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Graeme Holt, Kerry Wheelan and Alberto Gregori

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ETHICS IN PRACTICE

THE ETHICAL IMPLICATIONS OF RECENT INNOVATIONS IN KNEE ARTHROPLASTY

BY GRAEME HOLT, MBCHB, MRCS, KERRY WHEELAN, MBCHB, AND ALBERTO GREGORI, FRCS(ORTH)

Total knee arthroplasty is currently one of the most commonly performed elective orthopaedic procedures. It has been validated as offering relief from the pain associated with degenerative arthritis when that pain is unresponsive to medical therapy^{1,2}. Some recent innovations in arthroplasty surgery offer the potential for improved and more reproducible outcomes.

Minimally invasive arthroplasty has generated great interest among patients, arthroplasty surgeons, and health-care providers and has been the subject of widespread coverage in both the medical and the lay press. Much of this interest is based on the promise of the same or better long-term results and a shorter, less painful recovery, earlier mobilization, and reduced hospital stay and cost^{3,4}.

Computer-assisted surgery is another recent innovation that is gaining popularity among arthroplasty surgeons. This type of surgery has been validated by a number of studies that have shown its ability to improve the mechanical alignment of the lower limb after total knee replacement and to improve the reproducibility of this outcome measure⁵⁻⁷.

What Do We Mean by "Ethics"?

Medical ethics may be considered as a code of professional conduct, the foundation of which is commonly based on four principles—nonmaleficence, beneficence, autonomy, and justice—as described by Beauchamp and Childress

in their text: *Principles of Biomedical Ethics*⁸.

Nonmaleficence: Surgeons have an obligation not to inflict harm on patients, either intentionally or carelessly. "Primum non nocere," first do no harm, is one of the most fundamental aspects of biomedical ethics. Harm in terms of bioethics refers to physical harm, including pain, disability, and death. Unfortunately, all surgical interventions inevitably cause some harm and carry some form of risk, and so this principle is impossible to guarantee in any surgical procedure. It is important to point out that, for nonphysicians, nonmaleficence is acceptable behavior but, as physicians, we must go beyond nonmaleficence and act for the good of our patients.

Beneficence: Beneficence refers to the principle of intervening to benefit the well-being of an individual. As surgeons, this basic principle is what we try to achieve in every procedure that we undertake. Beauchamp and Childress highlighted the differences between the principles of nonmaleficence and beneficence. The duty to "do no harm" invariably prohibits actions, while the duty to help generally prescribes intervention. The duty of nonmaleficence is more universal than the duty of beneficence because "it is possible to act non-maleficently toward all persons, but it would be impossible to act beneficently toward all persons."⁸ Beneficence and nonmaleficence are inexorably linked to the principle of autonomy.

Autonomy: Autonomy derives

from the Greek words "autos" and "nomos," which together mean self-rule. Beauchamp and Childress define personal autonomy as "personal rule of the self, free from both controlling interferences by others and from personal limitations that prevent meaningful choice."⁸ Autonomy requires that an individual is independent from a controlling influence and has the capacity for intentional action. The most common way in which a surgeon demonstrates respect for a patient's autonomy is by obtaining the patient's valid consent for a surgical intervention. The consent process demonstrates respect for a patient's decision-making capacity. As it is impossible to guarantee beneficence or nonmaleficence, informed consent allows an individual to balance potential benefits against associated risks.

Justice: In addition to adhering to the principles described, surgeons have an obligation to promote justice in the distribution of health care. Distributive justice refers to fair, equitable, and appropriate distribution in society of a privilege, benefit, or service. Problems of distributive justice arise under conditions of scarcity and competition, when resources are not adequate to provide all that each individual requires. It is widely recognized that health-care resources are finite and that difficult choices must be made regarding the distribution of such resources. Justice is an important principle when we consider the introduction and application of new techniques that require appreciable funding and may indeed divert

funding from other areas of health-care provision.

If we consider total knee arthroplasty as a surgical intervention, it can be justified according to the ethical principles that we have discussed. The procedure is well validated in the orthopaedic literature and is accepted as an effective treatment for the intractable pain of degenerative arthritis¹². Patient autonomy is respected because we are able to give the patient sufficient evidence regarding predicted benefits and risks to allow that patient to provide informed consent.

During the last decade, improved access to the medical literature provided by the Internet and the press has caused a shift in the modern patient's expectations and knowledge. The general public is now much more aware of which treatments are available and which treatments should be available. This situation can create a number of difficulties, as the expectations may not be realistic or take into account the experimental nature of new surgical innovations. With this in mind, let us now consider the ethical issues posed by recent innovations in knee arthroplasty.

Minimally Invasive Surgery

Minimally invasive total knee replacement is a recent surgical innovation that has generated great interest among both patients and surgeons. The procedure involves not only the use of a smaller skin incision but also the use of alternative surgical approaches that are claimed to be less traumatic to soft tissues⁹⁻¹¹. The minimally invasive approach to the knee should not violate the extensor mechanism and should not violate the suprapatellar pouch¹¹. In addition to alternative anatomical approaches, modified implant designs are often necessary to facilitate the implantation of the prosthesis through limited incisions^{10,12}. Minimally invasive surgery represents the introduction of an entirely new surgical technique rather than merely the evolution of an existing one. Proponents of minimally invasive surgery have reported a number of advantages with such techniques, including reduced early postoperative

pain, reduced length of hospital stay and rehabilitation, earlier return to work, decreased blood loss, improved cosmetic appearance, and high patient satisfaction^{3,4,9}.

Despite reports of the potential advantages of minimally invasive surgery, the results of several studies have failed to confirm improved outcomes; indeed, a number of potential disadvantages of minimally invasive joint replacement have been reported¹³⁻¹⁶. These disadvantages relate to the difficulty of performing such surgery within a restricted visual field and are compounded by the issues related to learning a new exposure and technique. These issues may lead to implant malposition, intraoperative fracture, or neurovascular injury. Injury to skin and soft tissues can occur when excessive retraction is used, and most proponents recommend the use of specialized instruments^{10,11}. Damage to prosthetic bearing surfaces may occur at the time of implantation or relocation if the joint is not well visualized. The duration of surgery is often increased, which may lead to a higher rate of associated complications, such as thromboembolism and infection. A major disadvantage of minimally invasive techniques is that one or more of the aforementioned issues may have a profoundly negative effect on the otherwise positive long-term results that patients and surgeons have come to expect from conventional total joint arthroplasty.

For a surgical technique to be applied on a regular basis, it must offer outcome measures that are at least as good as those offered by conventional techniques. The outcomes of minimally invasive total knee replacement are difficult to evaluate scientifically for a number of reasons. Incision length, for example, is not well documented in the orthopaedic literature and, until recently, has not been a major focus of concern. The length of an incision varies with the limb position, and the "relative length" varies according to the size of the patient. In addition, there is no validated means of documenting the soft-tissue insult that occurs with surgery. The relative importance of the in-

tegrity of an anatomical structure, the manner in which that structure is detached, and the type of incision used are very difficult to quantify. Not only is incision length difficult to document, but we are not aware of any studies that have indicated that there is an increase in complications with the use of longer incisions.

Patient selection further confounds the evaluation of minimally invasive total knee replacement because not all individuals are suitable for a minimally invasive approach. Factors affecting patient selection also have been reported to have a significant influence on the long-term functional outcomes of arthroplasty ($p < 0.05$)¹⁷.

Minimally invasive total knee replacement gives rise to several important ethical questions. Can we satisfy the principles of beneficence, nonmaleficence, autonomy, and justice by introducing this procedure on a widespread basis? Despite the promise of early postoperative benefits, the primary concern with minimally invasive total knee replacement is reduced visualization of anatomical structures. Reduced visualization means that optimal component alignment and positioning are much more difficult to achieve consistently. Component alignment is one of the principal determinants of long-term functional outcome and implant longevity, but it can be validated only by long-term outcome studies. Therefore, the principles of beneficence and nonmaleficence cannot be satisfied. Since we cannot with any certainty advise patients of the potential risks or benefits particular to this technique, we cannot obtain truly informed consent. Patient autonomy is not respected unless it is made absolutely clear to the patient that the long-term results of minimally invasive total knee replacement are not known and may in fact prove to be inferior to the results of standard techniques.

Computer-Assisted Surgery

At present, most arthroplasty surgeons rely on either the naked eye or alignment jigs to align prosthetic components during total knee arthroplasty.

However, poor orientation of the implant or improper mechanical alignment of the lower limb may lead to implant failure and/or suboptimal functional performance^{18,19}. It is known that alignment errors of $>3^\circ$ are associated with more rapid implant failure and less satisfactory functional results^{18,19}. Computer-assisted arthroplasty was developed to allow reproducible improvements in the mechanical alignment of the lower limb during knee arthroplasty. The use of navigation systems is considered by some to be in the investigation stage as it is a relatively new technology with only short-term outcome data available. Long-term effectiveness in terms of revision rates, pain, and functional performance has yet to be evaluated.

Despite the lack of long-term outcome measures, however, the widespread introduction of computer-navigated arthroplasty does satisfy the ethical principles that we have discussed. Computer-assisted surgery is an adjunct to arthroplasty. The navigational equipment serves only to provide the surgeon with information regarding the alignment and position of components. The final choice of implant position and orientation still rests with the operating surgeon. Computer-assisted arthroplasty involves the use of standard surgical approaches to the knee and standard implants. Critics of computer-assisted surgery state that the duration of the procedure is increased. While this is certainly the case during the learning-curve phase, it has also been shown that, after a period of time, there is no significant difference in operative time²⁰. Beneficence is maintained because a number of randomized trials have shown the lower-limb alignment obtained with use of computer-assisted surgery to be superior to the alignment obtained with use of traditional methods; therefore, there is the opportunity to improve the final outcome and possibly reduce the need for a revision procedure⁵⁻⁷. Although the long-term effects of the improved alignment gained with this newly introduced technology have not yet been demonstrated, we know that the early

complication rates are similar to those of conventional techniques, thereby satisfying the principle of nonmaleficence. To maintain the principle of justice, we must consider the costs that would be involved, as computerized navigational equipment is expensive to purchase and could divert resources from other areas of health care. To our knowledge, no cost-effectiveness or economic analysis of computer-navigated arthroplasty surgery has yet been published. However, if we apply the utilitarian concept of justice, we can argue that this expenditure is justified. Considering the large number of patients who undergo total knee arthroplasty and the fact that navigation is known to improve limb alignment, the likelihood of implant failure and the need for expensive revision surgery may be reduced. However, the true utility of computer-navigated arthroplasty will remain unknown until long-term follow-up data are available.

Overview

Our desire to improve the outcome after surgery is what drives us to develop innovative surgical techniques. The potential to improve existing treatments through the development of novel techniques is coupled with the temptation to introduce these techniques on a wide scale without fully considering the associated moral and ethical implications. Many ethical dilemmas arise when a technique is incorporated into general clinical practice from its research phase⁸. One vital question that must always be foremost in our thoughts is: When does a new technique represent unacceptable experimentation rather than innovation? A new technique may not be better than the standard procedure. Therefore, true informed consent is absolutely essential. It is important for the surgeon to have a frank discussion with the patient about the potential benefits and risks of a new procedure as well as the surgeon's experience with that procedure. Patients often assume that the outcome of a new procedure such as minimally invasive total knee replacement will be better than the outcome of a standard technique. They may also underestimate the risks associated with

the new procedure, particularly if that procedure is termed a "minimally invasive" operation. Patients may not grasp the concept that, although a "minimally invasive" procedure has a smaller skin incision, the complications associated with that procedure may be equal to or even greater than those associated with a standard surgical approach. In addition, patients need to understand that they might not experience all of the benefits of a new procedure during the learning-curve phase of that technique. There is a strong argument for considering a new procedure as experimental until a clinical trial is performed to determine whether that procedure actually provides benefits to patients.

At present, minimally invasive techniques for total knee arthroplasty do not meet the ethical standards that are already met by existing conventional techniques. Minimally invasive total knee replacement should therefore be regarded as research, and consented to as such, until the procedure has been scientifically validated by a comparison with conventional methods in randomized studies with sufficient statistical power. The widespread use of a new technique should be delayed until the indications, pitfalls, and potential complications have been identified. To embrace a technique before it has been suitably validated may result in a step backwards in our surgical evolution. Surgeons who choose to offer these emerging techniques to their patients are encouraged to collect and compare the clinical outcomes of the two types of surgery in their own practice.

Graeme Holt, MBChB, MRCS
Kerry Wheelan, MBChB
Alberto Gregori, FRCS(Orth)
Department of Orthopaedic and Trauma Surgery, Hairmyres Hospital, Eaglesham Road, East Kilbride, United Kingdom G75 8RG. E-mail address for A. Gregori: gregoribub@aol.com

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