BONE IMPLANT INTERFACE

Hugh U. Cameron

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Preface

From its humble beginnings in the last century, the field of joint replacement surgery has expanded greatly, with at least half a million joints being inserted worldwide each year. The industry that has grown to supply these joints is vigorous, responsible, and research-driven.

The sharp end or sword point of this vast industry is the implant/bone interface. It is here that problems continue to be experienced. This interface has been intensively studied for the last 2 decades by orthopaedic surgeons, dentists, pathologists, scientists, and engineers. The information generated has become such a torrent that it is difficult for the resident in training, the practicing clinician, engineer, and implant salesman to keep abreast of the field. It is for these groups that this book has been written.

I have endeavored to bring together as much clinically relevant data as possible. No one person can cover this whole field and I therefore asked my friends and colleagues to help. I offer my sincere thanks to those who so generously gave of their limited time and hope that this book will not disappoint them.

Modes of fixation and problems arising at the interface are covered. Bone grafting has become so commonplace when artificial joints are used that I thought the bone/bone interface also demanded attention. Artificial ligaments are increasingly being used and this field is represented as well. Many of these chapters go into considerable surgical detail, because in some cases such as ligaments and bone grafting, the implant is extremely technique-dependent.

My hope is that this book provides a cohesive framework for those who work in the field, both clinically and in research and development. I hope that further avenues for research have been highlighted. I would like to thank the staff at Mosby–Year Book for their help in the compilation of this work.

—Hugh U. Cameron, M.B., Ch.B., F.R.S.C.(C)

CONTENTS

CHAPTER 1

Radiology of the Implant-Bone Interface

Hugh U. Cameron, M.B.Ch.B., F.R.C.S.C

For the majority of surgeons and engineers, the only tool available to examine the human implant-bone interface is postoperative, clinical x-ray. This is a poor instrument at best.

The limitation of clinical x-rays, as Albrektsson points out in Chapter 5, is that the *theoretical* maximal resolution power is 0.1 mm. In fact, the accuracy of the resolution power is much less due to the difficulties in obtaining reproducible projections and the lack of bony landmarks to serve as reference points for measurement. Insertion of a screw into adjacent bone can help with measurements by providing a fixed point. The presence of a hole in the implant can also help to determine rotation.[19]

If roentgen stereophotogrametric analysis is employed, smaller changes in implant position under load, inducible displacements, or, over time, migration can be measured. On normal clinical x-rays, migration of 2–3 mm must occur before it can reliably be detected and angular change of 4 degrees.[1]

X-ray data can be quite misleading. For example, unless each patient undergoes fluoroscopy, an impossible job if a large number of patients are involved, statements regarding radiolucency under the plate of the tibial component in total knee replacements are inaccurate (Fig. 1–1). A 4-degree change in the x-ray beam angle may completely conceal considerable radiolucency. One simple check is to measure the base plate thickness. If the base plate actually measures 3 mm thick, then any x-ray in which the base plate measures more than 3.5 mm thick has an angled beam and must be discarded (Fig. 1–2).

REPRODUCIBILITY OF CLINICAL X-RAYS

To improve x-rays taken of the same patient over time, the method of taking the x-rays should be as standardized as possible.

Hip

In the case of hip replacement, an anteroposterior (AP) x-ray of the pelvis, an AP x-ray of the hip to show the full length of the stem, and a Launstein lateral or modified frog leg view are required. A shoot-through lateral view is of no value (Fig. 1–3). To standardize rotation in the AP x-ray, the patient's

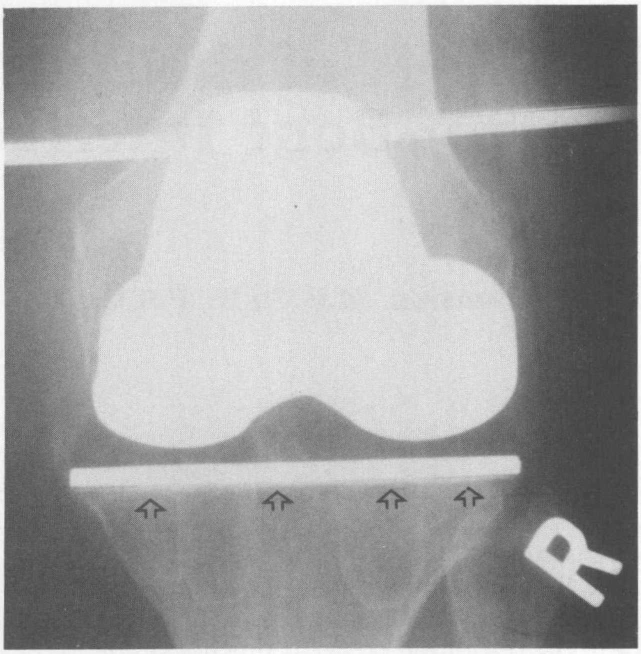

FIG 1–1
The edge of this x-ray shows continuous radiolucency under the base plate. A change in the x-ray beam of 4 degrees would obscure this finding.

FIG 1–2
In this x-ray of a bilateral case only one is an edge-on shot. As the thickness of each base plate is identical for both knees, the beam has angled, or more likely, the knee is not completely straight on the stem tibial side. Therefore, in this case, nothing can be said with respect to lucency under the plate on the stem side.

FIG 1–3
The foreshortened appearance of the shoot-through lateral makes interpretation of the interface all but impossible.

legs can hang over the end of the x-ray table so the tibia are vertical. The Launstein lateral film is taken with the patient turned slightly toward the side for x-rays, with the knee and ankle touching the x-ray table (Fig. 1–4).

Knee

The x-rays for a total knee replacement are a 3-foot standing AP, a lateral in 30 degrees of flexion, and a skyline x-ray taken in 30 degrees of flexion. To standardize rotation in the 3-foot standing view, an outline of footprints can be painted on the floor. A useful x-ray of the tibial base plate will be obtained depending on how the tibial component is inserted. If the component is inserted with a 10-degree backslope, an edge-on x-ray will not be obtained unless the beam is angled. Similarly, a fixed-flexion deformity will interfere with visualization.

A plastic box or frame can be used to position the leg for a lateral x-ray. The size of the limb will determine the degree of flexion, but an x-ray of the same patient will be reasonably reproducible.

FIG 1–4
A Launstein or modified frog leg lateral x-ray is required to study a hip implant.

These simple techniques will improve reproducibility even in busy, clinical x-ray units. However, it must be recognized that a fair percentage of clinical x-rays will be of little value in recognizing subtle changes.

DEFINITION OF RADIOLOGICAL TERMS

Words have a variety of meanings to different people. Accordingly, I will define what some words mean to me.

Bead Shed

If a porous coated system is employed for implant stabilization, beads may be lost. The process of coating application may result in variable strength of the coating. For example, a single bead may be held to the adjacent bead by one joint or "neck" as opposed to multiple necks. This joint is obviously weak and can give way, and the bead can fall free. This bead shed can occur under the following conditions.

Insertion Stresses

Insertion stresses may result in loss of the odd bead. This can be seen on the initial, postoperative x-ray.

Micromotion

Coating fatigue can occur as a result of micromotion. The tibial component in total knees, for example, may be well fixed to the underlying bone. The tibial metaphyseal bone is very compliant, especially anteriorly, and under load, some differential motion can occur between bone and implant. This motion can result in stresses at the interface, and it may be a source of bead shed but this is probably a fairly minimal factor. If micromotion was significant, shed would be much more common.

Macromotion

A loose implant moving on the underlying bony bed will always result in bead shed, usually in multiple zones (Fig. 1–5).

Wear Through

When the polyethylene of a tibial component in total knee replacement wears through, metal-on-metal contact occurs. This contact results in in-

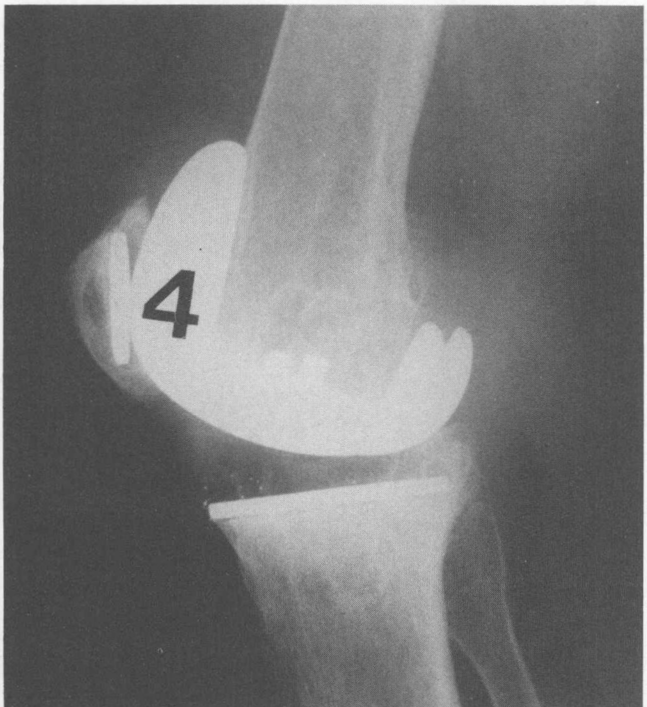

FIG 1–5
This tibial component is loose and has subsided. Multifocal bead shed from the tibial component has occurred.

creased transfer of stress to the metal base plate and multiple bead shed rapidly occurs (Fig. 1–6).

The x-rays of the implant must be divided into zones: the Gruen[16] zones in the hip and the Knee Society zones in the knees. Bead shed is defined as loss of more than two beads in any one zone. Although it is probably unfair to do so, single-zone shed can be eliminated as possibly due to insertional stresses, coating fatigue due to micromotion, and so forth. Multizone bead shed is the most sensitive radiographic measure of component problems in total knee replacement. It is not clear whether this is true for hip replacements. Bead shed may predate the onset of clinical symptoms by several years, but indicates that the implant is in a far from stable situation.

In one study on the comparison of stem versus nonstem tibial components in noncemented total knee replacements, there was little clinical difference at 5 years.[12] The sinkage rates were different: 3% sinkage for the nonstem components, of which 0.7% required revision, and 0.7% sinkage for the stem components, none of which required revision. Bead shed was markedly different: 25.7% for the flat plate tibia and 6% for the stem tibial component. If single zone bead shed was eliminated, multizone bead shed occurred in 17.3% of the flat plate tibias and in 1.7% of the stem tibial components. Bead shed from the femoral side was 2.1%, all being single zone.

The clinical results in this series were quite similar: 95% good or excellent. The majority of the bead shed cases were asymptomatic. It was concluded that a stem should be added to the tibial component in total knee replacement, if asymptomatic bead shed is thought to be significant. The bead shed test can only be used if the beads are large enough to be visible radiographically. Some plasma spray porous surfaces are too small to be seen, as are most hydroxyapatite (HA) coatings.

FIG 1–6
The plastic of this tibial component has worn through resulting in metal–metal contact. This rapidly leads to bead shed.

Distal Cortical Hypertrophy

Distal cortical hypertrophy occurs in two forms: apparent and true. Apparent hypertrophy is cortical expansion due to a loose femoral component. As the endosteal cortex becomes eroded, new bone is laid down in the subperiosteal region.

True hypertrophy is a result of abnormal stresses in a region. With cemented implants, it is common laterally in those with varus stem placement. Medial hypertrophy can occur with valgus stem placement.[20] This hypertrophy occurs over a fairly wide area at the stem tip.

In noncemented implants, hypertrophy tends to be much more localized, usually to the anterolateral cortex.[10] This localization results in increased stiffness of the femur in this zone and is a welcome sight, especially if the patient has end of stem pain, because the pain may then disappear.

Metallosis

If the polyethylene in a metal-backed component wears through, the contact of one metal with another will produce the liberation of metallic debris. This debris causes black staining of the tissues called *metallosis*. Metallosis is rarely seen with the initial cobalt chrome on cobalt chrome implants such as the McKee-Ferrar, Ring, and Sivash prosthesis.[6] Where there is point or line contact, such as after the polyethylene has worn through on a patella or tibial component, considerable metallic debris may be generated. This is particularly true if one of the components is softer than the other (i.e., cobalt chrome on titanium).

The metallic debris is occasionally severe enough that it can be seen radiographically outlining the interior of the joint (Figs. 1–7, *A* and *B*). Alone it is unlikely to produce symptoms, and other than that shown in Figure 1–7 such cases are rare.[11] Eventually chronic synovitis will result when coupled with plastic wear debris.

Lucency

From the implant-bone interface point of view, lucency is a dark line seen radiographically between the implant and the bone. The dark line is a fibrohisteocytic membrane.[7] The line may be progressive (i.e., becoming wider in subsequent x-rays) or nonprogressive (i.e., not changing from one year to another). The line may be complete and be seen in every projection completely surrounding the implant, or it may be incomplete and seen as not completely surrounding the implant, or it may not be seen in all projections. The line may be parallel or divergent from the implant. A divergent line indicates macromotion, and the implant is radiographically loose (Figs. 1–8, *A* and *B*).

Osseo Integration

Osseo integration cannot be seen radiographically. When present, there is usually no visible change at the interface (Fig. 1–9). Proximal stress shielding

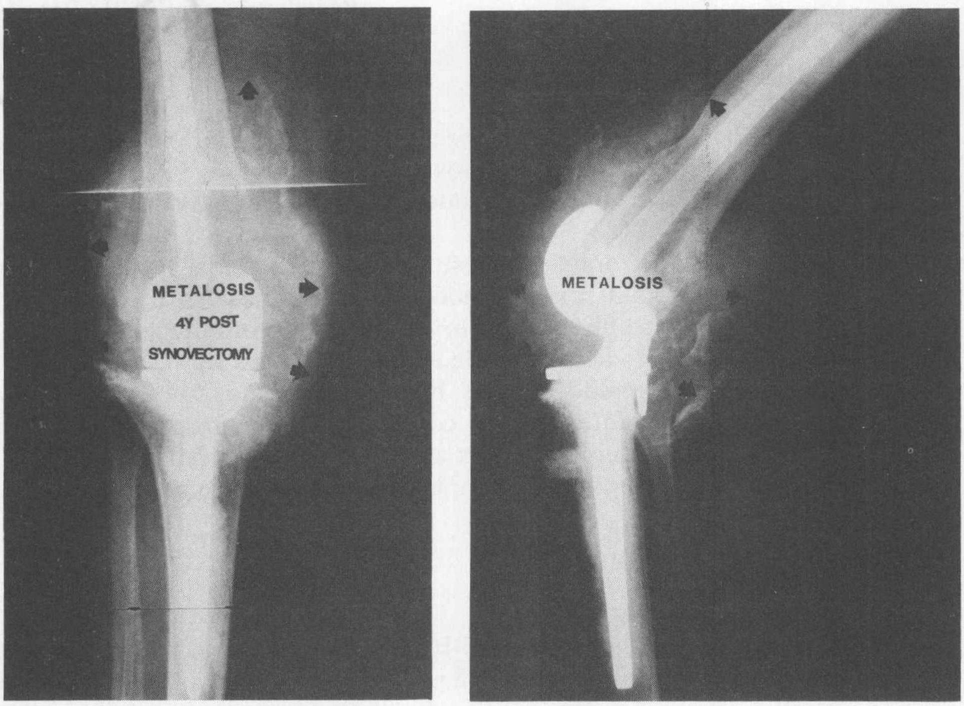

FIG 1–7
This original Guepar hinge had a metal-metal bearing. The metal spindle produced a severe amount of metallic debris sufficient to cause a synovitis. A synovectomy was performed. Four years later, the metallosis has recurred. This is the classic appearance of a severe metallic wear debris synovitis. It is of note that in spite of the degree of synovitis no osteolysis has occurred, and both components remain tightly fixed to bone.

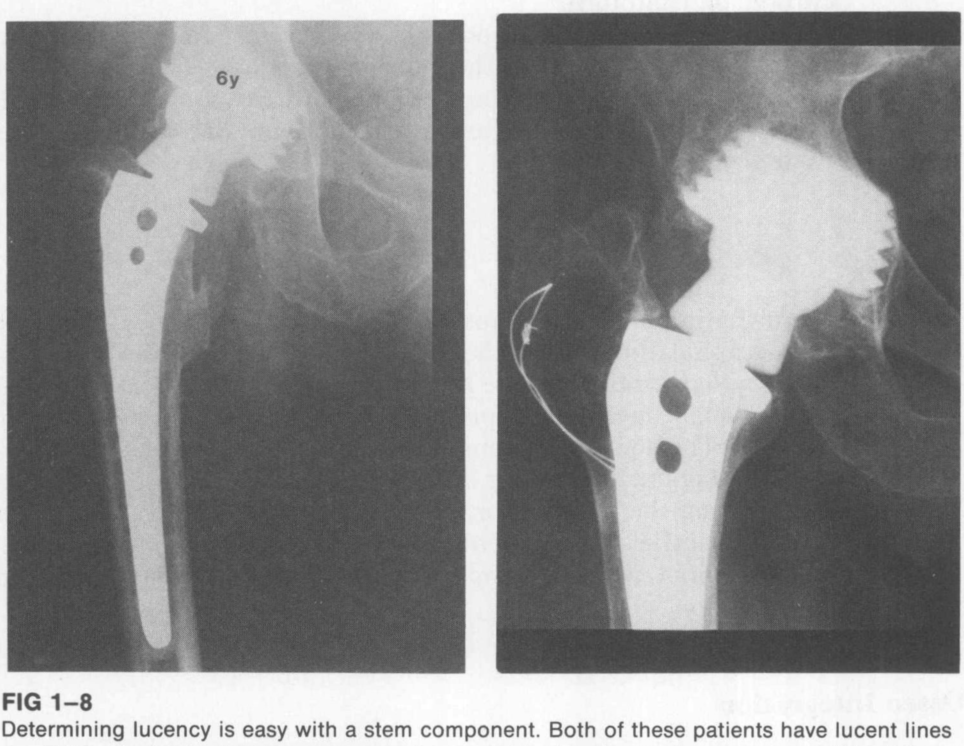

FIG 1–8
Determining lucency is easy with a stem component. Both of these patients have lucent lines parallel to the implant on the stem side (i.e., a stable situation). It is much more difficult to determine lucency on the acetabular side. One patient shows no acetabular lucency. The other patient shows lucency completely surrounding the cup with bone resorption from the depths of several of the threads.

FIG 1–9
This titanium alloy grit blast stem shows no unusual features radiologically. At revision, the stem was found to have large areas of osseo integration.

may occur, and occasionally, bony hypertrophy, either endosteally or subperiosteally, may occur (Figs. 1–10, *A-D*).

Osteolysis

Osteolysis is the dissolution of bone (Fig. 1–11), usually occurring in a discrete area.[17] It can have various causes, including infection, metastatic tumors, and so forth. Osteolysis caused by an acute or subacute postoperative infection tends to occur early and spread rapidly around the implant. Osteolysis that occurs with late infection in the presence of a well-integrated implant may remain fairly localized or may give rise to bone destruction that initiates adjacent to the joint and slowly spreads outward.

This dissolution is commonly seen as a result of a wear-debris granuloma. The granuloma develops from wear debris liberated from polyethylene and bone cement. One case in the literature found an absence of plastic debris.[5] This was a ceramic-on-ceramic noncemented component. The acetabulum was grafted, and the ceramic component migrated to where it contacted the stainless steel screws.

This wear debris is microscopical. It has been estimated that 40 billion particles of polyethylene are liberated each year from a polyethylene hip socket.[3] The presence of bone ingrowth or even dense, fibrous tissue prevents