

A RANDOMIZED CLINICAL TRIAL COMPARING CEMENTED TO CEMENTLESS TOTAL HIP REPLACEMENT IN 250 OSTEOARTHRITIC PATIENTS: THE IMPACT ON HEALTH RELATED QUALITY OF LIFE AND COST EFFECTIVENESS

Robert B. Bourne, M.D., F.R.C.S.(C)*
Cecil H. Rorabeck, M.D., F.R.C.S. (C)*

in association with

Andreas Laupacis, M.D., F.R.C.P. (C)
David Feeny, Ph.D.
Cindy Wong, M.Sc.
Peter Tugwell, M.Sc., M.D., F.R.C.P. (C)
Karen Leslie, R.N.
Ruth Bullas

SUMMARY OF CLINICAL RELEVANCE

Randomized clinical trials are considered mandatory before a new pharmaceutical agent can be released for public consumption. Surprisingly, randomized clinical trials are virtually unheard of in assessing a new surgical procedure or device. In this study, funded by the Medical Research Council of Canada, 250 osteoarthritic patients with mainly unilateral osteoarthritis of the hip were randomized as to whether they received a cemented or cementless total hip replacement. Patients were stratified for age (under 60 or over 60 years) and surgeon (RBB or CHR). All operations were done in the same operating room, utilizing the same direct lateral approach and surgical technique. Post-operative care was the same. The patients and the two clinical observers (KL and RB) remained blinded as to whether a cemented or cementless device had been inserted. Accurate patient cost was documented for each patient's in-hospital stay, as well as out-patient costs during the first year. Cost to quality adjusted life year data was then generated, such that comparisons could be made to other medical interventions (i.e. coronary artery bypass).

Several clinically relevant results emerged from this study, which the authors believe is the first randomized clinical trial comparing two orthopaedic implants.

- 1) Surgical patients are willing to be part of a meaningful randomized clinical trial. In this study, 78% of eligible patients agreed to participate.

- 2) Total hip replacement is an amazingly efficacious procedure, converting a patient with severe compromise of their quality of life to near normal health.
- 3) Total hip replacement compares favorably to virtually any medical or surgical treatment modality in terms of cost to quality adjusted life years.
- 4) Cemented and cementless total hip replacements are virtually identical in terms of patient specific, disease specific, global, utility, functional capacity and cost related outcome measures.
- 5) In an era of cost containment, data such as this study will have an important effect in insuring that cost effective treatments remain funded.

A 60 year old woman presenting with osteoarthritis of the hip in 1976 might have been offered a resurfacing arthroplasty of the hip. This procedure was considered an appropriate surgical intervention at that time. An investigation of the literature of the day suggested that surface replacement was indeed an efficacious procedure for the surgical management of osteoarthritis of the hip¹⁸. Its advantages were "intuitively obvious" and many surgeons in Europe and North America championed this device as a "conservative" total hip replacement. It was released by the manufacturers without substantial clinical trials and as a result it was several years before its deficiencies, namely those of acetabular loosening, femoral neck fracture and massive osteolysis, became apparent to the orthopaedic surgical community. This so called "conservative" surgical procedure turned out to be a radical procedure, making revision total hip more difficult because of major bone defects created by the attendant osteolysis. There are many other examples of failures and disasters in the orthopaedic literature, including the Mittelmeier hip as well as heat pressed polyethylene¹⁴. The question one has to ask is, "Could these failures and disasters have been

*Division of Orthopaedic Surgery, Department of Surgery University of Western Ontario

Correspondence to: Dr. Robert B. Bourne, University Hospital, 339 Windermere Road, London, Ontario, Canada, N6A 5A5. Telephone (519) 663-3512. FAX (519) 663-3838

prevented?" All orthopaedic surgeons are in agreement that cemented total hip arthroplasty has revolutionized the treatment of patients suffering from arthritis of the hip; nevertheless, with patients living longer and longer, surgeons, in conjunction with the orthopaedic industry, have attempted to improve the results of total hip arthroplasty by employing cementless implants. Is the new technology of cementless total hip replacements justified? To date, the efficacy of cementless arthroplasty, its cost effectiveness and its impact on health-related quality of life have not been investigated. As health care providers and as orthopaedic surgeons it is incumbent upon us to be able to justify to third party payers as well as our patients why we are doing what we are doing. Comparative studies comparing cemented to cementless total hip joint replacements are rare¹¹. To date, all have been retrospective and a randomized clinical trial to assess the efficacy of cemented and cementless has not been reported. Randomized clinical trials are used extensively to assess new medical interventions and new pharmacological interventions; however, it is rare for a randomized clinical trial to be used to assess a surgical intervention. The advantage of a randomized clinical trial, comparing two different operative procedures, is that it allows investigators to minimize bias by ensuring that most prognostic factors such as age, sex, weight and femoral type are similar in the two groups.

A randomized clinical trial comparing cemented to cementless total hip joint replacement has been performed at the University of Western Ontario. The purpose of the trial was two fold. 1) What effect does elective total hip joint replacement have on health-related quality of life when a cemented implant is compared to a cementless implant? 2) What is the cost-effectiveness of total hip replacement?

METHODOLOGY

A randomized clinical trial comparing cemented to cementless total hip joint replacement has been funded by the Medical Research Council of Canada. All surgery was performed under the direct supervision of the two senior authors (CHR/RBB). The Mallory Head Implant (Biomet, Inc.) was chosen for purposes of this study. The implant was chosen primarily because the geometry of the cemented and cementless implants were similar. In addition, the authors felt, in 1987, that a titanium implant (with cobalt chrome heads) was preferable to a cobalt chrome implant. All patients with osteoarthritis of the hip, either primary or secondary, between the ages of 18 and 75, presenting to the University Hospital beginning in October 1987 were asked to be part of the study. The exclusion criteria included other causes of hip joint arthritis, severe arthritis of the knees or the other hip, or any other condition which might be expected to affect rehabilitation.

Patients who had a revision hip on the other side or a poorly functioning contralateral hip replacement were also excluded. Individuals with medical illnesses which were likely to lead to death within five years were also excluded. All patients with osteoarthritis of the hip meeting the inclusion criteria were asked to be part of the randomized clinical trial. After appropriate explanation of the study, the patient was asked to be blinded as to whether a cemented or a cementless total hip arthroplasty had been implanted. The duration of blinding requested was five years. Of the individuals approached, 78% agreed. Of the 22% who refused, the principle reason for refusal included a preadmission bias to a cementless prosthesis (41%), no interest in the study (37%), and a small group who wished to know their implant (22%). Those patients entering the study were stratified by surgeon (CHR/RBB), as well as age - over 60 and 60 and under. They were randomized within each stratum. Patients were assessed preoperatively by an expanded role nurse (KL or RB), the study explained and the consent obtained. Post-operatively, all patients were reviewed in an identical manner at 3 months, 6 months, 12 months and yearly thereafter. Outcome measures analyzed included disease specific (Harris Hip score, d'Aubigne, WOMAC, MACTAR), global outcomes (sickness impact profile), and time trade-off techniques as a measure of utility and functional capacity (six minute walk). The first patient was operated on October 13, 1987 and the 250th on January 14, 1992⁹.

Health-related quality of life measures and the six-minute walk test were administered by a blinded study nurse preoperatively, and at each follow-up visit. Neither the nurse nor the patient were aware of the type of prosthesis the patient had received. In addition, at each follow-up visit, the patients were informed of their response to the quality of the questionnaires of the *previous* visit. This has been shown to decrease variability without decreasing responsiveness⁵.

The health-related quality of life measures (HRQOL) used included each of the following.

1) *The Harris Hip Score*

This is a commonly used instrument that was developed for patients with traumatic hip disorders and contains questions about pain, function and range of motion⁷. The best possible score is 100. Pain and mobility account for the majority of the score (44 and 47 points respectively).

2) *The d'Aubigne Score*

This instrument consists of three dimensions that receive equal weight, namely pain, mobility, and ability to walk¹³. The best possible score is 18.

3) *The WOMAC Osteoarthritis Index*

The WOMAC is a disease specific questionnaire developed for patients with arthritis of the hip or knee¹. It

consists of three dimensions (pain - 5 questions, stiffness - 2 questions, physical function - 17 questions). The questionnaire is reproducible and has been shown to be responsive to change in clinical trials². The best score for each item is zero using a 10 centimeter visual analogue scale.

4) *MACTAR*

The MACTAR is a patient specific questionnaire that has been developed and used in patients with arthritis. Prior to surgery patients are asked to identify the five physical activities that are most adversely affected by their hip joint arthritis. Thus each patient has his/her own set of specific activities that are assessed pre- and postoperatively using a 10 cm visual analogue scale with zero being the best possible score.

5) *The Sickness Impact Profile (SIP)*

The SIP is a behavior based questionnaire consisting of twelve dimensions³. The ambulation, mobility, body care and movement dimensions can be aggregated to form a global physical score. The SIP scores range from zero to 100 with zero being the best possible score. The SIP was developed in the general population and has good internal consistency and reproducibility and has been previously used to evaluate hip replacement. Because of concern about the length of time that each patient will be willing to be interviewed, three dimensions considered irrelevant for these patients were excluded (eating, concentration and alertness behavior).

6) *Time Trade-Off*

The time trade-off is a utility measure which reflects the improvement in over all health-related quality of life. Utility measures are used to calculate the cost per quality adjusted life years. In this study, utilities were derived using time trade-off technique which essentially asks patients "how many of their current years of life they are willing to give up in order to achieve full health". Prior to asking patients about their current health, patients were asked to rate three hypothetical scenarios which were designed to represent patients with mild, moderate and severe arthritis of the hip. The scenarios each covered six items: pain and stiffness, use of walking aids, analgesic use, night pain, ability to do house work, and socializing.

7) *Six Minute Walk*

The six minute walk is a measure of functional capacity in which the patient walks as far as possible on the same track with identical prompts over a six minute time frame⁶.

Two hundred fifty (250) patients were entered in this study (124 cemented and 126 cementless). In the cemented group there were 64 males and 60 females and in the cementless group 68 males and 58 females. Three

patients in each group did not return for follow-up; however, all of them report good function and none have come to revision. A total of six patients died since the initiation of the study, three in each group.

RESULTS

Of the 250 patients entered, 206 have been followed one year, 164 two years, 106 three years and 50 four years. For purposes of this paper, only the two year data will be presented.

1. *HARRIS HIP SCORE*

An analysis of the Harris Hip score preoperatively revealed no difference when the cemented group and the cementless group were analyzed (43 vs 42). Using this instrument to assess postoperative recovery, there was no statistical difference in the Harris Hip scores when cement was compared to cementless at any of the follow-up periods up to two years. At two years, the average Harris Hip score for the cemented patients was 96 and for the cementless patients 97. (Fig. 1)

2. *D'AUBIGNE SCORE*

An analysis of the d'Aubigne revealed no difference preoperatively between the cemented and the cementless patient, 9 vs 9. Postoperatively and at each follow-up period there was no statistical difference in the d'Aubigne scores up to two years when cemented hips were compared to cementless (17.4 vs 17.5). (Fig. 2)

3. *WOMAC*

The WOMAC osteoarthritis index is a *disease specific* questionnaire employing a visual analogue scale which assesses three dimensions - pain, stiffness and physical function. Preoperatively the WOMAC pain score averaged 6.0 in both groups. There was dramatic improvement when cement and cementless were compared at each follow-up visit out to two years where the pain score was 1.0 in both groups. (Fig.3) Similar findings were noted for each of the dimensions analyzed by the WOMAC.

4. *MACTAR INDEX*

The Mactar employs a set of *patient-specific activities* that are most adversely affected by this patient's hip disease. Hip disease affects individuals in different ways; however, the disabilities chosen by patients as being most important included difficulty with walking, difficulty with shoes and socks, difficulty with stairs, difficulty standing, night pain, insomnia, aching and soreness. When one analyzed these specific measures and compared cemented to cementless total hip replacement using the Mactar questionnaire, preoperative scores of 7.8 and 7.7 were reduced to scores of 1.0 and 0.67 when cemented and cementless patients were compared at two year follow-up. (Fig. 4)

FIGURE 1
HARRIS HIP SCORE

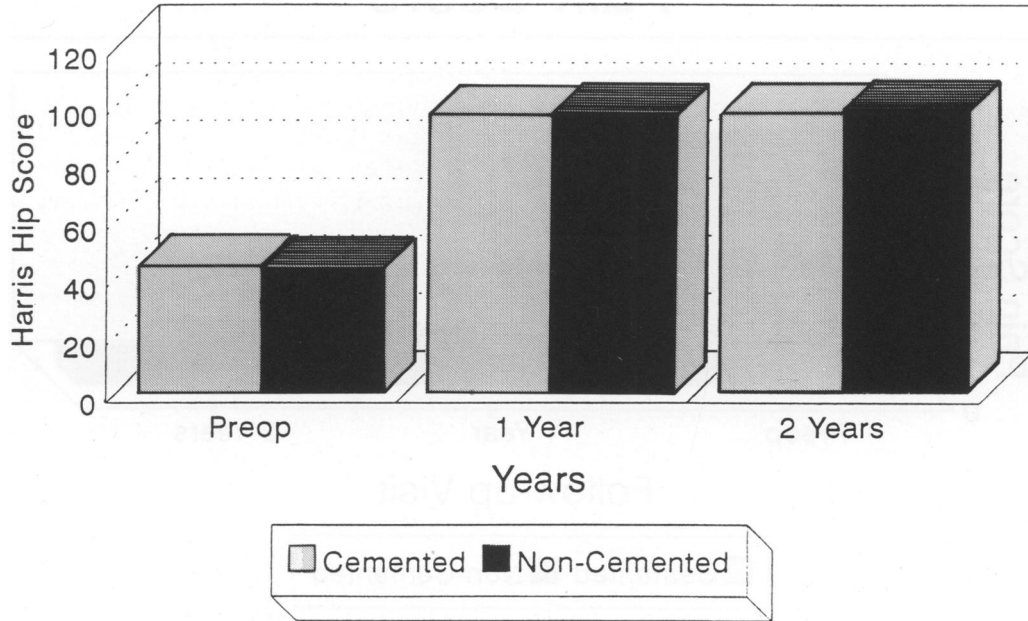
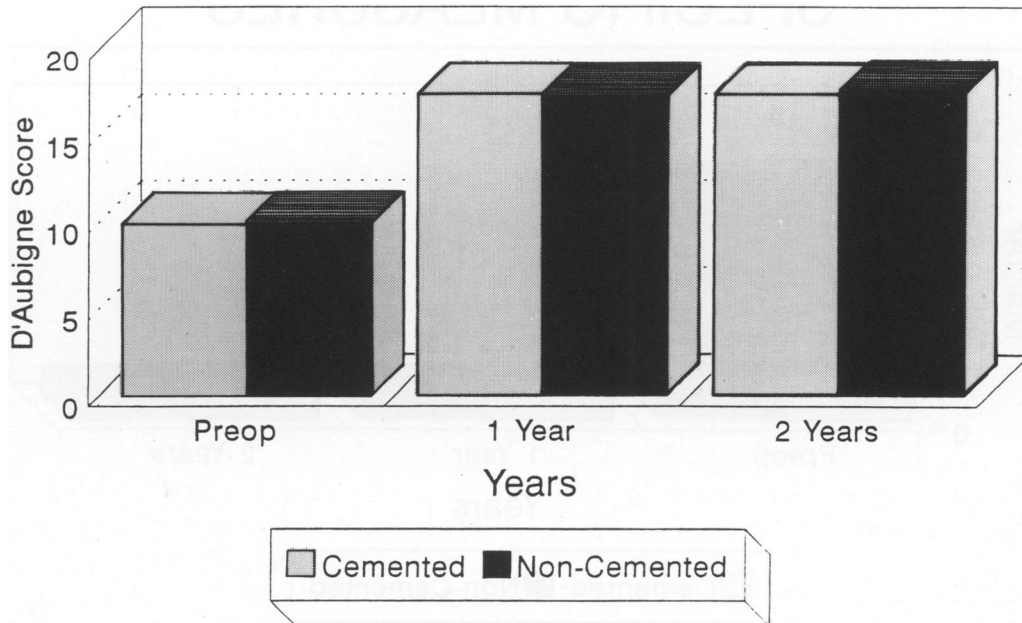
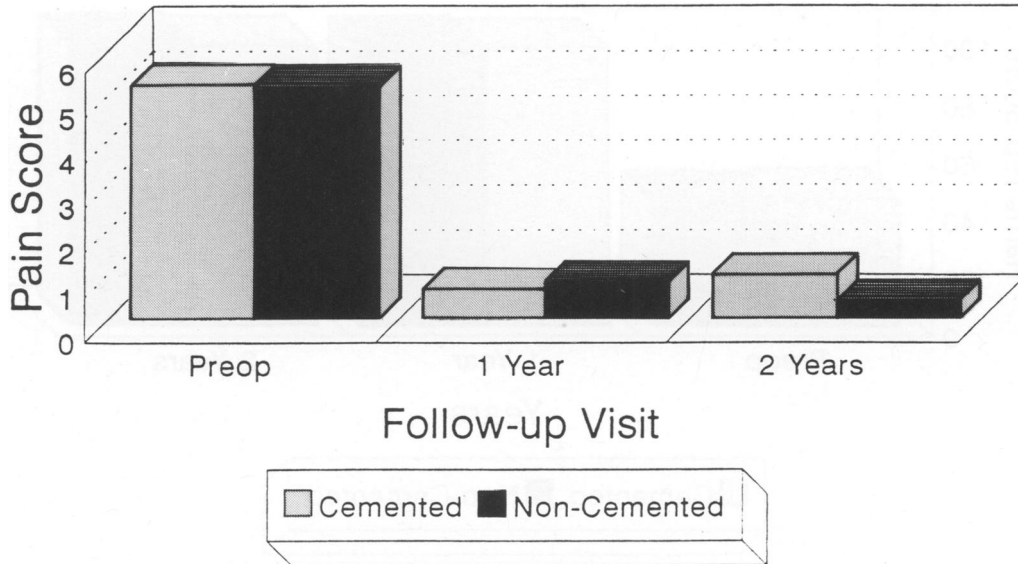


FIGURE 2
D'AUBIGNE



**FIGURE 3
WOMAC
Pain Score**



**FIGURE 4
RCT: MACTAR PATIENT
SPECIFIC MEASURES**

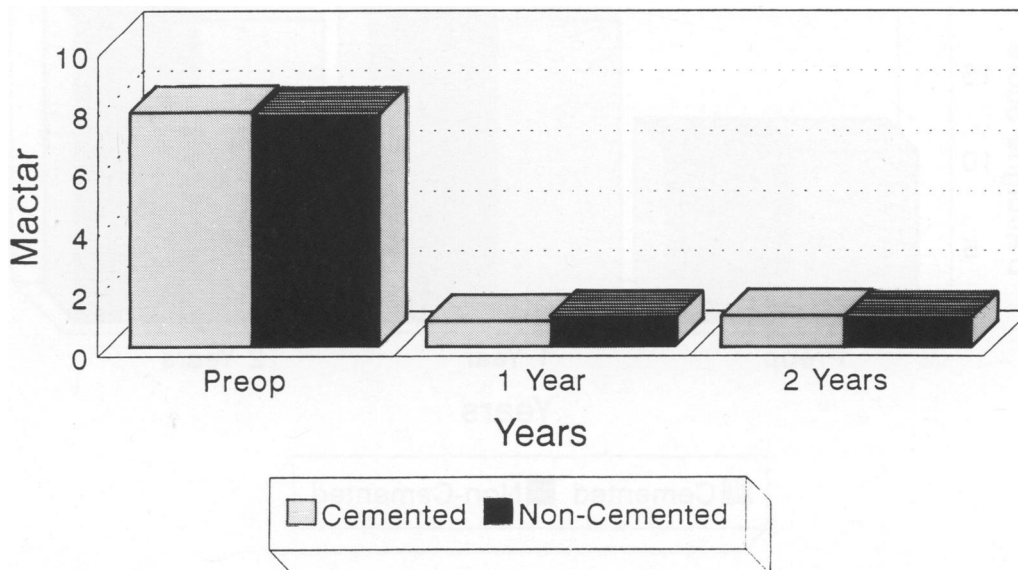


FIGURE 5
SIP: GLOBAL PHYSICAL

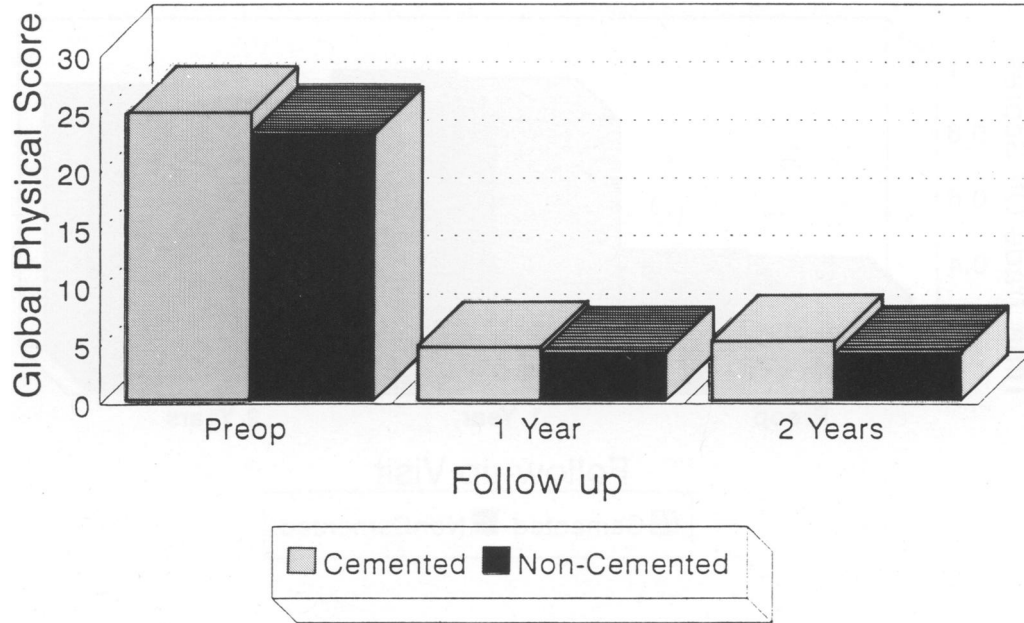


FIGURE 6
SIP: SLEEP / REST

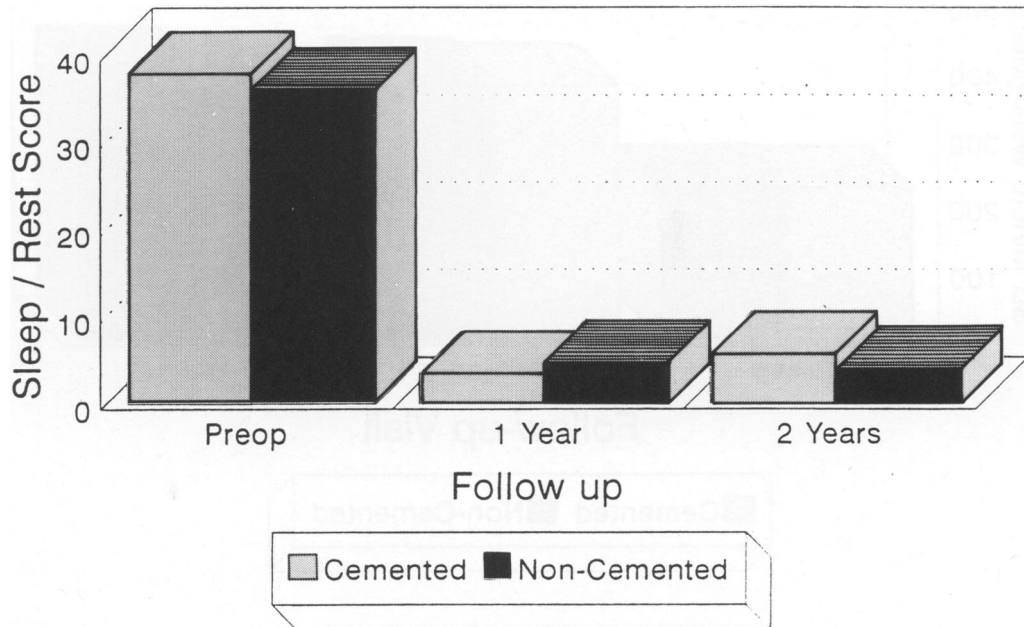


FIGURE 7
TIME TRADE OFF SCORES

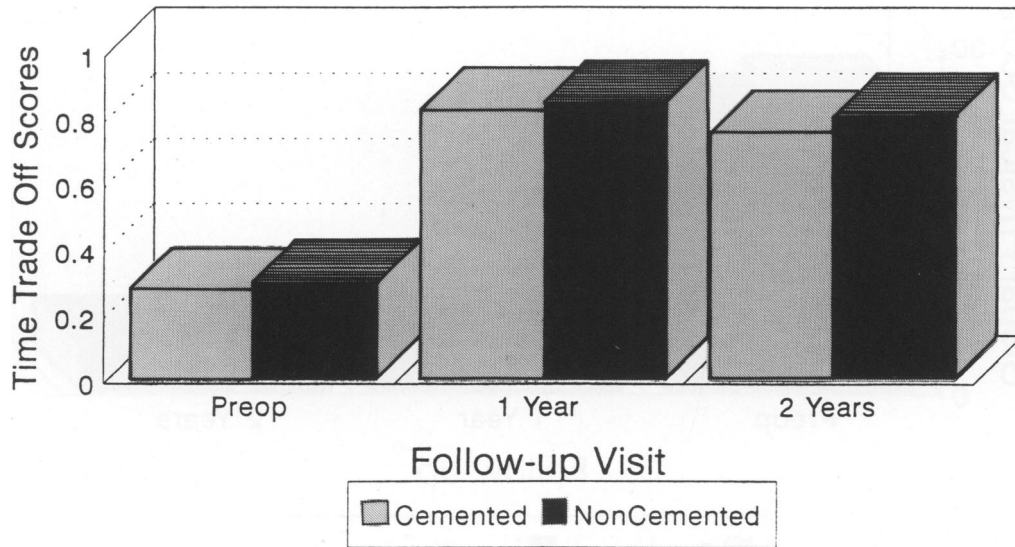
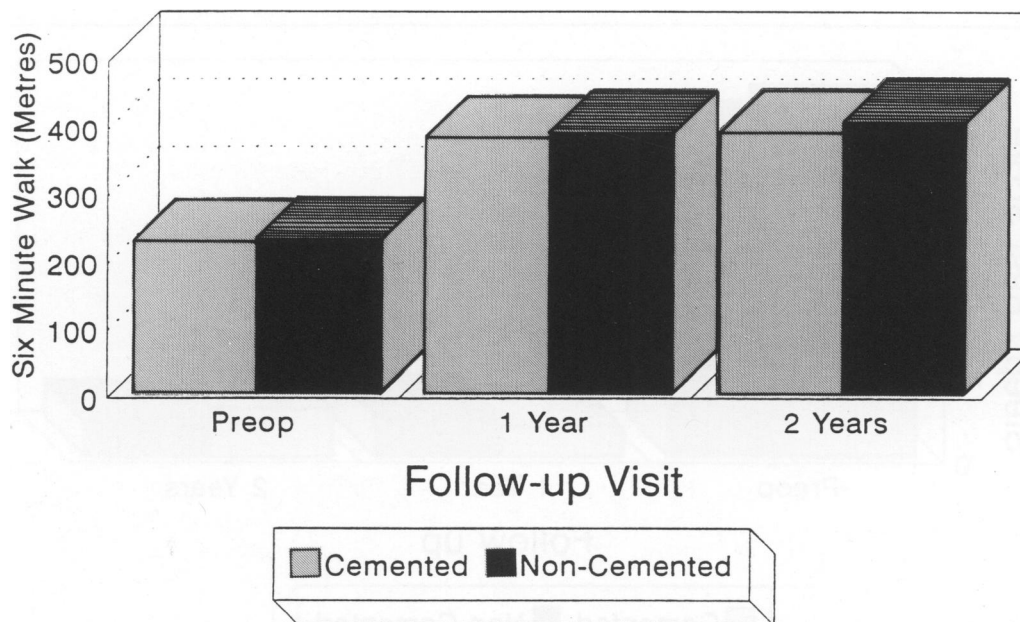


FIGURE 8
SIX MINUTE WALK



5. SICKNESS IMPACT PROFILE

The sickness impact profile measures the *patient's over all health-related quality of life* by analyzing 12 behaviorally-based dimensions including three physical dimensions (ambulation, mobility and body care) which can be computed to a global physical score. The preoperative global physical score comparing cemented to cementless was 25.2 vs 23.3. An analysis of the postoperative data at each follow-up period failed to reveal any statistically significant difference when cemented was compared to cementless out to two years (5.2 vs 3.2). (Fig. 5) When individual components of the Sickness Impact Profile were analyzed including recreation and past time, sleep and rest, similar results were noted. Total hip replacement, whether it were cemented or cementless, resulted in dramatic improvement in all categories. Preoperatively, it was evident that the patients' osteoarthritis had a dramatic effect on their ability to sleep and rest comfortably with scores of 37.9 for the cemented group preoperatively and 36.1 for the cementless group. Postoperatively, the scores for the same patients were reduced to 5.7 for the cemented patients and 4.1 for the cementless patients at two years. (Fig. 6) Similar findings were noted with each of the behaviorally based dimensions analyzed by the Sickness Impact Profile.

6. TIME TRADE OFF

The time trade off utility is a unidimensional global health-related quality of life measure with a value that ranges from 0.0 (indifference between life and death) and 1.0 (equivalent to perfect health). Patients were asked to rate the three hypothetical scenarios described in the "Methods" section, and also to rate their own current health state. Once again, cemented or cementless total hip replacement had a dramatic effect when this utility was used as an outcome measure. Preoperatively, the TTO averages for current health were 0.28 for cemented and 0.30 for cementless. At two-year follow-up the results were 0.76 and 0.81 respectively. Once again, there was no statistically significant difference when cemented were compared to cementless total hip replacements. (Fig. 7)

7. SIX MINUTE WALK

The six minute walk measures the distance a patient is able to walk back and forth along a 30 metre course in six minutes with the same individual administering the test and with the same prompting⁶. This is done preoperatively and at each follow-up visit. Total hip replacement whether cemented or cementless had a dramatic improvement on the distance walked using this measure. Preoperatively, the cemented patients were able to walk, on average, 227.1 metres while the cementless patients were able to walk 229.1 meters.

At two-year follow-up the cemented patients were able to walk on average 392.0 and the cementless 408.5 metres. (Fig. 8) There was no statistically significant difference between the two groups.

8. ECONOMIC

The cost of total hip replacement, comparing cemented to cementless was evaluated from society's perspective. Sixty patients form the basis of the detailed cost analysis for hospital in-patient costs. A cohort of 100 patients provided data on physician charges, follow-up charges and the cost to the Canadian health care system and Canadian society through the first postoperative year. Costs included visits to physiotherapists, to doctors, lost time from work, readmission to hospital, etc. These data expressed in 1988 Canadian dollars indicated the average cost of all patients (cement or cementless) to the system, including all physician fees, implant costs and time in the hospital was \$9,990. When one broke down the cost between cemented and cementless, the cemented implant cost the system \$9,853, and those receiving a cementless implant cost the system \$10,119. This difference relates to the difference in the cost of a cementless implant. An analysis of the outpatient cost for the first year postoperatively demonstrated an average cost to society of \$1,137. Once again, when one compared cemented to cementless there was little difference between the two groups. The average cost to the system for the cemented group was \$975 versus \$1,297 for the cementless group. The difference in costs in the first year postoperatively between cemented and cementless relates largely to the considerably longer distance the cementless patients had to travel to visit their doctor as opposed to the cemented patients. Distance from the University Hospital was *not* stratified as one of the variables and as a result, it evolved that the average cementless patient had to travel 223 kilometers to see their orthopaedic surgeon, whereas the average cemented patient had to travel only 142 kilometers. The number of physiotherapy doctor visits were identical for the cemented and cementless groups and the difference in costs is explained entirely by the travel distances. As well, an outpatient cost analysis including nursing visits, social service visits, readmissions to the hospital, etc. demonstrated no statistical difference when the cemented group was compared to the cementless group for the first year postop⁸. (Table 1)

Total hip arthroplasty seems quite cost effective compared to other interventions. Using our data, it is possible to calculate the cost per quality adjusted life years associated with total hip arthroplasty. Prior to surgery, the average patient assessed utility was ap-

TABLE 1
Out-Patient Care (1988 \$ Canadian)

	<i>All Patients</i>	<i>Cemented</i>	<i>Non-Cemented</i>
Physiotherapy	203	199	207
<i>Orthopaedic Clinic</i>			
—physicians' fees	123	123	123
—travel and parking	217	172	262
<i>Visits to Physician</i>			
—physicians' fees	16	17	16
—travel and parking	7	7	7
—opportunity cost	19	20	18
<i>Visits to Patient</i>			
—nurse/physiotherapist	72	44	99
—social services	76	45	107
<i>Admissions to Hospital - Hip Related</i>			
i) London	246	238	254
ii) Non-London	158	110	204
TOTAL HIP RELATED COSTS:	1137	975	1297
<i>Admissions to Hospital:</i>			
<i>Non-Hip Related</i>			
i) London	546	584	509
ii) Non-London	239	170	307

proximately 0.29 which increased to about 0.84 by three months, a change of 0.55. This improvement was maintained for the rest of the first year. Therefore, the average quality adjusted life year (QALYS) gained during the first year was $0.55 \times 0.75 = 0.41$. The cost per QALY gained from hip arthroplasty is therefore $\$11,127 / 0.41 = \$27,139$. If one assumes that the improvement in health related quality of life is sustained during the first three years (a reasonable assumption based on our data), and that the cost of hip related care is approximately \$500/year for each of the second and third years, then (ignoring discounting) the cost per QALY gained during the first three years after surgery is \$8,031. Using a recently suggested classification system for grading media technologies, hip arthroplasty is a Grade B technology (costs less than \$20,000 per additional QALY)⁸. Grades vary from Grade A (technology is both less costly and more effective than the relevant alternative) to Grade D (technology costs more than \$100,000 per additional QALY relative to the alternative, or is less effective and saves less than \$20,000 per QALY gained) to Grade E (technology is

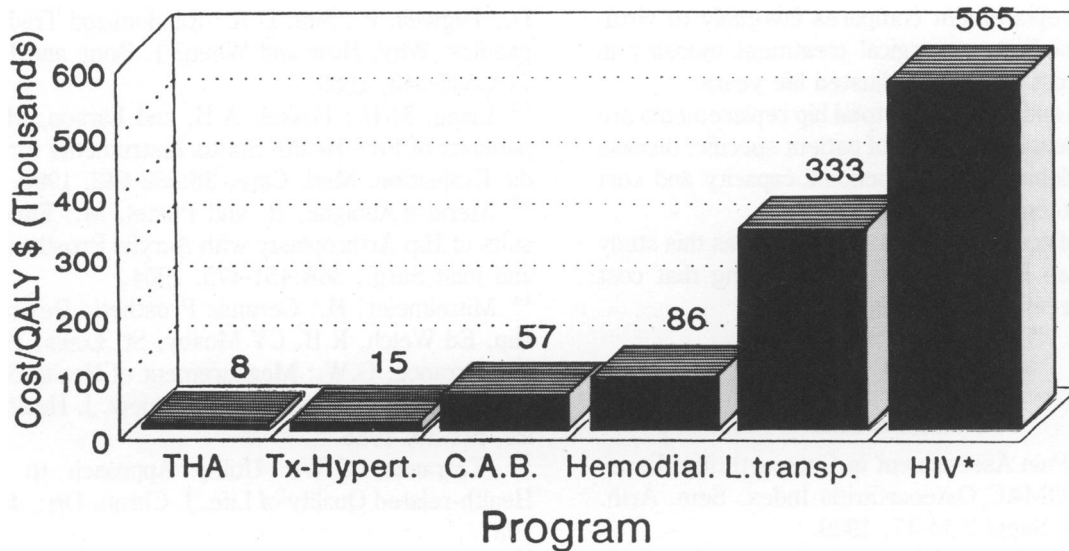
more costly and less effective)^{8,10}. Figure 9 graphically depicts the efficacy of total hip replacement compared to other medical interventions (i.e. the treatment of moderate hypertension, coronary artery bypass for angina, hospital hemodialysis, liver transplantation and HIV universal precautions).

DISCUSSION

This study demonstrated that it is possible to assess the efficacy of surgical intervention using a randomized clinical trial. Its strengths include the fact that the study was randomized, prospective, and has virtually complete follow-up with accurate cost data. To the best of our knowledge a study of this kind has not been reported in the orthopaedic literature.

The preoperative responses to the questionnaires administered to the patient indicate that osteoarthritis of the hip not only causes pain but also severely affects the individual's physical activity, social interactions, and over all health. While we, as orthopaedic surgeons, recognize that our patients are severely disabled, I don't believe that many of us recognize how severely disabled our patients

FIGURE 9
COMPARATIVE COST-UTILITY RATIOS



*cost/additional life saved

are. The preoperative sickness impact profile and time trade-off scores suggest that patients regard their health related quality of life as being as adversely affected than patients on chronic dialysis.

The improvements in health related quality of life after total hip replacements are rapid and complete, and affect all aspects of the patient's over all well being. For example, the improvement in the time trade-off score was particularly impressive. Two years postoperatively, the mean score was 0.79 which is better than the score these patients assigned to the best hypothetical scenario of a patient with mild arthritis. By comparison, the time trade off score of anemic dialysis patients did not improve once their anemia was corrected with erythropoietin, despite marked improvement in symptoms of fatigue⁴. The likely explanation for the difference is that a successful hip replacement returns most patients to near normal activity, while the dialysis patients are still uremic, on dialysis, and may continue to suffer from co-morbid conditions such as coronary artery disease.

This study has demonstrated that the in-hospital costs of total hip replacement, as well as the outpatient costs during the first year, did not show statistical differences when the cemented patients were compared to the cementless patients. The major costs during the first year postoperatively were for routine out patient visits to an orthopaedic clinic (4 during the first year), and the cost of

readmission for hip related problems (suspected infection and deep vein thrombosis). Seven of the 8 readmissions occurred during the first six months after surgery and thus it is likely that costs will decrease over the ensuing years, provided the hip continues to function well.

These data clearly indicate that comparing the cost of cemented and cementless hip prostheses will only differ significantly if there is a difference in the rate of revision surgery. Even though the cost of revision procedures must be discounted for a time, a large difference in revision rates between the two types of prostheses five or ten years after the original procedure *could* have an important economic impact. The authors plan to follow this cohort of patients for ten years, and thus should be able to address this important question.

The weaknesses of the study include the following. No attempt was made to estimate the cost of maintaining patients on the waiting list prior to coming into hospital, and a study of that is currently underway. The costs of relatives traveling to visit patients during the initial hospitalization were not calculated. In addition, we relied upon patients' diaries to estimate outpatient resource use. Nevertheless, we were impressed by the diligence with which patients recorded hip related events.

A number of clinically relevant conclusions can be reached:

- 1) Surgical patients are willing to be part of a meaningful randomized clinical trial. In this study, 78% of eligible patients agreed to participate.
- 2) Total hip replacement is an amazingly efficacious procedure, converting a patient with severe compromise of their quality of life to near normal health.
- 3) Total hip replacement compares favorably to virtually any medical or surgical treatment modality in terms of cost to quality adjusted life years.
- 4) Cemented and cementless total hip replacements are virtually identical in terms of patient specific, disease specific, global, utility, functional capacity and cost related outcome measures.
- 5) In an era of cost containment, data such as this study will have an important effect in insuring that cost effective treatments remain funded.

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