Chapter 3
A New Surgical Science

A new surgical science – total prosthetic joint replacement – has suddenly come into being. A heavy work load has suddenly been created in response to the availability of a successful new operation … orthopaedic departments planned for the future district general hospital will be unable to cope if they are to handle the routine orthopaedics for which they were designed.

When one tries to consider how highly specialised techniques can best be made available to a large number of patients … one has to face the fact that it is impossible, now or at any time in the future, and even in the most wealthy countries, to avoid some type of rationing. Rationing will have to be a product of educating surgeons in the methods of assessing the priority for surgery and self-discipline in patients fostered by education. (1970)

Caution

Charnley was fully aware of the implications of a successful hip replacement with the likely future demands and responsibilities. Once again the "Teflon Experience" was not without practical benefits.

- *I am making no attempt to encourage other surgeons to adopt this procedure for at least another three or four years or until an authoritative body such as the British Orthopaedic Association might request it … the designs have not been made available to manufacturers…*
- *This operation must be reserved …for very disabled patients and the warning that a second operation might be necessary after some years … should be given.* (1963)

The seriousness of the procedure, the need for regular follow-up and monitoring of outcome, as well as provision of revision facilities, are well documented.

- *An important aspect of the use of total prosthetic replacement is acceptance by the patient of a planned policy of "revision" with the establishment of a centre which holds itself permanently responsible for maintenance of this type of surgery* and
- *I regard it mandatory that any surgeon aiming to take up the "total prosthesis" should make available to the public a service which can cope with the maintenance operations* (1966)

B.M. Wroblewski et al., *Charnley Low-Frictional Torque Arthroplasty of the Hip: Practice and Results*, DOI 10.1007/978-3-319-21320-0_3

– *To countenance the insertion of total hip replacement into a patient of 25 years of age in 1971, without a service station planned and organised for 1996, is like selling motor cars without providing mechanics and workshops.* (1971)

Charnley's views are succinctly summarised in a statement:

– *We have continuously to ask ourselves what type of late failure we must be prepared for, and we must protect patients too ready to submit to this practice after seeing patients who have been dramatically "cured" by this method. The past history of the arthroplasty of the hip joint is no great credit to orthopaedic surgery.* (1967)

Training

– *I visualise the establishment of a limited number of specialist centres such as this at Wrightington to train the postgraduates in the technology, to take problem cases, to cope with secondary operations…*
– *It is essential that the technical skills acquired by members of the staff of a surgical centre should be handed on continuously so as to keep a body of men capable of handling the difficult secondary operations of the future.*" "*… by encouraging professionalism, by narrowing fields of activity, the quality of service can be raised and the cost per item lowered, … surgical residents turn out first class surgery because they are supported by a professional team which is not subject to continuous change.*
– *Uniform criteria can be established in large centres … the most dangerous unit is a small unit looking for work.*
– *We are ready to make contact with non-conforming minds, since this helps us to see our established techniques through non committed eyes.*
– *There is no sign of any trend towards copying the pattern established at Wrightington.*
– *Perhaps I am blind to defects of supreme specialization which may be obvious to others … perhaps for others the pressure of day-to-day work is obscuring trends which will soon require decisive action.*

Cost Implications

The demand for this type of surgery and the cost implications to the National Health Service were anticipated. The price of components was kept deliberately low. "*The NHS has to bear the costs.*"

Charnley took no royalties and any financial benefits were channelled into research. Neither the design nor the methods of manufacture of the prosthetic components or the instruments were patented. It was the rapidly increasing demand and commercial pressure on the manufacturer in the face of mounting competition and copying that forced Charnley to allow the release of the LFA components, but not

until the second half of 1970. Charnley informed the past Residents of his decision by a personal letter.

Statements made by Charnley many years ago serve as reminder of how far sighted he was.

Long-Term Follow-Up: The "First 500"

> *It was therefore decided upon to make a prospective study of those patients operated on between November 1962 and the end of December 1965 and to continue this annually until they could no longer attend. This would produce truly long-term studies …* (1970)

This attempt at "*truly long-term studies*" must be seen in the light of the continuing developments based on the ongoing clinical experience. All the operations carried out in the 3 year period November 1962 and December 1965, were included.

Some detailing of the various procedures is essential in order to offer a better understanding of the first 3 years in the history of the Charnley LFA.

Although referred to as the "FIRST 500" the total number of operations, and thus hips included, was 909. Patients' mean age at the operation was 65 years (range 22–86). The details are shown in Tables 3.1, 3.2, and 3.3.

Primary LFA There were 420 such procedures. Both the cup and the stem were fixed with acrylic cement. It is this group of 420 that was used as a "baseline" in subsequent studies.

Table 3.1 The Original "First 500" group selected by Charnley for an indefinite follow-up. All patients operated upon from November 1962 to December 1965 were included: 420 were primary LFAs

	LFA[a]	Press-fit cup[b]	Teflon to Press-fit	Teflon to LFA	Total
1962/1963	185	37	4	50	276
1964	47	193	18	40	298
1965	188	106		41	335
Total	420	336	22	131	909

[a]LFA: = cemented cup and stem

[b]Press-fit cup: = metal-backed cup with cemented stem

Table 3.2 "First 500" Press-fit cup group reviewed in 1983. Only 16 hips were available for follow-up

	Number	Died	Lost	Revised	Attending
1962/1963	37	21	10	4	2
1964	193	73	74	37	9
1965	106	30	44	27	5
Total	336	124	128	68	16
%	(100 %)	(36.9 %)	(38.1 %)	(20.2 %)	(4.8 %)

Table 3.3 "First 500" LFA group reviewed in 1983. Only 32 hips were available for follow-up

	Number	Died	Lost	Revised	Attending
1962/1963	185	88	66	13	18
1964	47	24	19	3	1
1965	188	78	86	11	13
Total	420	190	171	27	32
%	(100 %)	(45.2 %)	(40.7 %)	(6.4 %)	(7.6 %)

Fig. 3.1 Press-fit cup used without cement

Press-fit cup with cemented stem The design utilised the Smith-Peterson cup with an ultra high molecular weight polyethylene insert. An opening at the summit of the metal shell was machined into which a spigot of the UHMWPE cup would fit – protruding and thus serving as a locating guide into the pilot hole which was made in the acetabular floor as part of the reaming technique (Fig. 3.1).

> *The press-fit cup, not cemented in the acetabulum, though rigidly hammered into position at the time of the operation, the socket could rotate on its axis.*

The reason for introducing the press-fit cup was "*the recognition by mid 1963 … that the demarcation between radio-opaque cement and the bone of the acetabulum was becoming a common radiological occurrence*." The fear of the consequences of early demarcation of the bone-cement interface of the cup is reflected in the change of practice: out of 298 operations carried out in 1964, the press-fit cup was used in 211 (71 %). The press-fit cup was not used after 1965. From then on all cups were cemented because; "*demarcation of the cemented socket did not seem to be*

progressing beyond the amount visible at the end of the first year and … … a rather high rate of tilting and migration of the press-fit cup often leading to dislocation." (It may be of interest to point out that one of the longest follow-up successful LFA's was in fact a patient with bilateral press-fit cups with cemented stem – past 40 years) (Figs. 3.2, 3.3 and 3.4).

In this group of "First 500" – there were 153 revisions: Teflon to press-fit – 22, Teflon to LFA – 131. Thus, out of a total of 909 operations, less than half: 420, (46 %), were primary LFAs in the true sense. By October 1977 "*over 100 of this original group were able to attend or keep in communication by questionnaire … or by returning an annual radiograph taken near where they live*." (1979)

By 1983 only 48 hips: 32 LFAs and 16 with press-fit cups were available for follow-up. The dwindling numbers could provide only limited information that was essential to establish the clinical value of the operation but could not "*produce truly long-term studies*" as envisaged by Charnley.

It became clear that a new group of younger patients had to be selected. This decision was taken in 1974. "**Since 1974 we have had a policy that all patients aged 50 years or less at the time of the LFA are followed up indefinitely. Our reasons are life expectancy**, **the possibility of studying long-term outcomes**, **and the need for early intervention for impending failure**" [1]. Long-term follow-up can only be achieved with young patients.

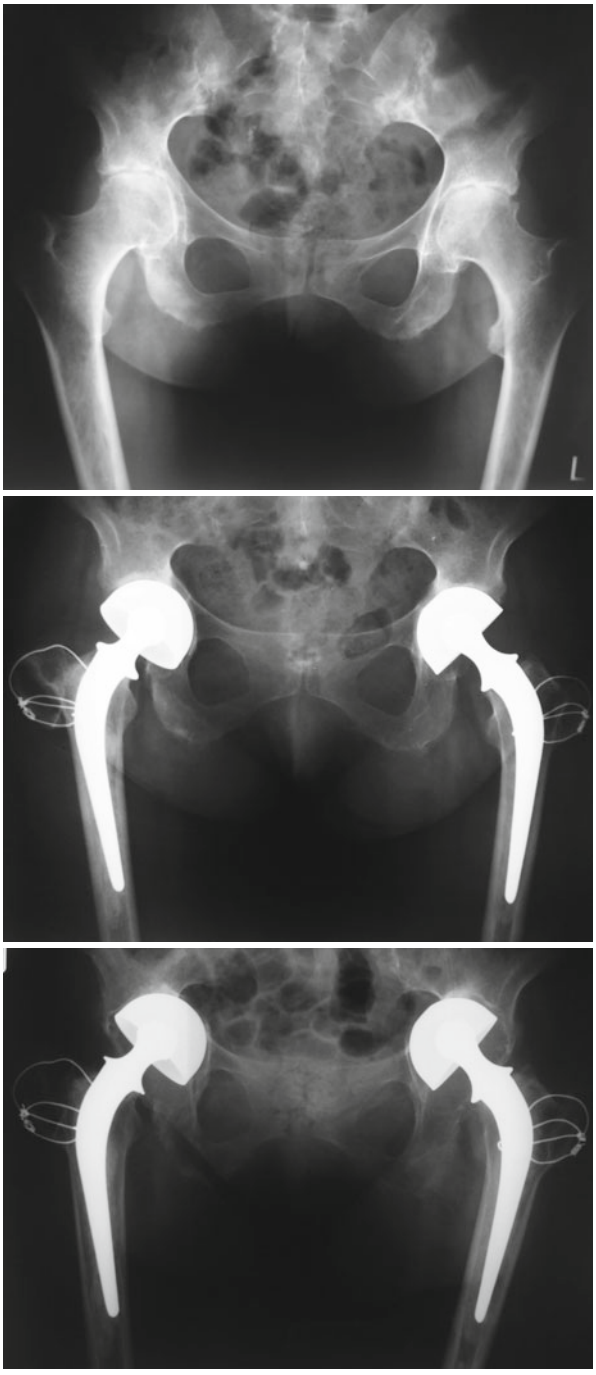
Such a decision brings with it aspects hitherto not considered: changes in the patterns of underlying hip pathology, longer life expectations and higher activity level, more frequent follow-up and intervention for failures, both radiographic and clinical. And yet such a policy had to be put into practice, not only to establish the true long-term clinical value of the Charnley hip replacement, but also to investigate the patterns of problems to come and use them as pointers for new developments.

Clinical success of total hip arthroplasty is often taken for granted subject to correct patient selection and sound fixation of the components. Various methods of assessing the early clinical outcome serve as a reassurance of adequate patient selection for the operation by the surgeon and not a measure of long-term success of the method. Clinical results do not reflect the mechanical state of the arthroplasty: at this stage of our knowledge good quality radiographs are more valuable.

One other factor was to become very prominent with time – the cost of the follow-up. Yet how was the progress to be assessed? Charnley wrote in 1971 "*To countenance the insertion of total hip replacement into a patient of 25 years of age in 1971*, *without a service station organised for 1996*, *is like selling motor cars without providing mechanics and a workshop*." Should "*selling motor cars*" continue "*without providing mechanics and a workshop*" – the after sales service?

This volume is the confirmation of the Charnley principles; **the continuing follow-up of patients under the age of 51 years**; **the operations carried out between November 1962 and December 1990**.

The collection and study of information is a continuing process. Clinical results and radiographic appearances are updated at each follow-up. Findings at revisions



Figs. 3.2, 3.3 and 3.4 Radiographs of bilateral press-fit Cups. Pre-operative, post operative, and at 42 years after surgery

are recorded. Explanted components and soft tissues are studied in collaboration with Universities. Information gathered serves for the introduction of evidence-based improvements in design, materials and surgical techniques. Each aspect now becomes a study in its own right as patients are continually added to the inevitably dwindling original group.

Bone Cement Interphase Study. Examination of Post-Mortem Specimens

If we are to contemplate total hip replacement in adults as young as 45 years of age with the idea of 25 years of a trouble-free life ahead, it is necessary to hold definite opinions on the histological nature of the bone cement interface.

At Wrightington Hospital by about 1965 it became obvious that it was imperative as soon as possible to obtain post-mortem material from ***highly successful cases*** *…*

The use of cement for component fixation and the study of the bone-cement interface has been an integral part of the concept, development and the technique of the Charnley LFA.

Charnley first used acrylic cement in 1958 for the fixation of femoral hemi-arthroplasties. Thirty five such procedures were carried out in the first year. "*The results were superior to those without cement*" [2].

Charnley considered that a lasting bond between bone and the acrylic cement could be achieved, certainly on the femoral if not acetabular side [3].

Aware of the clinical importance of long term histological studies Charnley approached a number of his patients with a very tactfully written request that their hip be bequeathed for post-mortem histological studies. Charnley prepared a letter explaining not only the need for the study but also accepting his own mortality (Figs. 3.5, 3.6 and 3.7). "*I would come by car with the necessary equipment to remove the specimen at the undertaker's premises…*"

Collection of Post Mortem Specimens

A standard metal box routinely used for sterilisation of various materials and instruments were ready for when a call came (Fig. 3.8). Either Charnley himself or the next available Senior Resident performed the duty.

Lateral incision down to the shaft of the femur, division of the femur – about mid-shaft – with the Gigli saw, then distal to proximal dissection of the femur, section of the pubic rami medially and the ilium posteriorly, skin closure. (The arthroplasty was not opened). The specimen thus secured was placed in the receptacle and filled with aqueous solution of formaldehyde on return to the Hip Centre.

TELEPHONE—APPLEY BRIDGE 521

WRIGHTINGTON HOSPITAL MANAGEMENT COMMITTEE

CENTRE FOR HIP SURGERY

WRIGHTINGTON HOSPITAL
Near WIGAN

1st August, 1966.

Dear

Private and Confidential

I am writing to some of my patients who have had the new operation, "low friction arthroplasty", performed on their hip, at least one year ago, to see whether they might be prepared to help me in medical research on this important problem of arthritis of the hip.

I am selecting patients whose ages are such that they are likely to predecease me by more than ten years, in the hope that they will bequeath their operated hip to medical research.

The great advances that we have made at Wrightington in the surgery of the hip joint are now established in the case of elderly patients, because elderly patients do not expose the artificial hip to the very great mechanical stresses which the hip experiences in middle and early middle age. One of the great problems we are faced with is the young woman (30 to 40 years of age), who has both hips stiff and painful as a result of being born with defective hip joints (congenital dislocation of the hips). Hips of this kind can survive the first 25 or 30 years of life without giving much trouble and then suddenly fail. We have no way of finding out if this new operation can be developed to suit this important group of patients unless we can get opportunities to study the sites where incipient defects are likely to develop after the artificial hip joint has been in position for a considerably number of years.

Animal experimentation in this work is of no use, because man is the only creature which walks with full weight on two legs. Experiments in the engineering laboratory in the same way are of restricted value because the most likely site of failure is likely to lie between the artificial hip and the living bone. It is quite easy to solve the mechanical problem inside the artificial hip joint itself in the engineering laboratory and we believe we have done this.

If the idea of making such a bequest should be repugnant to you, I sincerely hope you will forget this letter. In the case of your failure to reply to this letter I shall take precautions, through our records system, to make sure that you are never bothered again on this score.

If the idea of making this bequest appeals to you, (and I may say that it would be a noble gesture and of more value to research on the problems of younger patients than a donation of £250,000), the procedure to be adopted is quite simple and is as follows:-

1. Sign where indicated at the bottom of this letter and retain this letter in your personal documents.

2. Sign the copy of this letter which is enclosed, and return this copy in the stamped addressed envelope.

3. Insert the name and address of your eldest son or daughter where indicated.

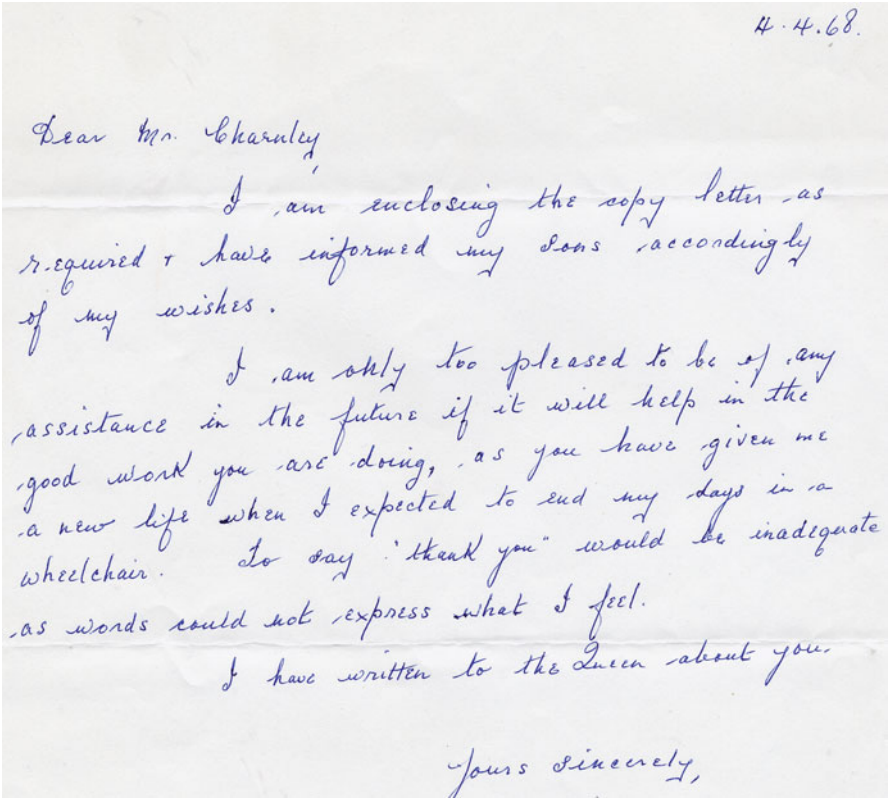
I have taken the decision to approach you directly on this topic because close relatives are always more disturbed about making a decision in this matter than are the patients themselves; indeed my attempts in the past to approach relatives on this matter so far have had only one successful outcome. I think that if it were known that a bequest of this kind was the earnest wish of their parent everyone would be happy to carry it out.

Kind regards,

Yours sincerely,

John Charnley, D.Sc., F.R.C.S.,
Consultant Orthopaedic Surgeon and
Director of Hip Surgery.

Fig. 3.5 Letter of bequeath from Charnley to his patients asking for their hip replacement after death



4.4.68.

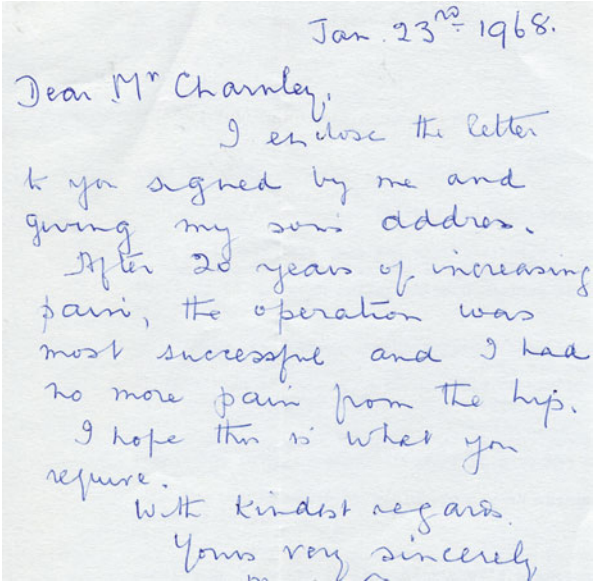
Dear Mr. Charnley,

I am enclosing the copy letter as required & have informed my sons accordingly of my wishes.

I am only too pleased to be of any assistance in the future if it will help in the good work you are doing, as you have given me a new life when I expected to end my days in a wheelchair. To say "thank you" would be inadequate as words could not express what I feel.

I have written to the Queen about you.

Yours sincerely,



Jan. 23rd 1968.

Dear Mr Charnley,

I enclose the letter to you signed by me and giving my son's address.

After 20 years of increasing pain, the operation was most successful and I had no more pain from the hip.

I hope this is what you require.

With kindest regards.

Yours very sincerely

Figs. 3.6 and 3.7 Letters from patients to Charnley giving permission for their hip replacements to be used for medical research

Fig. 3.8 Post mortem containers used to remove and store bequeathed hip replacements

Post-mortem Specimens

The very personal and sensitive manner in which Charnley approached the patients was very well reflected in what followed. There has never been a single complaint from the relatives. Even years after the study was completed it was not unusual to receive messages about the availability of further material from a recently deceased relative.

When the project was nearing completion 78 hips, retrieved from 57 patients, were available for the study. Majority of specimens, 44, were from female patients, while 13 were from male patients. This is a reflection of the clinical practice and the demand for the operation. Technical details of the preparation of the specimens for histological examination, as well as the interpretation of the various appearances, are outside the scope of this brief record.

The examination of the post-mortem specimens was completed by Professor Archie Malcolm under the sponsorship of the John Charnley Trust set up by Lady Charnley. The reader must refer to the original publications [2–10] on the subject.

Correlation Between the Radiographic Appearances, Histology of the Bone-Cement Interface of the Cup and the Clinical Results

There are certain aspects concerning the information derived from the study that for various reasons, have not been documented before.

These concern the correlation between the clinical results, as derived from the follow-up records, radiographic appearances of the bone-cement interface of the cup as observed on the final follow-up radiographs, and the histology of the bone-cement interface of the cup.

For the purpose of these particular studies 39 of the 78 specimens available had to be excluded. The reasons for exclusion are detailed in Table 3.4

The details of the clinical results were extracted from the records made at the last follow-up, graded for pain, function and movement according to d'Aubigne and Postel classification [11] as modified by Charnley [12].

All the radiographs were examined jointly by Professor R S M Ling OBE, FRCS, Mr M W J Older FRCS and Professor B M Wroblewski. The appearances were classified according to Hodgkinson et al. [13] and consensus was achieved in each and every case.

The Results

The 39 hips were from 30 patients; 29 from 21 females (8 bilateral) and 10 from 8 males (2 bilateral). The mean age at surgery for the whole group was 68 years 7 months (46 years 8 months – 80 years) and the mean weight 62 kg (37–87).

The underlying hip pathology was primary osteoarthritis in 25, Rheumatoid arthritis in 10, Idiopathic protrusio in 2, Paget's disease and congenital dysplasia – 1 each.

One hip had been operated upon previously by intertrochanteric osteotomy.

The mean follow-up was 5 years and 9 months (8 months to 14 years 5 months) while the time between the last follow-up and death was 1 year 11 months (2 weeks to 5 years 6 months).

Table 3.4 Exclusions from the study

22	Cemented stems with press-fit metal backed cup
6	Radiolucent cement used for both the cup and the stem
5	Revisions from Teflon to UHMWPE cups
5	Specimens previously sectioned for histology
1	McKee metal on metal arthroplasty

Clinical Results

These are shown graphically in Fig. 3.9. The most obvious feature is the severity of pain and disability of the patients accepted for the operation. Rest pain, clinically, and extensive changes radiologically, were the indications for the operation. Of the 39 hip replacements, 37 were considered to be completely pain free. Functional activity level and parameters are more difficult to assess objectively as they depend, to a large extent, on patient selection for the operation.

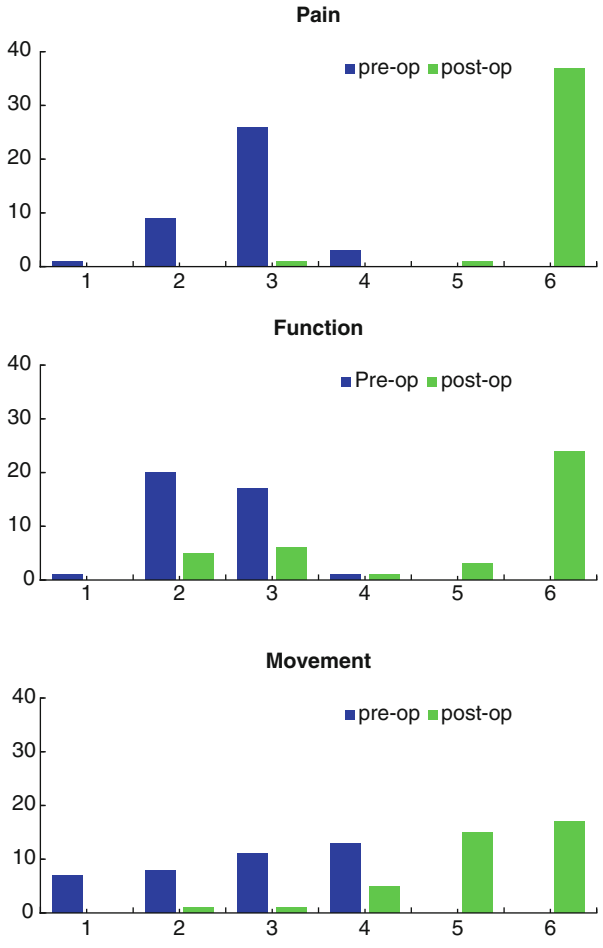


Fig. 3.9 Bar Chart showing clinical results in the post-mortem study. Before surgery and at the last follow-up before death

Radiographic Appearances and Histology of Bone-Cement Interface of the Cup

Radiographic appearances and the histology of bone cement interface was the main purpose of the study. The histological studies were carried out by Professor Archie Malcolm who suggested a classification which is shown in Table 3.5.

The correlation between the radiographic appearance according to Hodgkinson et al. [13] and histological appearances as defined by Malcolm is shown in Table 3.6.

The results of the study have shown that clinically the operation is uniformly successful. Freedom from pain is the main feature. Activity level depends on the patient selection for the operation.

Table 3.5 Histology of bone-cement interface of the cups examined. Classification suggested by Professor Malcolm and used in the study

Numerical value	Histological appearance	Fibrous membrane
0	Complete osseointegration	Nil
1	Areas of osseointegration Incomplete fibrous membrane	Incomplete
2	Complete fibrous membrane	Thin
3	- ditto -	Moderate
4	- ditto -	Thick
5	- ditto -	Gross

Table 3.6 Comparison of histological and radiographic appearances of the bone-cement interface of the cup in the 39 specimens studied

Fibrous membrane	Gross	5				x	x
	Thick	4			xx	xxxx	
	Moderate	3		xxx	xxxx	xxxx	
	Thin	2	xxx	xxxxx xxxxx	x		
	Incomplete	1	xxx xxx				
	Nil	0					
Radiographic appearance			None	Outer 3rd	Outer 3rd	Complete	Socket migration
Demarcation of the socket					Mid 3rd		

Conclusion

From the very detailed information gathered as a result of Charnley's foresight it is clear that

- **Clinical results** do not reflect the mechanical state of the arthroplasty; there is no correlation between the radiographic appearances and the clinical results. This is not unexpected. If we assume that arthritic pain arises from the articulation then replacement of the real articulation with an artificial can be expected to offer pain relief. "Fixation" of the cup is probably less important than maintenance of the position of the cup while reducing wear to the minimum possible. (Even the metal backed press-fit cups offered freedom from pain).
- **Histology of the bone-cement** interface of the cup reflects the radiographic appearances quite accurately. Total osseointegration was not found in any of the cases, although areas of osseointegration were found in six hips where bone-cement demarcation was incomplete [10].

It could be argued that lack of total osseointegration is an indication of failure. This may be considered to be correct if the objective was to achieve osseointegration. This could only be so on the assumption that osseointegration is essential for clinical success. This assumption, however, cannot be correct. There is no correlation between the clinical results and the radiographic appearances or the histological findings; osseointegration of the cup is not essential for clinical success.

(The metal backed press-fit cups were introduced because of the demarcation of the bone-cement interface observed in some cases. Osseointegration could not have occurred – yet clinical results were successful – some over many years (Figs. 3.2, 3.3 and 3.4). The method was abandoned because of cup tilting and dislocation, not because of pain.)

The explanation must be that osseointegration is not essential for clinical success, maintenance of the position of the cup however, is essential.

It is the change in cup position resulting in a progressive loss of bone stock, that becomes an indication for revision.

It is in this context that the low frictional torque principle in Charnley hip replacement allows excellent function over so many years. It is the progressive cup penetration leading to impingement of the neck of the stem on the rim of the cup, as well as the increase in the frictional torque, that set the limit on the success of this type of surgery.

Although clinical results remain the essential part of clinical practice, radiographic appearances are a better indication of the mechanical state of the arthroplasty.

Follow-up of patients must include radiographs; verbal or written information is not adequate for the assessment of the mechanical results of hip replacement surgery.

It is essential to distinguish between the clinical success of an operation for an individual patient and the long-term success of the method of surgery.

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