Joint Implant Surgery
& Research Foundation
NOVEMBER 2001

JISRF Update

INTRODUCTION

By Timothy McTighe, Editor

Cement fixation has stood the test of time. Lately, due to increase medical cost there has been a strong movement back to the use of cement as a means of fixation for primary THA. Many companies have been influenced to design newer systems that incorporate a common set of instruments for both cement and cementless stems. Caution is urged in making quick decisions concerning changing to these newer common systems.

Over the years the mechanical properties of PMMA, implant design and surgical technique have been studied and improved. As a result, aseptic loosening and product failure has not been a problem with regards to primary THA. However, design parameters are different for cement and cementless stems. By trying to standardize upon a set of common instruments for a cement and cementless system it is very probable that one design might be compromised.

Several variables can affect the basic outcome of cemented THA:

- Stem Geometry and Material
- Cement Mantle Thickness
- Component Position
- Surgical Technique

The two persistent problems that remain a concern with both cemented and cementless THA are dislocation and lysis.

Several factors can contribute to dislocation:

- Anatomical
- Technical
- Mechanical

This volume is dedicated to reviewing these factors and some of the newer approaches addressing these concerns.

In This Issue:

Page

Joint Implant Surgery and Research Foundation is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical /surgical study groups, including basic science projects that have lead to the development and marketing of significant Total Joint Replacement Implants.

FEATURE ARTICLE

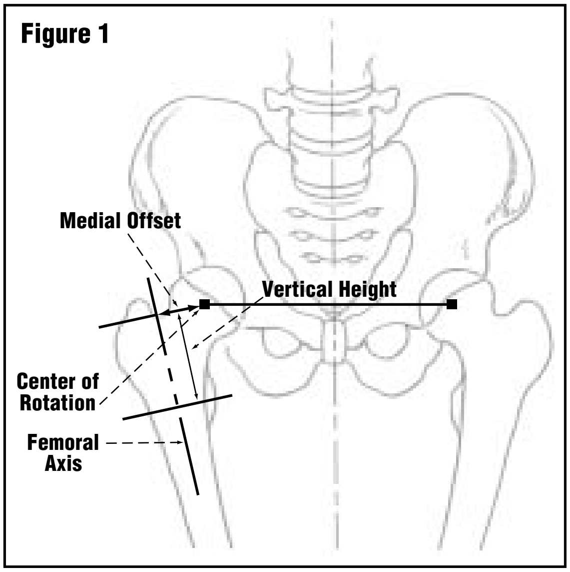
By Hugh U. Cameron, M.B. & Timothy McTighe

Femoral Design Concept that Aids in Fine Tuning the Restoration of Joint Mechanics in THA

Restoration of the hip joint mechanics is critical to a long-term successful outcome for total hip arthroplasty.[1] Two important angles need to be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, femoral head offset affects the joint reaction force.[2]

Replacement of the normal position of the femoral head is essential for correction of mechanical balance between abductor forces.[3] If vertical height is too short, joint stability is a problem. If too long, patients are very unhappy. Incorrect version angle can result in reduced range of motion and possible toeing in. Short medial offset will cause shortening of the abductor moments resulting in increased resultant force across the hip joint, and increasing the tendency to limp. Offset too great increases torsional and bending forces on the femoral component. (Fig. 1)

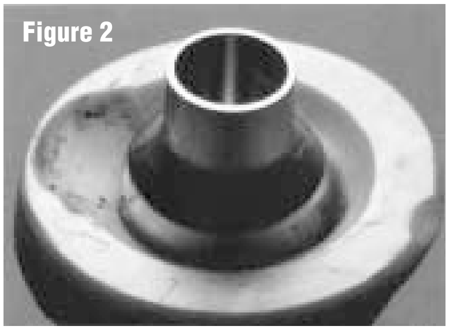
Figure 1



"Technique, technique, technique" as quoted by David Hungerford, M.D. is more important than design or material. With that said, we feel design features can aid in correcting technique related problems.

Surgical approach and technique not only affects soft tissue laxity but also can have a significant influence on component position. The most common surgical errors relate to malpositioning the acetabular component, however, malposition of the femoral component can contribute to increase component impingement and dislocation (Fig. 2).[4,5]

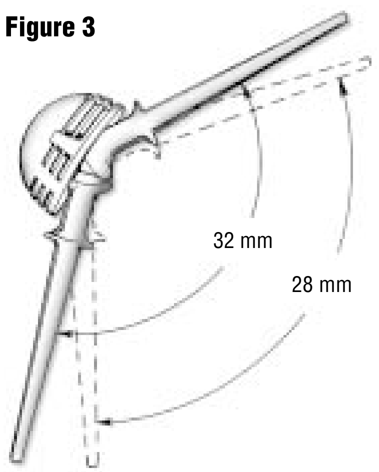
Figure 2



Malpositioning of a cemented stem not only can result in impingement, compromise of cement mantle thickness and dislocation but can significantly impact bone loss by requiring revision of the femoral stem. In addition, malposition can contribute to bone lysis by the increase of articulation wear debris.[6]

Two factors that can affect range of motion are component positioning and component geometry.[4] Although physiological range of motion vary for each patient an average of 114º of flexion is required for sitting. There is no question that increased range of motion results in better clinical results.

Figure 3



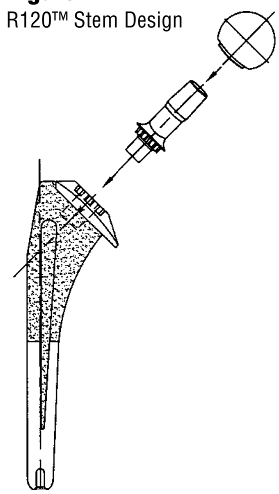
Head diameter, neck shape and skirts on femoral heads can all affect hip range of motion (Fig. 3)[1]

The following stem design approach is recommended in an attempt to aid in restoration of joint mechanics and to allow the surgeon a final opportunity to correct for malpostioning of implants due to technique, and /or bony deformity.

R120™ Modular Indexable Neck Cemented Stem

The stem is designed to use standard conventional cementing techniques. The shape of the stem is trapezoidal and along with a proportionally designed collar provides for optimal impaction and compression of bone cement. In addition, a teardrop shaped recess on the anterior and posterior portion of the implant increases the cement to prosthesis interface therefore increasing resistances to axial and torsional forces (Fig. 4)

Figure 4
R120™ Stem Design



The proximal stem features a matte surface, which enhances fixation of the implant to the PMMA cement, while the distal portion is polished allowing for ease of retrieval if necessary.

An optional distal PMMA stem centralizer is available depending on each individual's philosophy.

Proximally, R120 stems are designed in five (5) cross sections with three (3) interchangeable modular neck lengths of 32mm, 35mm, and 38mm and two angle variations of 8º and 12º. The proximal stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism are employed to ensure the proper head, length, version and offsets are obtained. (Fig. 5)

Figure 5

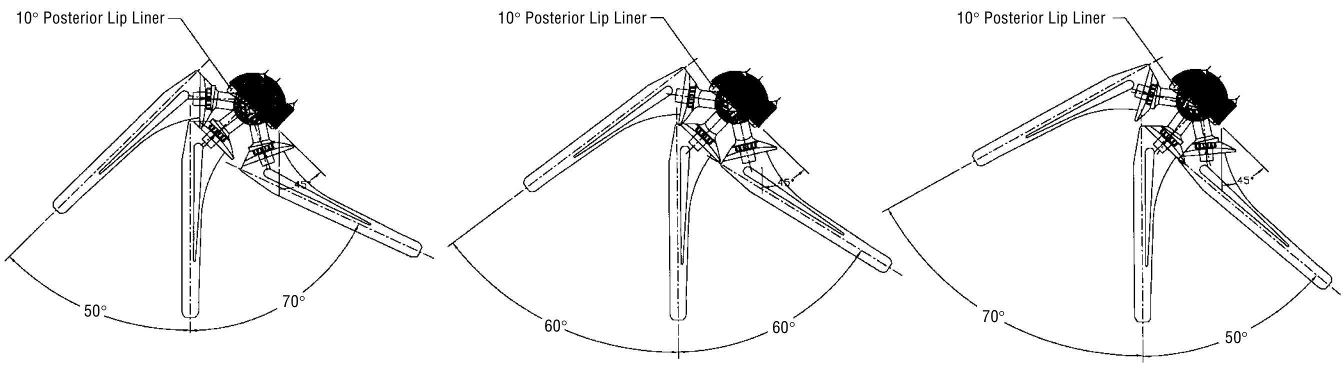
This unique design features twelve (12) self-locking positions providing several combinations of neck length version and offset for closer match to restoring hip joint mechanics.

This innovative approach provides the surgeon with the opportunity to intervene at the last possible surgical moment and fine tune the hip joint mechanics without disruption of the implant-cement-bone interface. In addition, it should provide for increased opportunity to surgically intervene for certain post-op complications, like component malposition, leg length discrepancy, dislocations and replacement of bearing surfaces, with minimal disruption of bony interfaces.

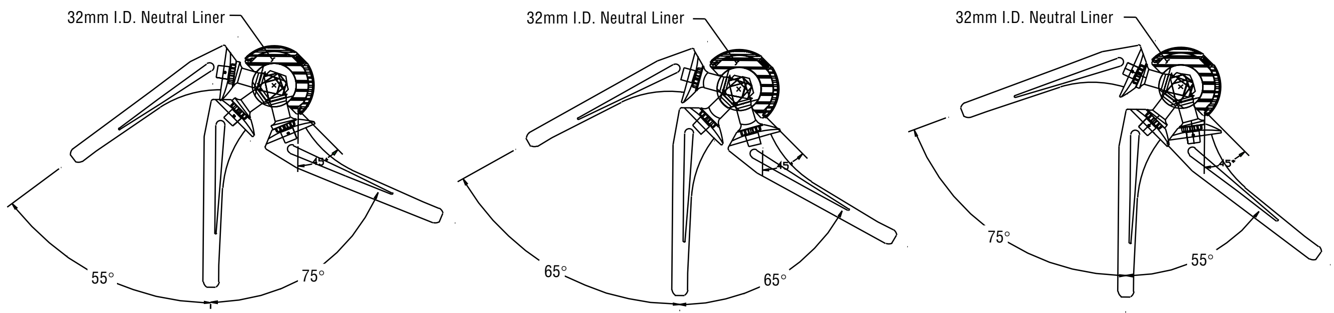
These are just some examples of the flexibility of using this unique Modular Indexable R120™ Neck System (Fig. 6).

The references for the pro and con use of modular couplings have been well documented and are too many to list here. We suggest the basic decision-making be left to the operating surgeon as to the advantages offered by modularity. In addition, we suggest each modular site needs to be evaluated on its own merits.

Figure 6



R120 Stem w / 28mm 0 Head Shown with 10° lip liner Indexable Neck position #0 Neck Angle 127°	**R120 Stem w / 28mm 0 Head** Shown with 10° lip liner Indexable Neck position #3 or #9 Neck Angle 135°	**R-120 Stem w / 28mm 0 Head** Shown with 10° lip liner Indexable Neck Position #6 Neck Angle 142°



R120 Stem w / 32mm 0 Head Shown with 0° lip liner Indexable Neck Position #0 Neck Angle 127°	**R120 stem w / 32mm 0 Head** Shown with 0° lip liner Indexable Neck Position #3 or #9 Neck Angle 135°	**R120 Stem w / 32mm 0 Head** Shown with 0° lip liner Indexable Neck Position #6 Neck Angle 142°

Modular necks have been used in titanium cementless stems in Europe successfully for years (Fig. 7). Both mechanical and clinical results have demonstrated the design approach to be safe and effective.[7,8,9] However, the authors here feel, for cemented application, cobalt chrome molybdenum alloy is preferable both for interfacing with cement and for providing less risk of fretting and/or corrosion at the modular stem neck junction.[10,11] The availability of modular necks and heads allow for unprecedented flexibility in restoring hip joint mechanics.

Only long-term outcome data will clearly demonstrate the viability of this modular neck design, however, basic mechanical principals and attention to the design features presented should aid the surgeon in fine-tuning and restoring normal mechanics to the reconstructed hip.

Figure 7

References:

1. Noble, P.C., Scheller, A.D., Tullos, H.S., Levy, R.N., and Turner, R.H.,: "Applied Design Criteria for Total Hip Prostheses," The ART of TOTAL HIP ARTHROPLAST, Grune & Stratton, Inc., Chapter 5, 1987
2. Denham, R.A.:"Hip Mechanics," J. Bone Joint Surg., 41B, 550, 1959.
3. Inman, V.T.: "Functional Aspects of the Abductor Muscles of the Hip," J. Bone Joint Surg., 29, 607,, 1947.
4. Lavernia, C., Barrack, R., Thornberry, R., and Tozakoglou, E.: " The Effect of Component Position on Motion to Impingement and Dislocation in Total Hip Replacement.," Scientific Exhibit AAOS 1998.
5. Daly, P., Morey, B.: " Operative Correction of an Unstable Total Hip Arthroplasty," JBJS, Vol. 63-B, No.9, Oct. 1992.
6. Chandler, D., Glousman, R., Hull, D., McGuire, P., San Kim, I., Clarke, I., Sarmiento, A.: " Prosthetic Hip Range of Motion and Impingement, The Effects of Head and Neck Geometry," CORR, No. 166, June 1982.
7. Viceconti, M., Baleani, M., Squarzoni, S., and Toni,.A.: "Fretting Wear in a Modular Neck Prosthesis". J Biomedical Material Research, Vol. 35, 207-216 1997
8. Viceconti, M., Ruggeri, O., Toni, .A, and Giunti, A.: "Design-related Fretting Wear in Modular Neck Hip Prosthesis" J Biomedical Material Research, Vol., 30, 181-186, 1996
9. Aldinger, G., Schobel, F., and Marquardt, K., " Further Improvements and Results in Cementless Total Hip Replacement with Interchangeable Necks".III Congress of the Federation of National Associations of Orthopaedics and Traumatology, Poster Exhibit, 1997
10. Holbrook, R.B., Brantley, A.G.U.," Fatigue Testing of Modular Hip Stems". Technical Monograph, Harrington Arthritis Research Center, 1998
11. Holbrook, R.B., Brantley, A.G.U.," Disassembly Force Determination of Omega II Modular Hip Stems". Technical Monograph, , Harrington Arthritis Research Center, 1998

New Approach for Preparation of Bony Surfaces for Cemented Total Joint Arthroplasty

By H.M. Reynolds, M.D., Richard "Dickey" Jones, M.D. and Timothy McTighe

There is a strong movement back to using bone cement in total joint arthroplasty as a primary fixation method. However, it is important to recognize its inherent biological mechanical limitations. Bone cement is a grouting agent and does not possess adhesive properties. Successful fixation is dependent upon the mechanical interface between cement, bone and implant.

Poor cement coverage and inadequate intrusion into trabecular bone are associated with stem loosening, while deep and uniform penetration is important to the success of THA.[1]

Clinical symptoms resulting from loose implants continues to be a significant problem and expose the patient to serious medical risks associated with revision surgery.

Current surgical technique for implantation of cemented implants consists of shaping the bony cavity with hand and power tools, followed by brushing and saline lavage. Surgical sponges or tampons are inserted into the cavity to dry the bone surface. The canal is then plugged and cement injected under pressures to assure interdigitation of cement into the prepared cancellous bony bed.

Cardiopulmonary disfunction has been reported as a risk factor associated with the use of cemented arthroplasty. The principle factor is attributed to particulate fat and marrow emboli.[2-10] Thorough cleaning of fat tissue and debris helps reduce the incidences of emboli complications.

The carbojet device was created for the use of using pressurized dry carbon dioxide gas to be used as a lavage to the bony surface, to clean and dry the area prior to cement implantation (Fig. 1).

Mechanical and clinical investigations of this device has proven this device to be safe and effective.

Figure 1

Carbojet Kit

The carbojet device is used as the final step in bone preparation, employed immediately prior to cement introduction. The flow of gas aids in removing fat and debris from the bone surface reducing interposed fluid between cement and bone.

The carbojet device consists of a reusable hand piece and a variety of nozzles, along with a pressure regulator needed for use with standard CO_2 tanks (Fig. 2, 3). The sterile CO_2 tube set features appropriate quick disconnect fittings and an in-line microbial filter for filtration purposes.

Figure 2

Femoral canal preparation.

Invitro testing has been conducted on human cadaver bone to determine impact force as well as the cleaning effectiveness as compared to standard pulse saline lavage devices. Results of the laboratory testing demonstrating a significant capability of cleaning and debris removal. In addition, testing demonstrated that a moderate gas flow rate is sufficient to clean and dry the bone. High flow rates have the potential for damaging soft tissue and fragile bony areas. The flowing gas of the Carbojet™, however, can be directed at the skin without discomfort or damage to soft tissue. An operating pressure of 50

Figure 3

Total knee preparation.

psi is recommended, the regulator delivery pressure is limited to 65 psi as an absolute maximum. The resulting gas flow rate is approximately 25 lpm.

Clinical surgical evaluations demonstrated interoperative monitoring to be uneventful. One year follow-up monitoring was also uneventful. Throughout the clinical use no complications have been encountered in using a Carbojet™ device.

Since 1993 and thousands of total joint surgeries surgical in-vivo impressions are the Carbojet™ device demonstrated improved or equivalent results as compared to pulsating lavage and cleaning cancellous bone prior to cement implantation.

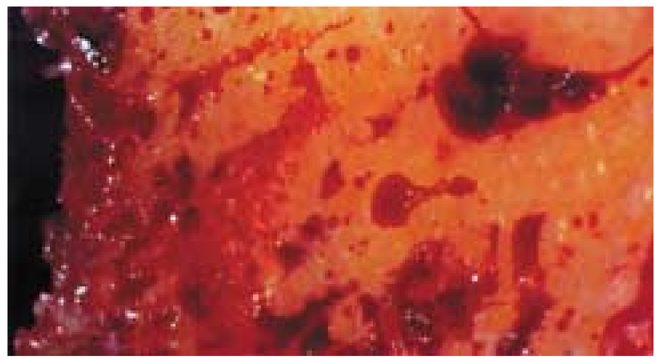
Compressed CO_2 gas has been employed as an insufflation medium in laparoscopic procedures for many years and is readily available at all hospitals.

Long-term fixation of cemented implants relies upon basic mechanical principles of inter-locking. Thorough intraoperative cleaning of fat, tissue and debris will help improve long-term fixation while reducing the risk of emboli. Mechanical and clinical testing to date has demonstrated that the use of dry carbon dioxide gas is a safe and effective way of preparing the bone prior to cement implantation and only additional clinical testing and long-term follow-up will determine if this device can improve long-term clinical outcome results.[1]

References:

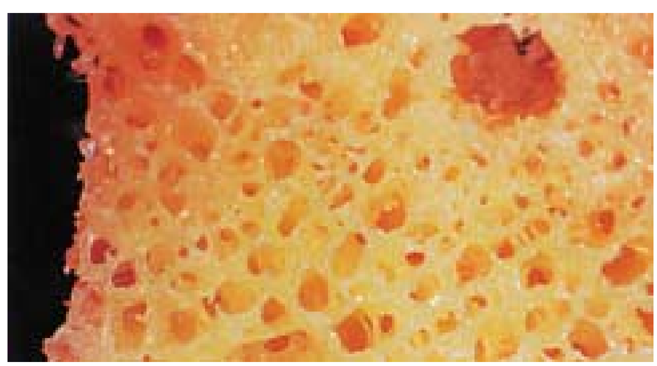
1. Amstutsz, HC. Clin Orthop Rel Res 170:21, 1982
2. Christie J, Robinson CM, Pell AC, McBirnie J, and Burnett R (1995). Transcardiac echocardiography during invasive intramedullary procedures. J Bone Joint Surg Br 77(3): 450-5.
3. Christie J, Robinson CM, Singer B, and Ray DC (1995). Medullary lavage reduces embolic phenomena and cardiopulmonary changes during cemented hemiarthroplasty. J Bone Joint Surg Br 77(3): 456-9.
4. Dorr LD, Merkel C, Mellman MF, and Klein I (1989). Fat emboli in bilateral total knee arthroplasty. Predictive factors for neurologic manifestations. Clin Orthop 248: 112-8; discussion 118-9.
5. Gelinas JJ, Cherry R, and MacDonald SJ (2000). Fat embolism syndrome after cementless total hip arthroplasty [In Process Citation]. J Arthroplasty 15(6): 809-13.
6. Giachino AA, Rody K, Turek MA, Miller DR, Wherrett C, Moreau G, O'Rourke K, Grabowski J, McLeish W, and Fazekas A (2001). Systemic fat and thrombus embolization in patients undergoing total knee arthroplasty with regional heparinization. J Arthroplasty 16(3): 288-92.
7. Monto RR, Garcia J, and Callaghan JJ (1990). Fatal fat embolism following total condylar knee arthroplasty. J Arthroplasty 5(4): 291-9.
8. Morawa LG, Manley MT, Kester MA, and Edidin AA (1999). Comparison of post-operative mental health status in TKA procedures using intramedullary and extramedullary instrumentation. 66th Annual Meeting of the American Academy of Orthopaedic Surgeons, Anaheim, CA. p.
9. Orsini EC, Byrick RJ, Mullen JB, Kay JC, and Waddell JP (1987). Cardiopulmonary function and pulmonary microemboli during arthroplasty using cemented or non-cemented components. The role of intramedullary pressure. J Bone Joint Surg Am 69(6): 822-32.
10. Parvizi J, Holiday AD, Ereth MH, and Lewallen DG (1999). The Frank Stinchfield Award. Sudden death during primary hip arthroplasty. Clin Orthop 369: 39-48.
11. Parvizi J, Sullivan TA, Trousdale RT, and Lewallen DG (2001). Thirty-day mortality after total knee arthroplasty. J Bone Joint Surg Am 83-A(8):-1157-61.

In vivo preparation for a Total Knee Cemented Device demonstrating the effectiveness of using CO_2 to clean and remove fat and debris, prior to cementing.



Tibial plateau after resection (shows blood, fat, and debris).

Same area after pulsatile saline lavage (shows fat and fluids remain).



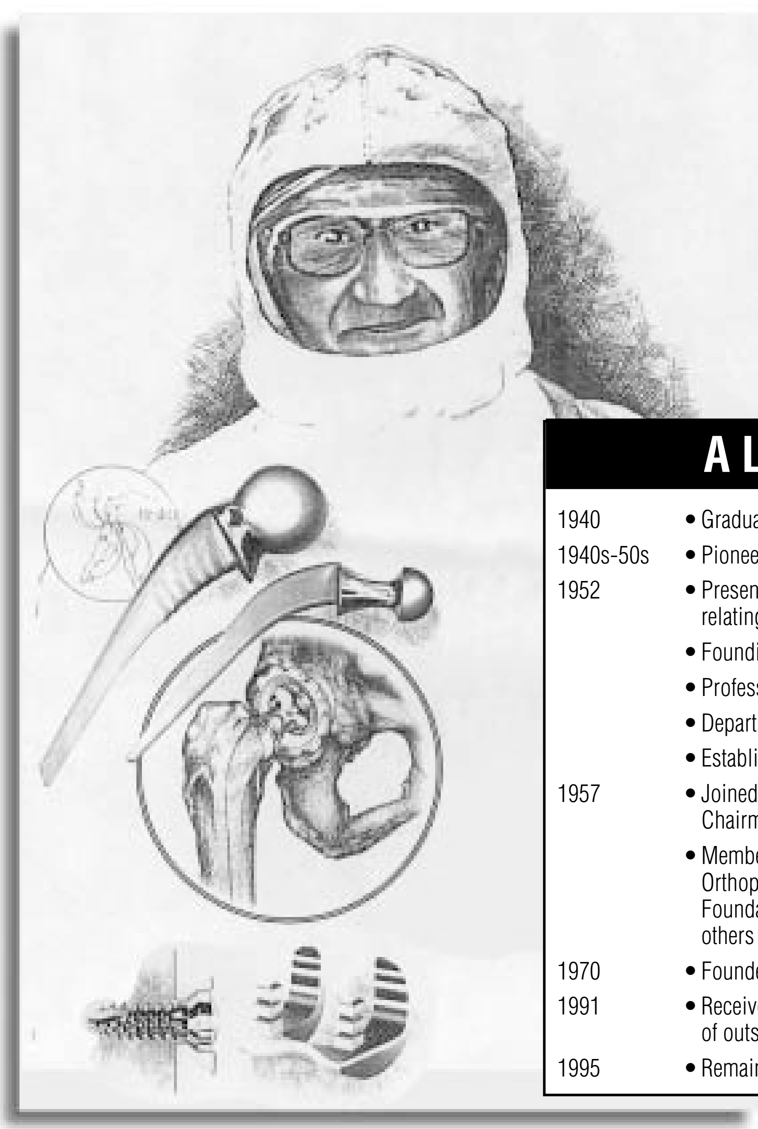
Same area after additional CO_2 lavage (shows reduced interposed fat and fluids).

Commentary

By Timothy McTighe

The tragedy of September 11, 2001 brings our emotions right to the surface. Watching the significant loss of life and the effect it is having on loved ones is heartbreaking. Times of this nature make one reflect on the important relationships in your life, current and past. It also places the importance of relationships first and foremost in your mind.

Significant relationships have been brought back to mind and I feel compelled to mention them here in an attempt to pay respect to all those that have suffered due to the tragic events of this September and to challenge every one not to take for granted the people that directly and indirectly effect their lives.



Charles O. Bechtol, M.D.

August 23, 1911 - July 16, 1998

Most people in the industry who know me understand the influence the Professor had on both my professional and personal life. He was a very special part of my life from 1974 till his passing in 1998. This is a time to reflect on his memory.

Charles and his lovely wife Louise shared many times with my wife Cathy and I, all over the world. We were honored to be part of the Memorial

A Lifetime Of Achievement

1940	• Graduate of Stanford Medical School
1940s-50s	• Pioneered the development of improved artificial limbs
1952	• Presented the first lecture to the American Academy of Orthopedic Surgeons relating engineering principles to orthopedic surgery
	• Founding member of the F4 Committee (biomaterials) of the ASTM
	• Professor and chairman of the Yale Medical School
	• Department of Surgery (orthopedics)
	• Established Yale Biomechanics Laboratory
1957	• Joined UCLA Medical School where he would serve as professor and Chairman of the Department of Orthopedic Surgery
	• Member and chairman of research committees for the American Academy of Orthopedic Surgeons, the Orthopedic Research Society, the National Science Foundation, the Los Angeles County and California Medical Associations, and others
1970	• Founded and chaired the joint Implant Surgery & Research Foundation.
1991	• Received the Academy of Surgical Research's Markowitz Award for a lifetime of outstanding contributions to medicine through experimental surgery
1995	• Remained an active consultant to the orthopedic industry

Services for Charles, and he still remains close in our hearts.

His genius will continue to be felt in the countless footsteps that might never have been taken or in the natural act of holding a child or picking a flower. In these simple ways the world will silently remember this extraordinary healer.

Joseph R. Shurmur, M.D.

August 2, 1941 - July 16, 1996

I started my career in orthopaedics as a Navy Corpsman during the Vietnam conflict and spent fours years (69-73) learning the basics of fracture treatment, surgery, traction, casting and had some interesting times with the Marine Corps specializing in field medical treatment.

Joe was a Lt. Commander in the Naval Reserve who had been called up for his two-year service commitment. He had just finished his orthopaedic residency training and was coming on board as my immediate commanding officer. I had the pleasure of serving with and working for Joe for almost two years prior to my being transferred to field duty with the Marine Corps.

Joe was not only instrumental in my professionally life but his strength of character provided me with the subtle traits of a role model for my personal life. I was honored to have been one of Joe's pallbearers and remain close to his family today. The following prayer was Joe's favorite and I believe provides a significant message for today.

Life is to live and life is to give and talents are to use for good if you choose. Do not pray for easy lives. Pray to be stronger. Do not pray for tasks equal to your powers. Pray for powers equal to your tasks - then the doing of your work shall be no miracle but you shall be a miracle. Every day you shall wonder at yourself… at the richness of life which as come to you by the grace of God. But everyone needs someone - knowing that somewhere someone is thinking of you.

- Fr. Solanus Casey, Capuchin

I would like to end this commentary by quoting a poem that illustrates what is becoming one of my most cherished traditions. I say this in honor for all the fathers that will not have a chance to create a special tradition for their sons and daughters weddings.

As a father of six I have had the pleasure of sharing the wedding day of two of our children. Our oldest son Jason was married in 1997 to Michelle. Two and a half years ago they brought Cathy and I our first grandson, Jack. This past June I had the pleasure of escorting my youngest daughter Katie down the aisle to David.

My toast to both couples could be called a prayer, a wish, a desire. I refer to it as:

A Fathers Thought

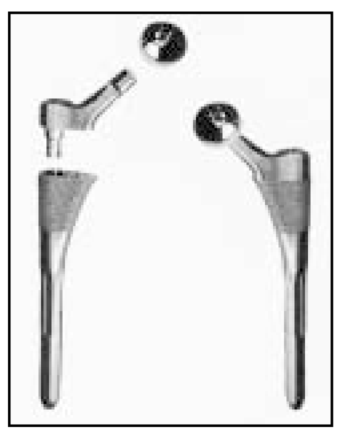
May there be light on every path you follow.
Wisdom to guide your every step.
Peace to confirm your every decision.

May you watch your thoughts; for they become words.
Watch your words; they become actions.
Watch your actions; they become habits.
Watch your habits; they become your character.
Watch your character; it becomes your destiny.

And know I will always be there.
May God bless you

NEXT ISSUE

Featuring Cementless Modular Stems



Joint Implant Surgery & Research Foundation
17321 Buckthorne Drive • Chagrin Falls, OH 44023
Phone: (440) 543-0347 •FAX: (440) 543-5325
TMcTJISRF@aol.com • www.jisrf.org