Surgery

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a report by

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Traumatic injuries create a significant burden of disease. In addition, lengthened life span has led to a larger number of older osteoporosis patients who are more susceptible to fracture, even with minor falls. The World Health Organization (WHO) estimates that in 1990 there were 1.7 million hip fractures that occurred as a result of osteoporosis. As population longevity continues to increase it is estimated that this number will exceed six million by 2050.1

Traumatic injuries include both low-energy injuries, such as falls, and also high energy injuries, primarily associated with motor vehicle and motorcycle accidents. Traffic injuries cause approximately one million deaths worldwide and result in more than 30 million severe or disabling injuries that are estimated to cost US$500 billion annually.1 During the forthcoming decade, several areas of technological advancements are likely to drive future costs for the care of these patients.

Growth Factors

While most fractures heal, it is estimated that 5% to 10% of fractures are either slow to heal delayed unions or fail to heal non-unions. Certain fractures are particularly problematic, including open, tibia, humerus, and proximal femur fractures. This greatly increases both the healthcare costs and the burden for the patient.

Significant advances have been made in the understanding of fracture healing at a molecular level. Beginning in 1965, with the discovery of bone morphogenetic protein by Marshall Urist, surgeons and scientists have envisioned being able to apply the appropriate growth factor or factors to improve the rate and strength of bone healing. This has led to the commercial availability of two bone morphogenetic proteins.

Bone morphogenetic protein–2 has been approved by the US Food and Drug Administration (FDA) for use in certain spine fusion procedures and for the treatment of open tibial shaft fractures.2 Bone morphogenetic protein–7, also known as osteogenic protein–1 (OP–1), has received a humanitarian device exemption for use in non-unions—fractures that have failed to heal.3 The current market price of these products is approximately US$5,000, which has greatly increased the cost per case.

For use in spinal fusion, the cost of BMP–2 has been ‘carved out’ of the pre-set Medicare diagnostic related group (DRG) payment. This means that the additional cost of the product is passed to the patients’ government insurance, rather than being absorbed by the hospital as an additional expense. Currently, payment for these expensive growth factors by other insurance carriers is negotiated on an individual case basis.

Future trends in growth factor research include percutaneous injection and combination ‘cocktails’ of growth factors.4 Percutaneous administration will decrease the costs per case, since additional operative procedure costs will be eliminated and in-patient hospitalisation reduced or also eliminated. If providers other then orthopedic surgeons become involved in percutaneous administration, their use may potentially increase to include cases in which treatment may not be appropriate or ideal. The

combined use of more than a single growth factor will result in increased costs.

Growth factors are also being studied for roles in repairing damaged cartilage—a substance that, unlike bone, has a limited ability for repair after damage. In addition, growth factors are being investigated as part of on-going tissue regeneration studies in numerous anatomic areas.

**Locking Plate Implants**

Displaced fractures often require surgical management for stabilisation. The three broad categories of fixation options are:

- external fixation;
- intramedullary ‘nails’ or ‘rods’; and
- plate and screw fixation.

Conventional plates rely on adequate screw purchase to maintain fixation and prevent plate loosening prior to adequate fracture healing. While in many circumstances this is adequate, such as in osteoporotic bone, this can prove unsuccessful. In addition, the extensive surgical dissection required for placement of conventional plates may further impair fracture healing.

Locking plate implants have recently been developed.5 These implants ‘couple’ the screw to the plate through a threaded connection, increasing the overall mechanical stability of the fixation construct. This technology is felt to be particularly useful in osteoporotic bone. Additional indications include fractures that occur near a joint or around prior joint replacement prostheses.

Currently, locking plate implants are priced at a premium compared with standard implants. While they are being used with increasing frequency, specific indications for their use remain in evolution.

**Bone Specific Implants**

Designs of orthopedic fixation devices, particularly plates, have increased dramatically in recent years. In part, the entry of additional orthopedic manufacturers into the field of trauma implants has fueled this expansion.

Traditionally, plates were not designed for any specific anatomic region. Rather, the appropriate sized plate was chosen and, if needed, bent to fit the contour of the injured bone. Currently, a wide range of bone-specific plates are available. These plates are pre-contoured to match the usual shape of the bone.

While offering certain benefits, the use of pre-contoured plates greatly increases the inventory requirements for implants. Unfortunately, the frequency of many of these fractures may be low and many of the plates may not ever be used in hospitals with smaller volumes. However, because of the unplanned nature of these injuries, many of which require emergency surgery, urgent availability of the implant is important. Futurists might even envision the ability to manufacture patient-specific implants on-site using computer-aided design (CAD)/computer-aided manufacturing (CAM) technology based on patients’ computed tomography (CT) scan data.

**Minimally Invasive Surgery**

Minimally invasive surgery, also referred to as ‘key-hole’ surgery, has gained popularity by offering smaller incisions, less post-operative pain and shorter hospital stays. In orthopedic surgery, minimally invasive approaches have recently been developed for total joint replacement and selected spinal surgeries.

Orthopedic trauma specialists have been using minimally invasive methods for the past 50 years, namely through intramedullary nailing. Intramedullary nails are inserted through small incisions using intra-operative fluoroscopic imaging. Some hip fractures can also be treated with a closed reduction and insertion of cannulated screws through very limited incisions.

Many hip fractures are treated with a sliding hip screw implant. While many of these are placed through standard incisions, a modified device has also been developed to permit this procedure to be carried out with smaller ‘minimally invasive’ incisions.

Some of the locking implant technology previously discussed has also been designed to allow a minimally invasive surgical approach. In addition, the use of computer-guided surgical instruments has seen limited applications in orthopedic trauma.

**Shock Wave Therapy**

This device is currently approved in the US for use in two inflammatory conditions—elbow epicondylitis and plantar fasciitis.6,7 Shock wave treatment is approved in all European countries, China and Taiwan.

Electrohydraulic shock wave therapy, similar to the treatment used for kidney stones, is also being explored for its use in the management of fracture non-unions.8 When surgery is not required for other reasons, such as

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angular deformity, this methodology may offer an alternative treatment for fractures that have failed to heal. The shock wave device can be transported to hospital for a single case use. It produces high-energy acoustic waves (shock waves). The non-invasive procedure is performed under anesthesia, either general or local, with the acoustic tube placed exactly over the area of treatment, ensuring that the shock wave’s focal point is located at the area of interest.

The mechanism of action is not yet fully understood but basic scientific research has shown that several processes can be initiated by shock wave therapy, including structural changes in the tissue, stimulation of bone growth, stimulation of the regenerative process of the tissue and structural changes in the calcium deposit followed by resorption of the calcium by the body.

**Summary**

Current and future technological advances in fracture healing biology are likely to play a significant role in driving the cost of fracture care. The direct expense of these products will need to be weighed by their potential benefits of improving the speed of healing and decreasing the rate of complications.

Time lost from work remains a significant opportunistic cost following traumatic injury. An earlier return to work and a lower rate of non-unions that require additional surgical treatment may offset the additional costs of this advanced technology.

Similarly, advances in implant technology will initially increase overall costs. While more manufacturers continue to offer competing products it is anticipated that the costs will stabilise or decrease. In addition, further clinical use will better define the indications for more advanced implants.

Other new technology advances, such as non-invasive treatment using shock wave therapy, may offer alternative forms of treatment for certain conditions. Challenges exist for the widespread adoption of these newer methods in the orthopedic community, since surgical treatment remains the accepted standard for many conditions. Owing to the fact that general musculo-skeletal and traumatic injuries produce a large burden of disease, there is likely to be on-going interest in new technology that may find a successful niche in this large market.