A HISTORICAL AND ECONOMIC PERSPECTIVE ON SIR JOHN CHARNLEY, CHAS F. THACKRAY LIMITED, AND THE EARLY ARTHOPLASTY INDUSTRY

Pablo F. Gomez, MD* and Jose A. Morcuende, MD, PhD

ABSTRACT

In the 1960s, Sir John Charnley pioneered modern total hip arthroplasty (THA) and spent the next two decades refining all aspects of the procedure, working with the commercial firm of Chas F. Thackray Limited, now a subsidiary of DePuy Orthopaedics, a Johnson and Johnson Company. We review here that relationship, in light of the complex relationships today that exist among industry, researchers, surgeons, and the public.

OVERVIEW OF TOTAL HIP ARTHROPLASTY ECONOMICS AND INDUSTRY

Osteoarthritis disables about 10% of people older than sixty, compromises the quality of life of more than twenty million Americans, and costs the United States economy more than 60 billion dollars per year.[1] There are now close to 300,000 THAs performed per year in the United States. The cost associated with each operation is approximately $13,339 in the United States,[2] and the cost of each implant has been reported to be approximately $8,017.[2] The calculated total cost of THA procedures performed in the United States during 1995 (a year in which 250,000 arthroplasties were done), was five billion dollars.[3]

Overall, THA has been found to be quite effective in terms of improvement in quality of life indices.[4] THA ranks highly among health care interventions, with a 1140/cost-per-quality-adjusted-life-year,[5] and compares favorably with the medical treatment of hypertension, coronary artery bypass graft surgery and hemodialysis for chronic renal failure.[6] Among all surgical procedures, only coronary bypass compares to THA in terms of effectiveness and improvement of life quality.

Department of Orthopaedics and Rehabilitation
University of Iowa Hospitals and Clinics
Iowa City, Iowa

***Correspondence:**
University of Iowa Hospitals and Clinics
4120D MERF
375 Newton Road
Iowa City IA 52242
e-mail address: pablo-gomez@uiowa.edu

However, one recent paper evaluating the adequacy of economic evaluations in THA literature found only two correctly performed investigations out of 68 papers in the subject.[7] The significance of this percentage is highlighted when compared to 11,078 papers about THA published in journals indexed in the National Health Library of Medicine of The United States. In addition, existing cost-effectiveness studies have generally been limited to the evaluation of hospital expenses[7] and have not included a global substantiation of THA use in today's cost-constrained health environment.

The orthopaedic industry has gone from a six billion dollar market ten years ago to seventeen billion dollars in revenues last year.[8] Five companies hold the majority of the THA market in America. These five are DePuy, Inc., a Johnson & Johnson Company,[i] Warsaw, Indiana, USA; Zimmer, Inc.,[ii] Warsaw, Indiana, USA; Stryker® Corporation,[iii] Rutherford, New Jersey, USA; Biomet Orthopedics, Inc.,[iv] Warsaw, Indiana, USA; and Smith & Nephew,[v] Inc., Memphis, Tennessee, USA.

[i] DePuy, Inc., was established in 1895 by Revra DePuy, on a promising fiber splint to replace the wooden barrel staves then used to treat fractures. They became the first commercial orthopaedic manufacturer in the world. After more than a century, the company has change ownership several times, the last owner being Johnson & Johnson Corporation. The same year that Müller give exclusivity rights to his prosthesis to DePuy, Inc., the company was acquired by the Indianapolis-based diagnostics company Bio-Dynamics, giving the veteran firm a needed economic boost.[3]

[ii] J.O. Zimmer initially began as the first DePuy sales representative. After several failed attempts to purchase DePuy Manufacturing, in 1924 Zimmer founded the company that bears his name. In *Orthopaedics Today*. Edited by Jackson, D. W., SLACK Incorporated, 2000.

[iii] Homer Stryker from Kalamazoo, Michigan, United States, was appalled by the lack of adequate instruments to operate upon his patients. He started this company in 194, which evolved into one of the leaders in the medical implant industry. In December 1998, Stryker, Inc., acquired Howmedica, Inc., from Pfizer, Inc., and doubled its size. Ibid. Edited.

[iv] Dane Miller, Niles Noblitt, Jerry Ferguson and M. Ray Harroff created Biomet, Inc., in 1977. After, a rough start, Biomet expanded and acquired several other manufacturing companies, which allowed it to consolidate and reach its position as one of the main players in today's orthopaedic industry. Ibid. Edited.

[v] Although the origins of this company can be traced back to 1851, Smith & Nephew (Pty) Ltd, Durban S.A., firmly started its orthopaedic venture in only 1931. Originally, Smith & Nephew manufactured only Plaster of Paris bandages. However, over the years it would buy Richards, Inc., and become one of the largest corporations for orthopaedic implants. Ibid. Edited.

Nevertheless, there are still reported opportunities for the orthopaedic arthroplasty industry's growth, as the trend toward expansion will continue for at least another two decades, according to investor analysts.[8]

SIR JOHN CHARNLEY (1911-1982) AND THE ROAD TO DEVELOPING MODERN TOTAL HIP ARTHROPLASTY

It was John Charnley who dominated the development of modern THA. In 1956 he noted:[10]

> *The cart has been put before the horse; the artificial joint has been made and used, and now we are trying to find out how and why it fails.*

Charnley was born in Bury, Lancashire, United Kingdom in 1911. In 1929, he entered medical school at the Victoria University of Manchester, where he qualified with MB ChB MRCS and LRCP in 1935.[vi] During that time Charnley also obtained a BSc in anatomy and physiology. At twenty-five years of age he became a Fellow of the Royal College of Surgeons at Guy's Hospital in London, the youngest physician to receive that honor. He was trained as a general surgeon, acquiring excellent wide-ranging diagnostic judgment and operative skill at the Salford Royal Hospitals, where he started January 1, 1937. During his period in Salford he worked with Mr. Garnett Wright and started to manufacture small apparatuses in Bury, England, where he had access to a lathe. After a year, he followed the advice of one of his professors in Manchester, Professor Rapper, and went to London to work in physiology with Professor RJS McDowall[vii] at King's College, London, where he was appointed as demonstrator in physiology in October 1938. However, when the opportunity presented, he returned to Manchester in 1939 and joined The Manchester Royal Infirmary as resident casualty officer. This was Charnley's first contact with orthopaedics, which at the time, even with the efforts of Sir Robert Jones and Gathorne Girdlestone, was considered a minor specialty.[viii]

Charnley's medical career was interrupted by the outbreak of war on September 3, 1939; he entered the Royal Army Medical Corps as a volunteer, beginning as a lieutenant. His postings included Northern Ireland, the Middle East and Dover, England, where he attended the wounded soldiers from the evacuation of Dunkirk, France. After this experience, he was posted as an orthopaedic officer to the Middle East as a major and officer in charge of No. 2 Orthopaedic Centre at Cairo.[12] During his stationing in Egypt, he met Dudley Buxton who was the consultant orthopaedic surgeon to the Middle East forces. Buxton opened an orthopaedic workshop at No. 4 BOW (Base Ordnance Workshop) and recommended that Captain Charnley to be in charge. Charnley made the workshop a success and designed, among other things, a walking caliper,[13,14] a modified Thomas splint,[15] and various other surgical instruments. This period was critical for Charnley, who had a febrile inventiveness. His workshop was a unit of the Royal Electrical and Mechanical Engineers, and he had the opportunity to work with skilled technicians. Following the war, he returned to England. Sir Harry Platt, later first baronet (1886-1986), acted as Charnley's and David Lloyd Griffiths' mentor.[ix] Platt was of the opinion that although Charnley had a great deal of experience with war surgery, he needed training in cold surgery.[x] Platt sent Charnley to a six-month rotation in the Robert Jones and Agnes Hunt Orthopaedic Hospital (founded as the *Shropshire* Hospital) at Gobowen, near Oswestry, in Shropshire, England.[xi]

It was in Gobowen that Charnley further became curious about the role of periosteum in bone healing. He persuaded a junior colleague to operate on him, removing a piece of cancellous bone from the upper end of his tibia, and implanting one piece above and other beneath the periosteum. Eventually, he developed osteomyelitis in his tibia and needed several surgeries for a cure.

[vi] These qualifications are the college degrees of the Britannic Medical Education curriculum. MB (Bachelor of Medicine) and ChB (Bachelor of surgery) are the primary qualifications. MRCS (Member of the Royal College of Surgeons) and LRCP (licentiate of the Royal College of Physicians) were considered secondary degrees and functioned as a safety net for medical students in case they failed in their MB degree.

[vii] Professor McDowall is best known for being a whisky connoisseur. He wrote one of the classic guides on the subject, McDowall, R. J. S.: The whiskies of Scotland. Edited, Chicago, Ivan R. Dee, 1987. He also gave numerous conferences about this beloved spirit.

[viii] Despite Sir Robert Jones's efforts during the First World War, orthopaedics was not completely established, as the general surgeons, a powerful guild, wanted to keep practicing orthopaedics, too. Manchester, however, was at the lead of the final consolidation of orthopaedics as a specialty in itself.

[ix] Lloyd Griffith was three years older than Charnley and was his senior practitioner. Although they were great friends, the relationship developed an uncomfortable tension when Lloyd Griffith was appointed as Chief of the Service at the Manchester Infirmary. Charnley's personality was not built to be the second in charge, and this, among other reasons, convinced Charnley to leave that hospital and look for an independent post in Wiles; see Waugh, W.: John Charnley: The man and the hip. Edited, London, Springer, 1990.

[x] *Cold Surgery* was the name given to elective surgical procedures in the British surgical jargon, in contrast with emergency surgeries that provided a totally different set of circumstances, and consequently, approaches.

[xi] Both names were judged too long for use, and the hospital is usually spoken of as *Oswestry*, and by the local inhabitants *The Orthopaedic.*

When Charnley finally returned to Manchester, he was appointed as observer in the orthopaedic department at the Manchester Royal Infirmary. For a few months he acted as chief assistant, and then replaced Miss Willis and became consultant orthopaedic surgeon in the department. Plat said of Charnley:[17]

> *The young men who, after such experience [training in general surgery] ultimately entered any one of the divisions—the so-called specialties—carried the hallmark of the generalist throughout their active surgical lives. This was especially true of John Charnley. His roots in the principles and units of surgery were deep and lasting.*

Charnley also had an powerful command of the English language. He describes the required qualities to be an orthopaedic surgeon, published in the *Manchester University Medical School Gazette*:[18]

> *The Orthopaedic Surgeon's faculties must be adaptable to a wide compass; the delicacy of a neurosurgeon, required in nerve and tendon surgery; the power and accuracy of a sculptor wielding the osteotome and heavy mallet; the engineering skill of a fitter, in using precision tools in bone grafting and internal fixation; the indefinable art of closed reduction in manipulating a fracture with the touch and craft of a bonesetter; pleasure in perfect dissection under a tourniquet, and satisfaction in the carnage of hindquarter amputation.*

At the suggestion of Harry Platt, and after fully committing himself to the study of hip arthritis,[xii] Charnley developed a hip center at Wrightington Hospital in Wigan, near Manchester, where he started as a visiting orthopaedic surgeon in 1949. The center, formally inaugurated in 1961, became the focus of Charnley's professional career. Charnley's early experiments on joint function were directed to understanding the friction and lubrication of animal and artificial joints.[21] He financed these studies and the materials involved, as with the lathe he bought in 1946, with royalties from his previous inventions, such as the walking calipers for soldiers he designed during the war. He considered the low friction principle to be the basis of THA design.[22] Serendipity occurred when he noted that a patient, whose left femoral head had been replaced with an acrylic Judet prosthesis, reported that "his left hip squeaked every time he leaned forward."[xiii] Charnley recognized the increased frictional resistance as the cause of this phenomenon and deduced the necessity to reduce the friction at the articular interface of the implant. Also, by applying hip biomechanical concepts that had been developed in the German school,[xiv] during the 1930s, he understood that in addition to maintaining low frictional resistance at the articular interface, it was necessary to minimize the turning force (torque) transmitted from the metal femoral head to the socket. This can only be achieved by reducing the diameter of the femoral head component. Charnley therefore introduced a 22.2 millimeter femoral head. He believed that anything smaller was associated with an unacceptably high incidence of dislocation.[22]

In 1956, he started using polytetrafluoroethylene (PTFE), which was self lubricating. Initially, he employed it as synthetic articular cartilage, lining the acetabulum with a thin shell of the plastic and covering the femoral head (which he reshaped) with a hollow cup of the same material. The chemical structure of PTFE is similar to that of Ultra High Molecular Weight Polyethylene (UHMWP) except that the pendant hydrogen atoms on the carbon backbone of the polymer molecule are replaced by fluorine (PTFE belongs to the family of fluoropolymers). As a consequence, PTFE has a density of 2.2 f/cc, higher than the 0.94 f/cc of the UHMWP. PTFE is often (and incorrectly) referred to in the orthopaedic literature as Teflon®, which is the trade name for a family of PTFE resins produced by DuPont, Wilmington, Delaware, USA. Charnley's acetabular components were fabricated from Fluon resin produced by Imperial Chemical Industries in Great Britain.[23] Subsequent universal failures after spectacular early successes persuaded him to remove the femoral head and replace it with a metal prosthesis. Unexpectedly, the PTFE defied laboratory predictions and exhibited significant wear within the first few years. Two main disadvantages of PTFE were discovered only after implantation in three hundred patients. First, the PTFE exhibited elevated wear rates *in vivo* of up to 0.5 mm per month.[24] Second the PTFE wear debris elicited an "intense foreign-body reaction." Charnley understood the basis for this from experiments on himself years

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[xii] Charnley's contributions to orthopaedic surgery were not limited to his invention of THA. He also published landmark treatises in trauma and compression arthrodesis: Charnley, J.: The Closed Treatment of Common Fractures. Edited, Edinburgh, Livingston, 1974.; and Charnley, J.: Compression arthrodesis: Including Central Dislocation as a Principle in Hip Surgery. Edited, Edinburgh, Livingston, 1953. Paradoxically, the father of modern joint replacement initiated his academic career studying and succeeding in the fusion of joints.

[xiii] Charnley always acknowledged the importance of serendipity. One of his favorite aphorisms said "*You have got to be able to see where others do not appreciate the importance of fortuitous facts.*" *Waugh, W.: John Charnley: The man and the hip. Edited, London, Springer, 1990.*

[xiv] During the first decades of the twentieth century, German medicine provided many advances in the understanding of body physiology and disease etiology. Friedrich Pauwels (1885-1980), for instance, described the basic concepts of hip biomechanics, such as transmission of loads around the articulation, lever length and gluteus medius' role in the torque forces around the hip, and gravity center variation during limp.

ago while in Gobowen. In addition to the experiment on his own tibia, he had also experimented on himself and injected two specimens of "finely divided" PTFE into his own thigh[25] where he described in himself that the particles excited an aggressive foreign body reaction. In patients, he pointed to this inflammatory process as a possible loss of bone stock:[26]

> *After surgery, then came the dreadful weeks . . . PTFE proved unsuitable, not so much by its low resistance to wear, as by the adverse tissue reaction caused by wear debris.*

Colleagues reported that every time Charnley did a PTFE revision it was "like observing a monk pouring ashes over his own head."[27] Charnley also attempted to use glass-filled PTFE (under the trade name of Fluorosint), but despite promising *in vitro* test results the composite also performed poorly *in vivo*.

Subsequently he was offered a new material, ultra high molecular weight polyethylene, but he despised this, depressed by PTFE's failure. UHMWP produced by Hoechst (Oberhausen, Germany) was first widely adopted in the textile industry and was distributed throughout Europe during the 1950s for use in the impact bearings of mechanical looms. Despite Charnley's refusal, one of his more resilient assistants mechanically tested the material and found it to have superior wear properties to PTFE. Extensive testing demonstrated that UHMWP was a more suitable plastic for the construction of artificial joins and Charnley inserted the first UHMWP socket, labeled RCH 1000, in November 1962.[24]

RCH was Hoechst's early trade name for UHMWP. RCH designated the resin manufacturing location (RuhrCHemie AG, Oberhausen, Germany) and 1000 indicated that the polymer was UHMWP. The qualities that made this material the choice for early THA, namely its excellent wear resistance, low friction and high impact strength (relative to other polymers), have not changed substantially during the last four decades.[28] The microstructure complexities of UHMWP give rise to a range of mechanical behaviors, depending upon the processing, thermal and radiation exposure, storage and prior mechanical history of the polymer. Today, over 90% of the UHMWP used in orthopedics is produced in the form of a fine white powder, or resin, which is then consolidated through ram extrusion, slab molding, or direct compression.

Orthopaedic surgeons borrowed from the dental community a form of acrylic cement suitable for surgery, PMM. Kiaer and Jansen of Copenhagen reported attaching plastic cups to femoral heads with acrylic bone cement in 1951, and Haboush of New York used bone cement to secure a femoral prosthesis. It was Charnley, however, who noted that the points of direct contact between an implant and bone, requisite for a tight fit, were the points where the bone would absorb and leave the implant inadequately supported. His momentous publication, *Anchorage of the Femoral Head Prosthesis to the Shaft of the Femur*,[29] signaled a turning point in hip arthroplasty. He suggested that the bone cement acted as a "grout," not as glue, so that fixation was achieved by interlocking and not by adhesion. The cement was forced into all available interstices, so the weight of the body was dispersed over a large area of bone. This bold and generous use of cement improved fixation by a factor of two hundred. Heat generated during polymerization was absorbed by the metal prosthesis, which acted as a heat sink.

Charnley's surgical skills were remarkable. He had the capacity to complete an operation two to three times faster than his colleagues. His postoperative care was carried out through distinctive clinical pathways. Patients were encouraged to return for evaluation at regular intervals. Data were meticulously collected. Charnley's registrars and fellows advanced through a program of steady responsibilities, first observing, then assisting, and finally performing the operation. He would not permit the use of his prosthesis by an inexperienced surgeon, and insisted on the personalized training of his fellow colleagues.

His contributions to orthopaedic surgery were recognized both nationally and internationally with numerous awards, including the Knighthood in 1977, and a Lasker Foundation Clinical Medical Research Award, also known as the "American Nobel Prize" in 1974 (joining an elite group of luminary surgeons who had received the award—Alfred Blalock in 1954, and Michael DeBakey in 1963), and knighthood in 1977. The Lasker award committee in 1974 stated:

> *Combining his talents as an orthopaedic surgeon and biomedical engineer, Professor Charnley conducted original laboratory and clinical research . . . the introduction of the use of methyl-methacrylate as a plastic cement to firmly affix the prosthetic components to the bone . . . While the pioneering work on joint prosthetics, going back to 1908, cannot be ignored, the present advances were made possible by Professor Charnley's unique concepts. . . . it is estimated that 50,000 Charnley-type hip operations are performed annually in the United States alone . . . For his combination of engineering skill and clinical acumen, and for his development of the concept and technique of total hip joint replacement . . . this 1974 Albert Lasker Clinical Medical Research Award is given (www.laskerfoundation.org)*

CHARNLEY AND CHAS. F. THACKRAY LIMITED

Charnley was quite conscious of the importance the industry had in the development of his prosthesis:[24]

> *In Britain it is not considered good form to acknowledge commercial undertakings in too glowing terms, even though the work would not have been possible without their collaboration.*

The relationship between John Charnley and the commercial firm of Chas. F. Thackray Limited (now a subsidiary of DePuy Orthopaedics, Inc., a division of DePuy, Inc., a Johnson & Johnson Company),[xv] Leeds, England, provided grounds for the growth of Charnley's implants. The successes and frustrations of the process are recorded in the abundant correspondence maintained between Charnley and the company until Charnley's death in 1982.[xvi]

In 1902, Charles Frederick Thackray (1877-1934) and H.S. Wainwright bought from Samuel Taylor a pharmacy he had established in Leeds in 1862. They had bigger plans than just the pharmaceutical retail businesses, and in 1905 bought a sterilizer for dressings, initiating the expansion of the businesses. From 1918 on, the focus of the company was surgical equipment. Initially, they fabricated instruments for Lord Moynihan, one of Leeds' most prominent surgeons. Thackray Sr. died in 1934, and his two sons C. Noel and W.P. (Tod) took over the commercial and manufacturing operations.

The first description of orthopaedic implants by the company dates from 1947. At that time Charnley was looking for a firm to develop hip fracture devices after he quarreled with Down Brothers Ltd, of London, his previous associate. The instrument curator at the Manchester Royal Infirmary put him in contact with Thackrays, and the company worked the first gadgets of what would prove to be a fructuous partnership.[30]

With the help of Arthur Hallman,[xvii] the chief of development in Thackrays, the firm started producing low friction arthroplasty devices in 1963; they were in charge of the manufacture of the UHMWP sockets and the femoral prostheses. However, the heads were polished at Charnley's lathe in Wrightington. Importantly, the firm contributed £1 to the research fund at the hospital for every prosthesis used.[16]

Charnley was demanding with the company. He wrote at least two letters a week to them. This was not particularly pleasant for Thackray's technicians and executives because, aside from perfection in the workmanship, he also demanded low prices (from a letter dated January 26, 1968):

> *. . . your firm may have been influenced by my desire to keep the cost of the implant as low as possible. . . . I now feel that you have plenty of latitude in the price . . . compared with world prices, to cover a considerable capital investment looking towards a long-term dominance in this field.*

However both parties remained loyal to each other. The label distributed with every implant sold, summarized the philosophy behind its production:

> *The Total Hip Prosthesis contained in this package consists of a plastic socket made of High Density Polyethylene for the acetabulum and a stainless steel femoral head. Both components have been developed by Mr. J. Charnley Dsc, FRCS, at Wrightington Hospital. Chas. F. Thackray Ltd., has been granted sole rights of manufacture in return for which they contribute to the Wrightington Hip Centre Research Fund. All prostheses are manufactured under carefully controlled production techniques which meet rigid requirements as laid down by Mr. Charnley. Quality control of the product includes a final inspection of a representative proportion in the Research Laboratory at Wrightington Hospital. Mr. Charnley has authorized the issue of this statement.*
>
> *Chas. F. Thackray Ltd*

Neither Charnley nor the company patented their invention,[xviii] not that this would have prevented duplication, and numerous variations on the implant began to be produced around the world. Initially, Charnley, in his idealism, did not think there were any problems because his name was associated with those products, but the reality proved to be quite different.

Later, Maurice Müller (b. 1918), founder of AO (Arbeitsgemeinschaft für Osteosynthesefragen), would visit Wrightington on multiple occasions during the 1960s, and in 1967 he started large-scale production of his own version of a Charnley type prosthesis through Protek AG, Münsingen, Switzerland (later merged with

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[xv] In 1990 Chas. F. Thackray Limited merged with DePuy, Inc., Warsaw, Indiana, United States, and became DePuy International Inc., still based in Leeds. After the acquisition of DePuy, Inc., by Johnson & Johnson Corporation in 2000, DePuy, Inc., and DePuy International were merged and became DePuy Orthopaedics Inc. Hereafter, I will be referring to the original company when using the term Thackray, as the actions I am describing took place during the 1960s and 1970s.

[xvi] This correspondence was reviewed in a comprehensive book about John Charnley and his life, written by Waugh, W.: John Charnley: The man and the hip. Edited, London, Springer, 1990.

[xvii] An excellent instrument maker and craftsman, Hallman was deeply appreciated by Charnley, who learned from him many of the techniques used in the manufacturing of his ideas. After Hallman's retirement, and when defective material arrived at Wrightington, he commented "I am quite sure that this defective workmanship would not have occurred in the days of Mr. Hallman." Ibid. Edited.

[xviii] Charnley never thought it would be necessary. He had a vision of medicine as a profession formed by idealistic individuals looking over interests different from monetary ones. This attitude explains his willingness to share his name and credit. Nevertheless, at that time, litigation processes were extremely slow and in many cases unproductive, in an epoch where copyright issues were still in their infancy.

Sulzer Medica) a company that distributed the implants made by Mathys and Sulzer (now Centerpulse, a Zimmer, Inc., company)[xix] Münsingen, Switzerland. Charnley became a personal friend of Müller and agreed to give his name to the implant, so the Charnley-Müller prosthesis was born. However, Müller changed some of the features of the prosthesis, making the head bigger (30mm) and increasing the available number of neck lengths, but he also modified the surgical technique. Importantly, Müller did not use osteotomy of the great trochanter for application of the femoral component, something that Charnley considered a basic feature of the surgery. Partly because of this, Müller's technique and implant became preferred by some in North America over Charnley's laborious procedure. Also, Müller was extremely entrepreneurial and ambitious. He recognized an opportunity, and instead of trying to directly sell his products in America through his company Protek AG, as Charnley and Thackrays were trying to do, in 1968 he associated with an American company, DePuy, Inc.[31] to distribute his prosthesis in the United States. DePuy, Inc., had been the pioneer of orthopaedic implant manufacturers in the United States, and was an established local industry, exceeding Thackrays in financial resources, and experience.

This situation affected Charnley, as we can infer from one of his letters to Thackrays expressing new doubts about the utilization of his name:

> *Müller attached my name to his prosthesis out of courtesy because we are close personal friends and because he was acknowledging my pioneer work. . . . The situation has now changed in so far as my operation is certainly a more extensive mechanical procedure than his . . . those manufacturers who in the past have made the Charnley-Müller with the 30 mm head should now drop my name . . . . (10-28-1970)*[16]

A typical example of the situation Charnley and Thackrays was experiencing was the 1968 visit to Wrightington of Charles Bechtol (1912-98), from The University of California at Los Angeles, Los Angeles, California, United States. He, along with three other California surgeons, were planning to start a 100-bed centre for hip surgery and had decided to choose Charnley's low friction arthroplasty as their starting model. Both Charnley and Thackrays expected the development of franchise arrangements. But the transaction was never completed. Bechtol's group never used Thackrays' prosthesis, but developed their own modification of Charnley's model with Richards Medical Company, Memphis, Tennessee, United States (acquired by Smith & Nephew Inc., in 1986).[32]

Eventually, this type of situation put enormous pressure on Thackrays as they saw business leaving them, evidenced in a letter sent to Charnley four years later:[16]

> *It is certainly not our wish to produce a larger headed model, but all the time we are being pressed by our foreign agents who seem to insist that there is as much demand for the Müller type, as for your small-headed variety, mainly required by the not-so-good surgeon, where he can use an easier operative technique.*[16]

Charnley never gave up and did not alter the design of the implant, its material nor the size of the femoral component head (22 mm). What did change, in the early 1970s, was the direction of the company. After C.N. Thackray Sr. died, his brother W.P. (Tod) took control of the company. If there was any change in the partnership with Charnley, it was positive. The new management was committed to being competitive, and by 1971 they were producing five different types of stems and four sockets, with an output of approximately nine to ten thousand hip implants a year.[30]

Low friction arthroplasty devices had been in use for at least eight years when the Food and Drug Administration of the United States asked for laboratory testing of their toxicity. Frustrated, Charnley expressed that the best proof he could provide was his own healthy patients, alive and without signs of disease several years after THA, and that it was an error to exclusively rely on laboratory tests, something that in his opinion was symptomatic of modern scientists and technicians.[xx]

The unregulated North American medical world of the 1970s provided a sharp contrast to British circumstances. Thus, different companies began trying Co-Cr and titanium alloys for the production of their implants. This put Thackrays on the spot due to Charnley's reluctance to use material other than stainless steel. However, after the financial difficulties of the company in the American market became evident, Charnley concurred with the decision to use Co-Cr alloys for a portion of the prostheses intended for the North American market. Nevertheless, he never used the new alloys in

[xix] Sulzer Medical, in an effort to recover from a highly publicized lawsuit over defects found in its artificial hips and knees, changed its name to Centerpulse AG, just before it was bought by Zimmer, Inc., on October 2, 2003.

[xx] Charnley's position in this respect was well known. He was a staunch skeptic of the AO techniques and principles for the treatment of fracture. He maintained that the best experimental model was inferior to an adequate clinical judgment. I must note, however, that this position was fundamental in Charnley, and it was developed well before any personal schism developed between him and AO's founder, Maurice Müller. Charnley's positions in this matter can be reviewed in an excellent recount of AO history by Schilich. Schilich, T.: Surgery, Science and Industry. A Revolution in Fracture Care, 1950s-1990s. Edited, 349, New York, Palgrave Macmillan, 2002.

his surgeries, and felt that implant failures attributed to stainless steel were the result of implant misuse and poor indications:

> *I have indicated from time to time that Thackrays will be overtaken in the United States by the build-up of publicity against stainless steel in favour of very sophisticated and expensive alloys . . . many of my loyal pupils can no longer risk using stainless steel . . . a number of surgeons who are on the bio-engineering bandwagon are teaching that stainless steel is no longer acceptable . . .(3-3-79)*[16]

In the end, Thackrays were unable to conquer a significant share of the American market, not even in the early 1980s when most THA sales were cemented implants. Its sales never represented more than two percent of the United States total market. Fortunately for both surgeon and company, the story was different in England, and stainless steel implants are still in use in Wrightington. By 1990, the year when Thackrays was overtaken by DePuy, Inc., and became DePuy International, Inc., it had about 50% of sales in the British market. This allowed Thackrays to maintain a continuous funding of research at Charnley's laboratory.

Charnley benefited economically from his implant and at his death had accumulated wealth of over £300,000. Nevertheless, money was never his main concern, and he commonly sacrificed personal benefits in favor of what he thought was right.

SUMMARY

The history of total hip arthroplasty is particularly interesting because it mirrors dramatic changes in priorities and values in Western culture over the last decades. Every implant design and company is a world with its own tale. The necessary involvement of the industry has provided invaluable resources for solutions to problems associated with the use of arthroplasty implants. It has also fomented a competitive environment driving the development of multiple approaches to THA design and technique. Orthopaedic surgeons need to act as checkpoints and critical evaluators of developments in the specialty, especially when economic interests are so closely related to the development of products, surgery, patient care, and medical education. Industry has become a partner in, and an important shaper of orthopaedics. Orthopaedic surgeons and corporations should be able to together turn the corner into a new century of progress.

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