Over the past 2 decades, there has been a resurgence of interest in the use of decompressive craniectomy for a variety of neurological emergencies, including severe traumatic brain injury, stroke, subarachnoid hemorrhage, severe intracranial infection, dural sinus thrombosis, and inflammatory conditions. The rationale for surgical intervention is that, by providing extra space into which the injured brain can expand, intracranial pressure can be reduced, thereby preventing life-threatening herniation of the cerebellar tonsils and improving cerebral perfusion. The surgical procedure is technically straightforward, and numerous studies have demonstrated that in the context of life-threatening cerebral swelling, mortality can be reduced, and many patients go on to make a good long-term recovery.

Unfortunately, this is not always the case, and many patients survive only to be left with severe neurological disability. Indeed, for many years, the concern among clinicians has been that surgical intervention would convert death into survival with a level of disability that patients and their families may feel to be unacceptable. Recently, 2 meta-analyses have been published of the 6 randomized controlled trials comparing decompressive hemicraniectomy with standard medical therapy in patients who develop malignant cerebral swelling after middle cerebral artery stroke. Both analyses would seem to provide unequivocal evidence that use of the procedure can reduce mortality; however, there remains controversy regarding long-term outcome, patient selection, and some of the ethical issues that require consideration.

Long-Term Outcome
What Is the Aim of Decompressive Hemicraniectomy?
Traditionally, the stroke literature has assessed outcome on the modified Rankin Scale (mRS) score and used a dichotomy between favorable (mRS score 0–3) and unfavorable (mRS score 4–6). That implies that clinicians attempt to provide patients with a favorable outcome where, on the mRS score, the fundamental determinant of a favorable outcome is that a patient can walk unaided and therefore has a level of independence, albeit with some degree of disability, and an unfavorable outcome is one where a patient is unable to walk and is therefore dependent. But we should question whether this is an acceptable division as it stands and whether the current use of it retains that acceptability.

In the pooled analysis of the 3 European stroke trials published in 2007, it was only possible to demonstrate a significant improvement in favorable outcome by recategorizing favorable as a mRS score of \( \leq 4 \). This would therefore include patients who were unable to walk unaided and unable to attend to their own bodily needs without assistance, but it could be argued that, given that these are relatively young people and the alternative would be not to survive at all, a patient may reasonably want to be given the chance to risk survival with an mRS score of 4 (immobile and dependent) in the hope that they will either achieve an mRS score of 3 or learn to accept a level of disability that they might previously have deemed unacceptable.

Retrospective Consent
In an attempt to evaluate this argument, investigators have asked patients whether they regret having had the surgical decompression and whether they would have provided consent (where it possible that they could be asked) if they had known their eventual outcome. Several studies have demonstrated high levels of so-called retrospective consent which, on superficial examination, seem to justify the ongoing use of procedure because unfavorable (mRS score 4–6) may not necessarily be unacceptable. However, adopting this position is inherently problematic in the
light of a commonly invoked ethical concept of critical interests—the idea that one’s most important values ought to be those made when in full command of one’s faculties.16

Acceptance or Adaptation?
Obtaining a positive response when asking a patient whether they would agree to an intervention that has enabled them to stay alive, albeit with a considerable alteration in functional status, is certainly a testament to the human will to survive and ability to adapt to adverse and challenging circumstances.14 However, it would be injudicious and perhaps misguided to interpret this as a mere variation of the consenting process and, therefore, a validation of the surgical intervention no matter what the eventual outcome. When answering the question "Are you glad to be alive?" One is inclined to say, "As distinct from what?" to show up the absurdity of being asked that question. Few, apart from those that are suicidal, are likely to say "No, I'd rather be dead."

A more realistic interpretation of the responses of such patients is that they may have adapted to a level of neurological disability that they might previously have deemed unacceptable, a phenomenon observed in many circumstances.14,17 Although this may be a reflection of diminished cognitive capacity, it is perhaps of questionable relevance to assess the actual life values of the patient. Given the uncertainties, retrospective consent seems not to provide a sufficient justification for the procedure, especially when it is believed that the most likely outcome if the patient does survive is that of severe neurological disability, which in sound mind a patient may reject when faced with an antecedent choice.14 This ethical zone of uncertainty especially applies to patients over 60 years of age because it is in this group of patients that there is controversy about possibly unacceptable outcomes and lack of substantial benefit.

Patient Selection
Decompressive Hemicraniectomy in Patients Over 60
The Decompressive Surgery for the Treatment of Malignant Infarction of the Middle Cerebral Artery (DESTINY) II trail compared decompressive hemicraniectomy with standard medical management in patients over the age of 60 years.19 The investigators concluded that hemicraniectomy increased survival without severe disability among patients ≥61 years of age with a middle cerebral artery infarction and found that, among survivors, 63% of those in the hemicraniectomy group gave retrospective consent to treatment. Overall, this would seem to support the ongoing use of the procedure in this age group because it is difficult to argue that it is not on a patient’s best interest to have surgery if they are able to state that they are satisfied with their outcome and they would do the same again.

However, closer examination of results shows that of the 27 survivors in the hemicraniectomy group, only 11 could adequately answer the question. The remaining 16 had to have a surrogate response from their next of kin because they could not adequately answer because of either severe aphasia or neuropsychological deficits. Given that only 7% (or 2 patients) achieved an mRS score of 3, the remaining 25 patients achieved an mRS score of either 4 or 5. Assuming those patients with an mRS score of 3 responded positively, among the remaining 25 patients, 16 patients could not walk without assistance, could not take care of their basic bodily needs and did not have sufficient neurocognitive function such that they could answer a relatively simple question. Given what many informed commentators of sound mind would regard as an unacceptable outcome,18 these findings encourage a reconsideration of the conclusion that survival was increased without an increase in severe disability. One should ask: “Severe disability as assessed by whom?” And once that question is posed, we are likely to want to go beyond paternallistic clinical assessments or scoring systems to embrace a more empowered and informed patient perspective.20

Outcome Prediction
Overall there is no simple answer to the complex question of outcome and the uncertainty that lies between patient resilience or adaptation and patient interests. It may be that before performing a surgical decompression as a perceived life-saving intervention, all efforts must be made to establish that the most likely long-term outcome would be acceptable to that individual based on either their stated or known wishes and their own particular values. A one size fits all approach is likely to disappoint many patients and their next of kin, but the conversation is likely to be important because those who survive reflect on what has eventuated. The difficulty has always been the uncertainty about outcomes, one sided decision-making (eg, in relation to futility), and the lack of accurate outcome prediction, and consideration may need to be given to the development of prediction models similar to those seen in the context of traumatic brain injury and practices of responsive discussion that conduce to good joint decision-making.

The CRASH collaborators’ (corticosteroid randomization after significant head injury) web-based outcome prediction model is an example based on the data obtained from the MRC CRASH study.21,22 (Figure 1) The model provides a percentage-predicted risk of unfavorable outcome at 6 months (defined by the Glasgow Outcome Scale as dead, persistent vegetative state, or severely disabled), and those predictions can be used as a surrogate index of injury severity that can be useful as a means to stratify patients according to injury severity.23,24 Comparing the percentage-predicted risk of an unfavorable outcome with the observed long-term outcome provides an objective assessment of the most likely long-term outcome in patients who require life-saving decompressive surgery (Figure 2). No such models currently exist for stroke patients; however, given the amount of data now available, it would be feasible to develop a similar model based on prognostically important factors, such as age, presenting Glasgow Coma Scale, pupillary function, infarct size and location, and comorbidities.

There are limitations when using this type of data analysis, and it should only be used to support and certainly not replace clinical judgment, but the predicted risk does provide a useful index of injury/disease severity and may provide supportive information to help a clinician and those forced into the decision-making role consider the long-term consequences and realistic outcome expectations as part of the discussion with surrogate decision-makers.
Ethical Considerations

In the emotionally charged atmosphere of an acute stroke, it would be difficult to withhold therapy in a young person if there was at least some chance of survival with an unacceptable level of disability, and the possibility of unacceptable dependency was acknowledged and accepted by those making the decision. Treatment based on such reasoning can be justified even if the eventual outcome seems unacceptable to the injured party because risks and uncertainties are inevitable in all fields of medicine, and we are remarkably resilient and adaptive beings with only quasi-stable life goals and values. In addition, based on certain religious, cultural, or personal values, certain individuals may feel that life is sacrosanct and worth preserving under any circumstances. These individuals may also be willing to run the risk of survival with severe disability in the hope that they may achieve a good functional outcome. They might also want the opportunity to adapt and learn to live with a level of disability that they and many others, perhaps, might previously have thought to be unacceptable. Although these views may fall outside what is deemed acceptable to the majority, they should nonetheless be acknowledged and respected.

However, our responsibilities to a patient who expresses a definite view that they would not want to survive with severe disability (either previously voiced or documented) are quite otherwise. In such a case, an individual surgeon cannot reasonably assume that they have consent for the operation. If they did proceed, they would have to justify acting on their own judgment against a properly considered assessment of the wishes of the patient (there might, for instance, be a complaint that the surgeon proceeded in arrogant disregard for the expressed wishes of the patient).

Before we consign a patient to survival with a severe disability, we have an obligation to establish that this would have been acceptable to them. The larger community also has to determine the value we place on life at any cost. The
considerations here are not only financial but also personal and ethical and require us to exercise careful judgment about our actions. Although there will always be uncertainty when considering prognosis, the development and clinical use of prediction modeling may remove some of the confounding issues and provide an objective assessment on which to base meaningful clinical discussion.

Future Directions
Notwithstanding the unequivocal survival advantage demonstrated by these meta-analyses, there are certain issues that need to be taken into account when considering future avenues of research. The first issue is that of surgical morbidity. Although technically straightforward, there is little doubt that the procedure is associated with significant morbidity. Again, although technically straightforward, there is little doubt that a cranioplasty procedure has significant morbidity. The second issue is that of improving standards in medical management. A recently published trial demonstrated a lower mortality in patients who had been treated with a strict standardized medical management protocol when compared with the medical management arms in the other trials.

If further randomized controlled trials are to be conducted, both of these issues will require consideration to determine which patients can derive maximal benefit from the procedure.

Disclosures
None.

References

Key Words: brain — decompressive craniectomy — ethics — outcome — stroke

Downloaded from http://stroke.ahajournals.org/ by guest on July 14, 2017
Outcome Following Decompressive Hemicraniectomy for Malignant Cerebral Infarction: Ethical Considerations
Stephen Honeybul, Kwok Ming Ho and Grant Gillett

Stroke. 2015;46:2695-2698; originally published online August 4, 2015;
doi: 10.1161/STROKEAHA.115.010078

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/46/9/2695

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Stroke can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Stroke is online at:
http://stroke.ahajournals.org/subscriptions/