may be demonstrated by the existence of 47 recognized morphotypes.

Using custom prostheses, good cortical contact can usually -be obtained along the full length of a prosthesis medially; however, laterally this may only be achieved in the distal half of the stem. Anatomical considerations mean that the proximo-lateral portion of the stem can only contact with cancellous bone. There is, however, the possibility of good cortical contact in the mid-lateral portion of the stem and also useful contact with good quality cancellous bone proximo-laterally. The risk the designer must take in optimizing this lateral support is in impinging on the greater trochanter at insertion.

When the prosthesis is manufactured intraoperatively using the Identifit™ system, the surgeon becomes the designer, and can work to optimize the cavity. The Identifit™ software can complement the work of the surgeon by designing a prosthesis for the cavity which can still be inserted.

The prostheses manufactured in Torino using the Identifit™ System have passed through three distinct design phases resulting in three different proximal shapes, each trying to enhance the level of lateral support.

The final design phase has placed a greater emphasis on lateral geometry which, from a biomechanical point of view, gives the stem an improved resistance to the torsional and vertical components of the joint reaction force.

Moreover, this appears to give improved clinical results together with a very satisfactory radiological appearance.

A PROSPECTIVE COMPARISON OF TITANIUM VS CHROME COBALT FEMORAL HEADS IN CEMENTLESS TOTAL HIP ARTHROPLASTY

By TP Gross, WJ Murzic, JK Taylor, WL Baryar

This is the first clinical series comparing chrome cobalt to titanium bearing surfaces using the same femoral component design. Titanium and its alloys have been implicated in several reports on metallic-wear debris. Polymethylmethacrylate (PMMA) cement, ultra high molecular weight polyethylene (UHMWPE), and metal debris have been shown to be associated with osteolytic lesions and inflammatory membranes around both stable and loose prostheses. The in vitro wear characteristics of titanium alloy against UHMWPE are inferior to cobalt-chrome or ceramic combinations against UHMWPE.

Forty-two patients had 51 primary uncemented total hip arthroplasties. One was lost to follow-up. All patients had a titanium alloy custom stem (Techmedica) and a Harris-Galante (Zimmer) acetabular component. The first 25 patients had a femoral head made of titanium alloy (Ti-6AI-4V), the next 25 had chrome-cobalt femoral heads. The titanium head group had an average age of 43 and weight of 150, while the chrome-cobalt head group had an average age of 50 and weight of 174.

At 4 year follow-up there were 4 cases with femoral osteolysis in the titanium head group (16%) and none in the chrome-cobalt head group. The follow-up in the titanium head group is approximately I year longer than in the cobalt-chrome head group. There have been 3 additional cases of osteolysis in the titanium head group at 5 years of follow-up for a total incidence of 28%. There were 4 loose prostheses in the titanium head -group, 2 were due to pad separation from the stem. In the cobalt chrome head group there was I loose prosthesis due to pad separation.

There were a total of 10 re-operations, 5 head and liner exchanges for osteolysis with well fixed components, and 5 femoral revisions for loosening (3 with pad separation and 2 for failure of ingrowth). In all re-operated cases where titanium heads were present (9 cases), the

prosthetic head appeared burnished; in all but one the articular pseudocapsule was stained gray to black. In the one case where a cobalt chrome head was encountered, these findings were absent. The femoral membranes of those cases where the stem was revised (5 cases), also were stained darkly. In every re-operation, the acetabular component was found to be well-fixed. There was no evidence of wear of any of the acetabular liners.

The joint capsule was examined using H&E stains to look for metallic particles, and polarized light microscopy to look for polyethylene. In the cases with titanium heads (9 cases) metallic intracellular articular debris, but no polyethylene debris was found.

A CLINICAL AND RADIOGRAPHIC EVALUATION OF 337 CUSTOM MADE PROSTHESES: A ONE TO SIX YEAR FOLLOW-UP STUDY

by JJ Bougault, JN Argenson, M Pizzetta, JM Aubaniac

We evaluated by clinical and radiographic assessment a group of 337 consecutive custom made total hip arthroplasties performed in our orthopaedic department.

Material and Method

On a total of 468 cases of custom replacement we selected 337 cases, excluding the patients who lacked one year follow-up. This study evaluated three designs; Egoforrn, Medinov and Symbios. Egoform I is designed with morphological data provided by two radiographs, 126 cases have been realized. Medinov used CT-Scan views to draw the prostheses, and 6 cases were performed. Since 1990 we are using the Symbios procedure whose design is based on the numerical CT-Scan data, 205 prostheses have been implanted.

Results

The mean follow-up is 30 months with a minimum of I year and maximum of 6 years. The clinical evaluation is realized according to the Harris hip score, adding the assessment of thigh pain.

The radiographic analysis studies prosthesis stability by: stem positioning and migration. The bone-prosthesis fixation is evaluated by dividing the femur in 16 areas, for each area is recorded: endosteal new bone, lucencies, cortical hypertrophy, osteolysis. The total amount of stress shielding is evaluated according to the C. Engh classification. Ectopic ossification is also recorded with Brooker criteria.

Eleven complications requiring revision occurred: two for trochanter non union, two for loosening, five dislocations, and two infections.

Discussion

The proximal fill provided by custom implants may increase the recovering of the function.

PROBLEMS AND CONSEQUENCES FOLLOWING PELVIC TUMOR PROSTHESES

by R Gradinger, H Rechl, R Ascherl, A Kolling

Introduction

Anatomical reconstruction following pelvic tumor resections, especially of the Ila and Ilc type, is a surgically high demanding procedure. CAD/CAM techniques, allowing 3-D-Imaging of anatomical structures based on CT scans has been used through the last couple of years to improve planning and reconstruction, as well as the prosthetic design.

Material and Method

From 1977-1992 24 tumor prostheses have been implanted for primary and secondary malignant tumors of the pelvis, mostly following type Ilc resections. Diagnoses was Chondrosarcoma in 6, Ewingsarcoma in 4, Osteosarcoma in 4, Reticulumcellsarcoma in 1, malignant fibrous Histiocytoma in 1, metastasizing hypernoephroma in 3, -thyroid-ca in 3, and, -breast-ca in 2 patients. In 19 of those 24 patients we used an intraoperative adaptable implant system which was described by us in 1986. In 12 of those 19 patients our 3 dimensional planning strategy has been applied using a original sized model of the patient's pelvis.

Results

It is well documented, that internal hemipelvectomy, especially if reconstructed with pelvic mega prostheses, has a high complication rate. In our experience there were problems with postop dislocations, disconnection of the conus between fixation device and acetabulum, one prosthesis fracture following trauma and skin perforation due to prominent fixation screws and the prosthesis. There were also problems with external rotation contractures, due to extensive muscle resections and hence alteration of the muscle balance at the hip joint.

Discussion and Conclusion

The postop joint stability was improved by the 3-1) planning procedure and the use of overlapping PE-Kuroki-Inlays and anti-dislocation sockets. The conus can be secured with a splint and a roughened surface, and a fixation device has been changed to a stronger design with fixation screws in the direction of the biomechanical stress lines. We avoid designs with prominent edges, and use tissue transfer if the soft tissue coverage is insufficient. In 2 patients with external rotation contractures and subluxation of the hip a secondary partial release of scar and muscle tissue at

the greater trochanter and the pseudocapsule improved malposition of the extremity function.

Just recently, as a result of our experience with pelvic endoprosthetic reconstructions, we have been able to replace a hemipelvis in combination with a total femur in a patient with metastasizing breast cancer.

COMMENTARY

By Earnest A. Eggars, M.D.

Future of Custom Hip Prosthetics

For over a decade there has been a shift from conventional cemented systems to alternatives without cement. Although experience with methylmethacrylate was excellent, progression of time brought an increased incidence of aseptic loosening and varying degrees of bone destruction.

Orthopaedists responded with improved cement technique and conventional cementless prosthetics. The plethora of systems have developed with different shape, length, modulus, and surface treatment. Certainly clinical and laboratory studies have shown that the quality of initial fixation is closely associated with accuracy of fit and patient performance. Questions remain about the relationship between bone prosthetic fit and asymptomatic. We have established that there must be some degree of contact between stem and endosteal surface, along with maximum proximal and distal fit, and rotational stability.

Complications of aseptic loosening, stress shielding, and thigh pain are well documented. Biologic ingrowth fixation has not become a "given", and continued pain from any of the foregoing complications does result in revision surgery .

Custom prosthetics have been in the surgical arena for over a decade. Early use may have centered around treatment of tumor and serious bone loss. Since the mid-80s various primary and revision custom implants have developed as a result of radiographic measurement, CAT-SCANS, and inter-operative mold (Prof. Mulier). Thusly, the role in requirements of custom prosthetics is changing, and the production of quality in a shorter time has pushed technology to new limits. A closer relationship between the physician and the engineer has developed and consistency of excellent results beyond the early "learning curves" have become a reality.

Studies reported at the International Symposium of Custom Made Prostheses have suggested that more secure initial fixation and proximal fit do tend to improve proximal load transfer. The Identifit™, or molded hip, has been shown to have rotational stability equal to that of cemented prostheses. The proximal geometry of the femoral prosthesis and a stable distal fit appear to be key elements to clinical success. Further studies with variations in surface geometry are under way, including transverse ridges, step-off, and porous coatings. Distal stem treatment with fluting may also add to proximal stability.

While custom implants have better overall fit characteristics compared to off the shelf prostheses, there still remains the proof over time of clinical superiority. The incidence of proximal atrophy, subsidence, loosening, and transmission of particulate debris into the isthmus will be watched closely.

Customization in hip surgery is rapidly gaining momentum both in the U.S. and Europe. Engineering interest and input has been remarkable. As series of cases increase, costs are dramatically falling. The introduction of technology, engineering principles, and many pioneering surgeons will change the geometry, the preferential fit, and even the surface treatment of femoral implants in the future.

I am currently doing all my primary cementless hips using the custom XPress™ services from DePuy. My early clinical impressions are very good as compared to my previous cementless experience and are in the process of being worked up for publication.

(Ex-Press™ Stem)

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