

## By the numbers

**75,629**

Total knee replacements  
in the UK

Source: National Joint Registry  
2008

**£30,000**

Price of old surgical steel  
instrument kit

Source: RCA Helen Hamlyn  
Centre

**£195**

Target price of new  
plastic instrument kit

Source: RCA Helen Hamlyn  
Centre

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# Instrumental Design

Creating new opportunities and exposing hidden risks in the health care eco- system

Modern health care systems are as vast and complex as they are essential to the existence of a healthy society. Eliminating risk in this context is not only a moral imperative but also a prudent business decision and a precondition for establishing general trust in the system. Developments in medical treatment, devices, and procedures are subject to high levels of scrutiny so as to avoid reckless risk-taking at the expense of someone's quality of life, or their life itself. Yet this calculus does not account for an important factor—the status quo. By slowing down the innovation cycle we also extend the life of existing solutions.

As a giant in the field of orthopedic implants and related products DePuy, a subsidiary of Johnson & Johnson, had enjoyed a long period of success but was still anxious to enhance their ability to innovate and continue challenging the status quo. Using the specific problem of total knee replacements as a test case, DePuy asked the Helen Hamlyn Centre (HHC) at the Royal College of Art in London to help them rethink the tools used in surgery, and through this collaboration provide a model that would allow DePuy to more rapidly develop products better suited to the challenges faced by surgeons and their patients.

For good reason, innovation within health care must pass muster of rigorous review boards, making it one of the most challenging contexts to innovate within. The risk inherent to this approach is its implicit assumption that the status quo has been consciously chosen, when many of the conditions we take for granted have come to be out of coincidence or contingency rather than explicit design and decision-making.

*“We are very conservative... If we try to use a new-fangled thing and it goes wrong... it ruins someone's life. Progress has been evolutionary rather than step change.”*

-Professor David Barrett, Consultant orthopedic surgeon, Southampton University Hospital<sup>1</sup>

## Hard Data

### Client

DePuy

### Core Design Team

Helen Hamlyn Centre

### Stakeholders

DePuy, RCA, surgical staff, patients, hospitals, insurance providers, National Health Service

### Sector

Health care

### Start date

September 2006

### Status

Ongoing

### % of project spent in understanding phase

n/a

### Project cost

Tens of thousands of Euros

## Key Individuals

### Helen Hamlyn Centre

**Rama Gheerawo**,

Deputy Director

**Maja Kecman**, Designer

**Lisa Stroux**, Designer

**Karina Torlei**, Support,

Future of Surgery Forum

### InnovationRCA

**John Bound**,

Co-Director

Innovation efforts are not evenly distributed. The heterogeneous landscape of innovation within the health care sector has yielded a situation where some decisions are guided by very deep accumulations of knowledge and supported by intensive research and development, while other choices are made in an informational context which has barely changed in decades or even centuries – whether this is the result of problems going unseen or a lack of clear funding support for the problem area.

One challenge to innovation in health care is the extreme degree of skill and expertise of the physicians, nurses and hospital staff who form the core of the system. Paradoxically, these are the individuals who know the functional requirements of their tools and procedures best, yet typically have the least amount of time to apply that knowledge towards improving tools and techniques. In effect, a practitioner adept at improvisation can cause a negative net impact to the health care innovation ecosystem by prohibiting the specific inadequacies of the tools and practices they improvise around to bubble up to parties who are able to develop and disseminate systemic solutions. Improvisation allows the best surgeons to develop coping mechanisms that allow them to produce successful outcomes even when their instruments fail them, but why accept this additional risk if it can be mitigated?

## The Advocacy Gap

The surgical theatre is one of the most demanding environments on earth. High-stakes and time-sensitive, surgery is a stressful endeavor, the brunt of which is borne by the surgeons themselves who are ultimately responsible for the success or failure of an operation. We expect the medical equipment used in these situations to be highly tuned to their specific use. The question is, “from whose perspective?” When observing knee surgeries in multiple contexts the HHC found that some of the best surgeons have adapted to their tools so fluidly that they’ve developed a blindness that prevents them from seeing the deficiencies of the instruments.

Surgeons have extremely demanding needs but are also highly competent individuals able to adapt quickly to evolving situations by developing on the spot coping mechanisms. The intense focus of the operating theatre doesn’t leave much room for meta-conversations about the efficacy of tools. As soon as surgery is over the focus quickly moves to other patients and other operations. In effect, this means that the instruments have very brief windows of use during which time the primary users are intensely focused on not allowing failures of any kind, for any reason. These instruments, which should be the focus of significant attention, receive relatively little.

*“I am covered in blood and fat and it has no grippy handle... it flies out of my hand every now and then. It’s appallingly bad design.”*

-Professor David Barrett describing a mallet he uses in knee surgery, the design of which has remained unchanged since the 19th century

**DePuy**  
**John Naybour**, Director,  
Strategic Marketing

**Consultants**  
**Martin Bontoft**, User  
Research & Design  
Strategy  
**Gareth Jones**

Compared to the remaining lifetime that a patient will live with their artificial knee, the surgery is over in a flash. The patient experiences the new knee all day, every day. Embedded within the human body, the implants have natural advocates in the patients who receive them, who can and will complain about pain or discomfort and make sure that their voice is heard. With the implants naturally receiving so much more attention than the instruments, it's no surprise that the implant innovation cycle is approximately one third that of the instruments used to install them<sup>II</sup>. Without a comfortable implant surgery would be pointless, but nevertheless the surgical procedure itself is a significant risk and any opportunity to reduce that risk is important.

## Can Steel Be Too Strong?

The importance of instrumentation can be observed in the respect garnered by the term "surgical steel," an honorific reserved for the highest grade of equipment. The power of surgical steel's "brand" has spilled over to other industries such as appliances and automobiles where stainless steel enjoys a similar level of respect and commands an added premium. As a recognized indicator of sterility, durability, and strength, surgical steel has become a veritable precondition for medical instruments.

Yet it might be possible for something to be too durable. The long lifespan of stainless steel surgical instruments decreases their **apparent need** of replacement: why replace something that has such a long usable life still available?

Satisfying DePuy's desire to have a single use instrument and addressing ease of use questions raised during fact finding, the HHC proposed instruments made primarily out of surgical grade plastic. Given the entrenched perception of stainless steel as the de facto standard in surgical instrumentation, this was not an easy discussion to broach with the Design Surgeons DePuy identified to vet the work of the HHC. John Bound of InnovationRCA, who helped build the connection between the HHC and DePuy, noted that "surgeons are very attached to the instruments that they use and vociferous about saying which they like and don't like."<sup>III</sup>

The suggestion of plastic as a material for surgical instruments also dredged up memories of earlier plastic tools, such as hammers and mallets, which had proven to be failures. It was important to acknowledge these earlier failures, but the applications were not chosen carefully using balanced decision making: requiring weight and heft to be effective, it is no surprise that a plastic hammer was not received well!

Confident in the ability of modern plastic to stand up to the rigorous standards of medical applications and even provide additional benefits, the HHC team organized an **analogous items** workshop where examples of high quality, high value, dependable plastic items were presented for discussion and testing. By gently pointing out that many of the people in the room owned luxury vehicles, the cabins of which were fitted out with various plastic pieces, as well as demonstrating camping and sporting equipment constructed from high performance plastic, the team was able to slowly convince the Design Surgeons that plastic could deliver on their needs.

## As Regular as a ‘Chip Shop’

The demand for orthopedic surgery, and especially knee replacements, is growing in the UK. During the 1990s incidence rates total knee replacement surgery more than doubled<sup>IV</sup>. With 75,629 total knee replacements during 2008<sup>V</sup>, the market is expected to grow as the Baby Boomers continue moving into later stages of life and living longer.

Using current practices and instruments, a surgeon may average one hundred knee replacements per year. Attempting to capture the regularity of the majority of knee replacement operations, the colloquial term of art used in the surgical community is a “chip shop operation,” as discovered by the HHC’s research team. Although the term may be cheeky, it zeroes in on an essential aspect of surgical practice that will become increasingly important as the volume of required surgeries increases. The existing imperative to deliver effective surgery will be compounded by the necessity of doing more surgeries in the same amount of time for the same or less money. Innovations allowing more procedures, cheaper or more effective operations, and reducing the level of risk involved with any and all stages of the process will take an advantaged position in the market.

In anticipation of the changes coming to the market and eager to maintain their position as an industry leader in orthopedic products, DePuy engaged the HHC to help them rethink knee replacement surgery from first principles.

## A Space of Possibility

When DePuy approached the HHC one thing was clear: a single-use instrument was the way to go. Everything else was up for grabs. HHC Senior Associate Maja Kecman, along with a team including Lisa Stroux and Karina Torlei, began by opening a broad space of possibilities to learn about DePuy’s business and explore sources of inspiration that a design process could contribute. The attitude was confident but humble: “using design, let’s see what we can get done.”

*“Design ethnography is a search for inspiration rather than statistical truth.”*

– Rama Gheerawo<sup>VII</sup>

These initial meetings used techniques such as eyes-closed visioning sessions where surgeons were asked to imagine and narrate and role-play their process in slow motion. Other activities gave participants a forum to share their aspirations and apprehensions, all with a focus on the familiar procedures of surgery. Although it may sound tedious, these methods were an important step toward slowing down the fast-paced, high-stress decision-making environment of the operating room into something that was accessible to discussion and open to redesign. These early conversations would play an important role later in the process as the HHC sought to design to the observed and expressed needs of the users, rather than simply accepting the inherited specifications of the status quo.

## Redefining the user

With a basic understanding of the concerns of the surgeons who form one important user group, the HHC expanded the definition of “user” to include the patient being operated on as well as those in supporting roles such as scrub nurses, technicians, and hospital staff involved in transportation, handling, sterilization, and assembly of surgical equipment. Observing how these different groups of individuals interacted allowed the designers of the HHC to consider the total ecosystem, ensuring that their proposed solutions were durable and responsive not only to the needs of the surgeons, but across the entire patient and medical device journey.

As a global supplier, DePuy’s products are used in countries around the world, so teams were sent to the United States, United Kingdom, and India to find out how culture affects the surgical process. Through video and in-person observation, the HHC team discovered that the formality of the operating room varies by culture. For example, nurses and surgeons in India were observed to have a more rigidly hierarchical relationship than in the US, introducing an element of anxiety that increases stress in an already stressful environment.

## Looking Closely

Standing out from many hours of observation was a key finding: that surgeons were in some cases willfully misusing their instruments. Focusing on two out of six steps, replacing a knee involves using a bone saw to remove the tip of the femur and tibia so that an artificial joint may be inserted in its place. The steel “jig” currently still in use for this purpose is heavy and cumbersome. It is a telescoping instrument which locks onto the shaft of the femur itself and is positioned with the help of an ankle clamp. Due to its weight, any shift in balance or an accidental slip has the potential to injure the patient by tearing fragile tissues or inducing bruising resulting in a longer recovery period. Faced with a cumbersome instrument, some of the surgeons interviewed and observed by the HHC opted to “freehand the cuts” – avoiding the jig and its potential pitfalls altogether. As leading practitioners, the surgeons were still able to deliver a high level of care, but they were nevertheless relying on coping mechanisms in lieu of effective instruments that fluidly supported their work.

Video ethnography figured heavily in the HHC’s observation of surgeons, surgical staff and the operating environment. Over a dozen operations were captured with both wide angle and close up footage yielding nearly 50 hours of video. Using a spreadsheet to catalogue surgical steps and time increments for each step, the design team and ethnographer were able to identify 147 coping mechanisms and as many as 110 problems that were not being addressed by the surgical team.<sup>VIII</sup> In addition, detailed surgical step timing revealed “dead time” during the operation that in some cases accounted for as much as half of the total time the patient was in the operating room.

Observation, enabled by the lens of design ethnography, provided the design team unfettered access to the austere and often highly personal surgical space. Video ethnography in particular proved that standards of care content with the inefficiencies and resulting coping mechanisms developed by conscientious practitioners. Even in some situations where very high levels of care were being given, these outcomes were despite evident blind spots within the ecosystem of the operating theatre, the hospital, and even the health care system at large. By acting as unbiased outside observers, the HHC's design team could ask basic questions about seemingly unimportant things to assist in illuminating these blind spots and turning them into opportunities for redesign.

While "gold standards" of care are important within the medical community, ultimately every surgeon is an individual with their own abilities and strengths. The goal may be consistent across most knee replacements, but surgeons were found to have individual techniques allowing them to complete the surgeries successfully.

## **Narrowing in on a solution**

The HHC spent three months defining the problem before attempting to sketch a solution. During this period the relationship with DePuy was not always easy. As the client, DePuy was expecting results in a linear manner. In contrast, the design process employed by HHC took advantage of the early explorations to build a platform for accelerated design development, during which time the results delivered would exceed the client's expectations.

Over a period of a couple weeks exploring potential solutions through sketches and physical models, the HHC team synthesized the insights from their design ethnography and research process into a proposed solution. As the unveiling of the concept drew near, nervousness in the office grew. Walking into DePuy's conference room for the presentation, the memory of the exacting standards and rigorous demands of DePuy's Design Surgeons made the HHC team apprehensive about revealing a proposal that required a radical departure from DePuy's previous instrumentation.

To the relief of both the client and the design team, the proposal was well received. John Naybour, Director of Strategic Marketing at DePuy, described the design work of the HHC as being beyond comparison with DePuy's internal process: "we couldn't have gotten [to those results] using our internal product development process."<sup>IX</sup>

It was clear that the new single use instrument would have benefits over the reusable instruments: cost reduction and simplification of handling, storage and use by avoiding sterilization. But the proposed plastic instrument appeared to have additional benefits. The plastic ankle clamp fit more snugly around the patient's ankle and thus the new jig provided a more stable platform for the surgeon's saw. Accuracy of implant insertion was likely to be improved because of increased stability and ease of positioning on the leg with minimal risk of additional injury. Elimination of instrument staging steps would improve the efficiency of surgery turnaround, allowing a surgeon to increase the number of surgeries they can perform in a given week.

DePuy has since moved the instrument prototype into a formal production process. Clinical trials will begin soon, followed by ethical board reviews, and product release. While production of a new instrument demonstrates the success of the DePuy-HHC collaboration around a particular challenge, it is the transformation within DePuy that suggests the potential of a design-led process. DePuy now uses the design methodology as a blueprint for its internal product development processes and DePuy's in-house designers have been released to lead product development.

## **New Opportunities At New Scales**

On the heels of this clear demonstration of value, DePuy extended their collaboration with the HHC by expanding the inquiry to look at the instruments in conjunction with their handling and transportation.

Beyond the scope of the implant and the instruments used to install it, there are also broader concerns existing at the scale of the health care system at large. The patient, surgeon, implant, and instruments each have their own unique “journeys” through the health care system that intersect at different points. The ecosystem of care involved in replacing a knee covers many contexts, each falling under different areas of expertise, budgeting, and oversight which makes it difficult to achieve redesign at a systemic level.

A second design brief asked the HHC to investigate the trays that are used to store and transport reusable surgical instruments, thus expanding the scope of potential interventions to match the broader scope of the Helen Hamlyn Centre's initial research. Through a similar process of pinpointing existing problems, identifying opportunities for intervention, and designing solutions, the HHC developed two tray prototypes over a period of six months in 2007. This work has since been continued by DePuy and has been integrated into their product line. Since beginning their collaboration with the HHC, DePuy has experienced above-market rate growth.<sup>X</sup>

A third collaboration between DePuy and HHC was started in 2009 investigating the future of surgery itself. Moving from the instrument, to the operating environment and now to the practice of surgery, the design team is negotiating progressively larger scales of issues and challenges faced by health care providers. This project will have many focuses from new concepts and products to facilitating an ongoing discussion with experts from many fields under the Forum on the Future of Surgery. The HHC's design team will continue to use its patient-centered approach to guide research, development and delivery of new solutions for better health.

## **A Pathway to Strategic Improvement**

Having set out to refresh their internal product design and development processes, DePuy found a capable partner in Royal College of Art's InnovationRCA and Helen Hamlyn Centre. Entering into their fourth year of work together, the value of HHC's design-led contribution to DePuy is validated by DePuy's willingness to extend their work across multiple scales of challenges and through several rounds of project funding. As DePuy continues to introduce more fruits of this collaboration to the market, further opportunities to evaluate the value of HHC's contributions will arise.

Central to the success of HHC's design work was their ability to act as a neutral party, using the design process to integrate multiple silos of expertise and include an expanded definition of "users" and their needs. This neutrality springs from two factors: First, that the HHC is part of the Royal College of Art and thus benefits from its status as a noncommercial entity established for the pursuit of knowledge. Although DePuy continues to work with private consultancies for other product-related services, they specifically sought a university engagement that would be well positioned to offer the long-term relationship they sought to cement culture change within their organization.

Secondly, that HHC approached the problem from a design perspective allowed them to interface with experts from a broad variety of fields without being perceived as biased. In some cases, the challenge was actually the opposite: it sometimes took considerable effort to establish a relationship of trust between the HHC's design team and an expert, the latter assuming that the conversation should remain at the level of styling or aesthetics. For designers seeking to work on strategic issues, the challenge of conveying the seriousness of this intent persists. The HHC team was able to overcome these initial apprehensions on behalf of their collaborators through persistence and by demonstrating an ability to engage the technical aspects of the field and utilize literature from their area of inquiry. Most importantly, the HHC team demonstrated that they could deliver on the promise of their process by providing solutions of marked improvement over what was accepted as the gold standard of the time.

Traditional research into the subject was paired with design ethnography techniques to provide a productively enriched definition of the problem space. Video observation, role playing, and conversations about analogous items were used by HHC to slow down the fast paced, intense decision making environment of the operating theatre and insert the possibility to carefully question the status quo, catalyzing new opportunities for redesign of previously invisible failure points.

With a constant focus on outcomes and allowing themselves a high degree of freedom to explore many pathways to success, HHC went beyond optimization of sub components to deliver strategic insights into untapped opportunities and previously invisible or unmanageable risks.

This can be seen in the use of surgical plastic which satisfied DePuy's desire for a single use instrument at an acceptable cost, thus opening up further opportunities for rethinking the business model of the instruments and their implants. Inherent to the design of the new instrument are risk-reducing factors as well, such as the better-fitting ankle clamp that will eliminate the need for surgeons to freehand cuts out of the interest of serving their patients.

From a broad perspective, HHC used design to escape the perils of “sub optimization.” Whereas previous cycles of product design had resulted in parts of the hospital ecosystem being meticulously designed as individual “sub” components, HHC’s work focused on illuminating the relationships between these bits –including people, things, and processes – and beginning the design process from the insights gleaned. Although HHC’s work resulted in specific product designs, these were informed by rigorous research and were robust enough to fundamentally redefine relationships and in effect, begin a redesign of the ecosystem from the bottom up.

**Written by Bryan Boyer & Justin W. Cook**

**Version 1.01**

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## Timeline

### Instrument project

September 1st, 2006

Funding for surgical instrument project received

October 1st, 2006

Project kick-off

November 1st, 2006

From October to December, hospital visits to observe surgery (around 15 operations in 5 different hospitals in the UK)

January 1st, 2007

First concept presentation and observation insights to DePuy (internal)

January 1st, 2007

Design Surgeon workshop in London

February 1st, 2007

Surgical observation in Mumbai, India

March 1st, 2007

Sketch models and concept presentation to DePuy (internal)

March 14th, 2007

Surgeon meeting in Salt Lake City to show initial concepts as CAD renderings and workshop on perception of plastics

May 1st, 2007

Final presentation to DePuy - physical prototypes shown

June 1st, 2007

Surgical instrument project ends

June 1st, 2007  
Surgeon meeting in Chicago. Cadaver workshop

### **Tray project**

July 1st, 2007  
Funding for instrument tray project received

February 1st, 2008  
Instrument tray project ends

### **Future work**

March 1st, 2008  
Funding for three years worth of projects

April 1st, 2011  
Three year project cycle ends

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## **Footnotes**

### **I**

"Forum on the Future of Surgery, Friday 6 February 2009, Royal College of Art, London." <Link>

### **II**

Naybour, John. Interview. March 2009.

### **III**

Bound, John. Interview. April 2010.

### **IV**

Dixon, T. Et al. "Trends in hip and knee joint replacement: socioeconomic inequalities and projections of need." *Annals of the Rheumatic Diseases* 63 (2004): 825-830.

### **V**

"National Joint Registry for England and Wales 6th Annual Report." Hertfordshire: National Joint Registry, 2009. <Link>

### **VI**

Kecman, Maja. Interview. November 2009.

### **VII**

Gheerawo, Rama. Interview. November 2009.

## **VIII**

Bontoft, Martin. <http://www.bontoft.com/work%20images/depuy.htm>

## **IX**

Naybour, John. Interview. April 2010.

## **X**

Naybour, John. Interview. April 2010.