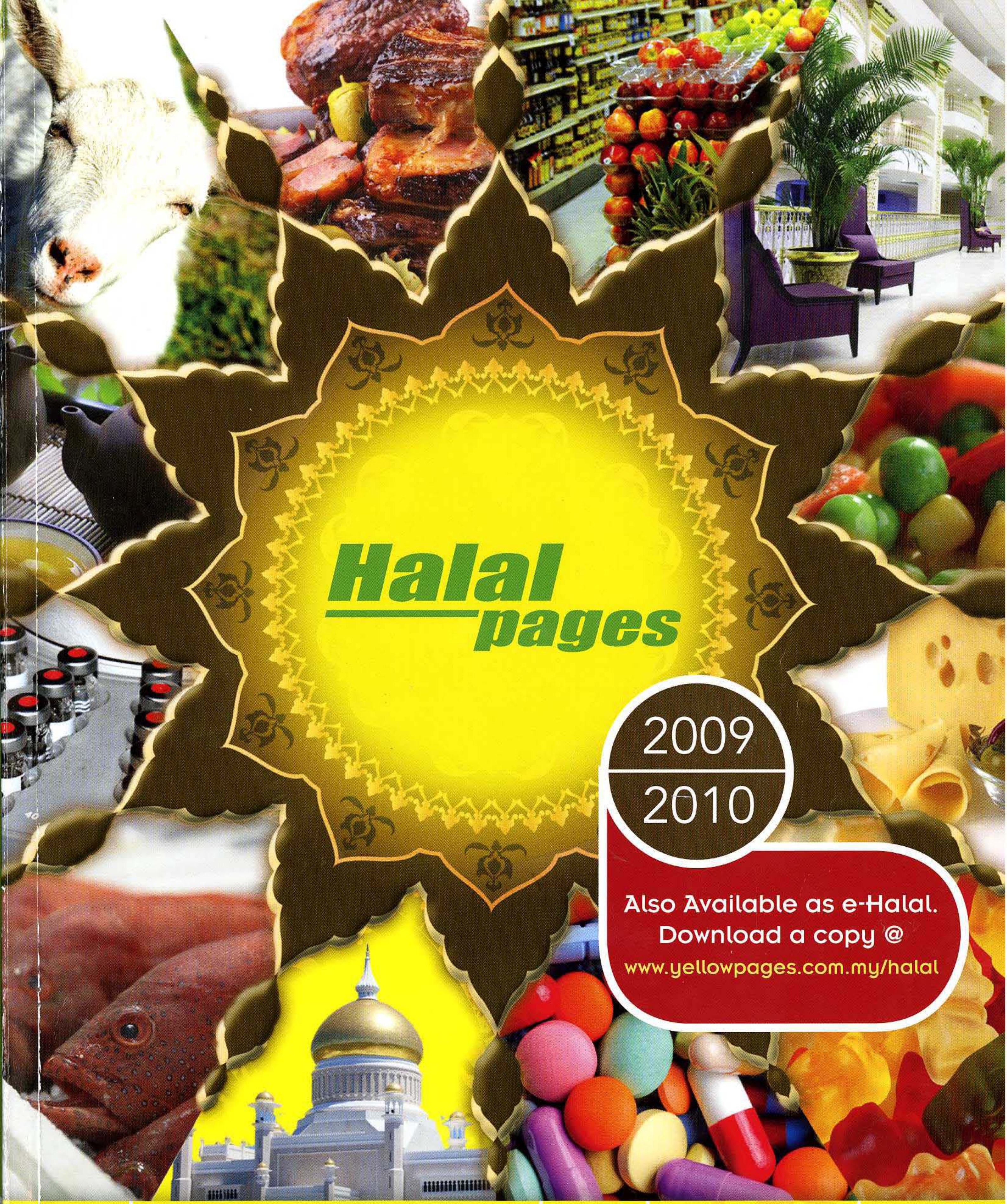

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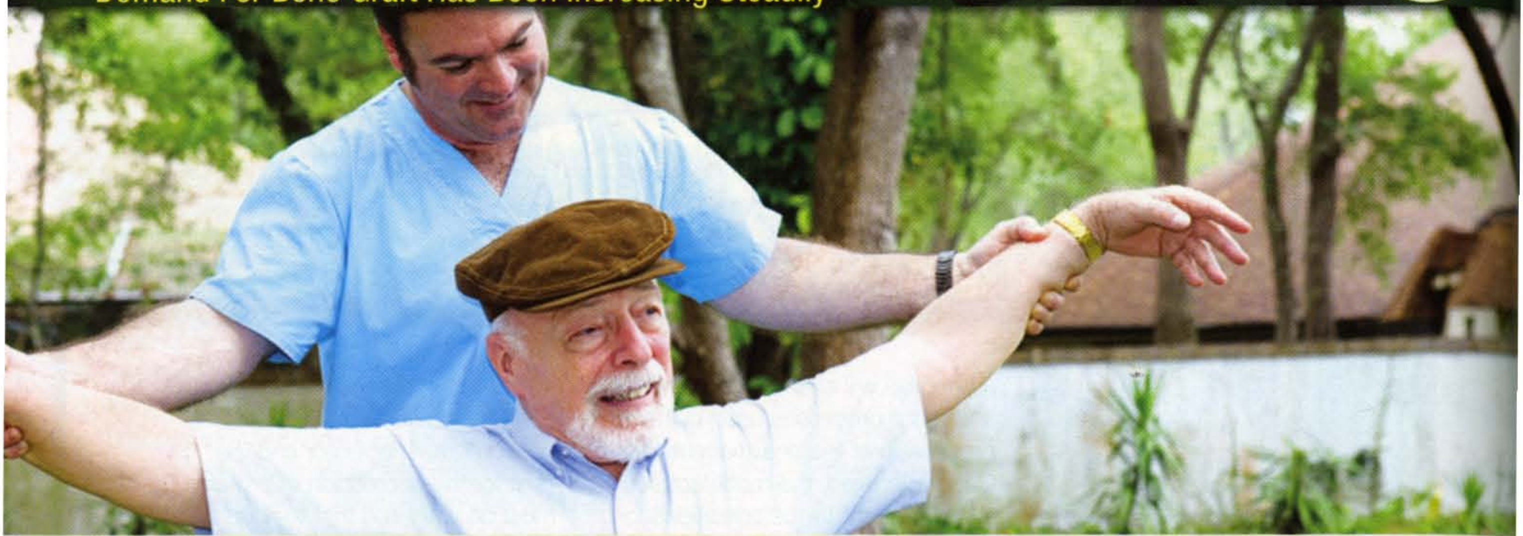
Synthetic Bone As A Solution For Halal Bone Grafts Implantation

Demand For Bone Graft Has Been Increasing Steadily



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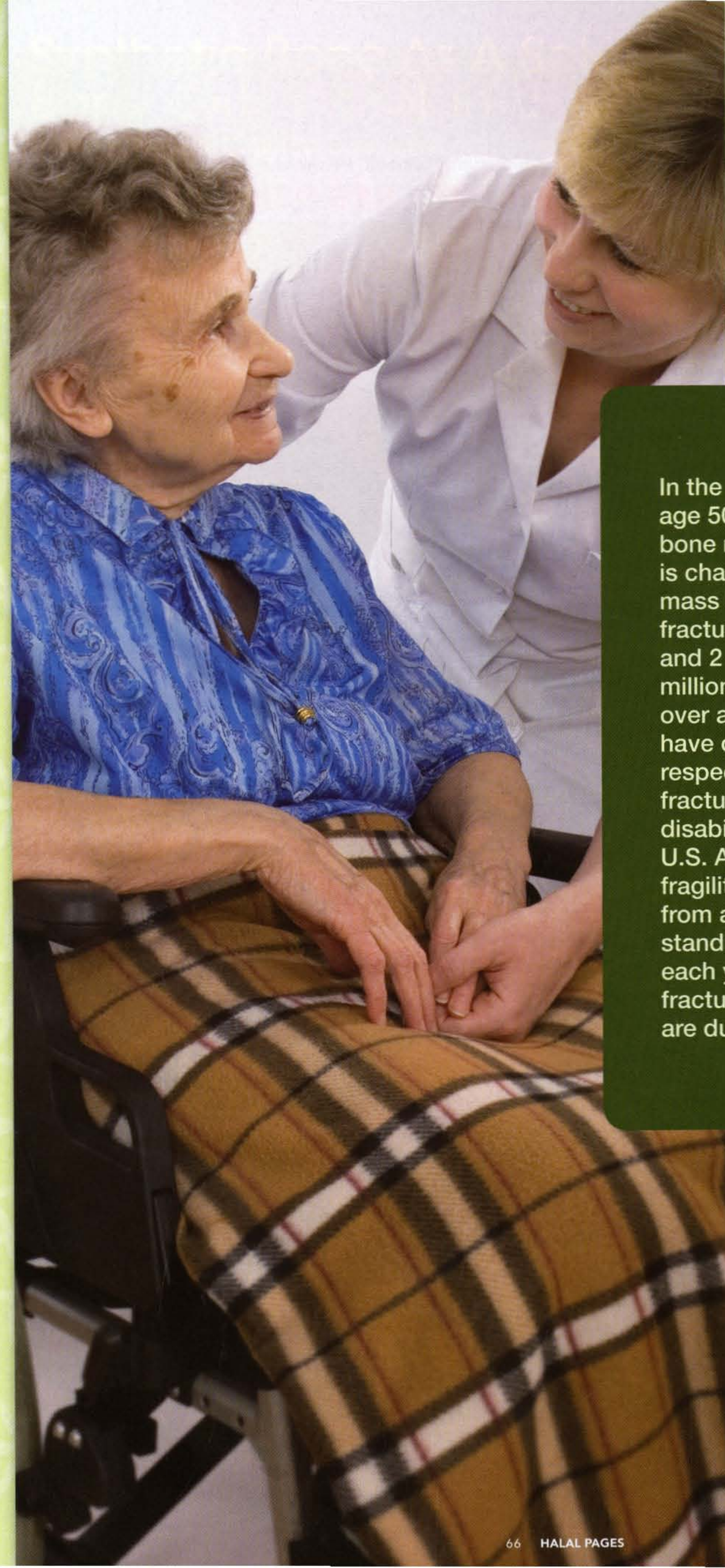
Bone Graft: Introduction

A strategy applied when bone loss occurs for instance due to bone injuries, genetic malformations and several diseases often require implantation of graft. Types of bone grafts derived from living bones are conventionally used for bone implants, in the forms of autografts, i.e. bone grafts taken from the patient's body, allografts, i.e. taken from another human body, or xenografts, i.e. from animal bone. The use of autografted bone substance involves additional surgery causing donor site morbidity, longer in operative time and facing contouring difficulties.

The use of allografted bone substance requires several considerations: pathological clearance to ensure that the bone is free from any disease or harmful bacteria or viruses, the method is legal, allografting is an acceptable culture in the society, etc. Regarding the use of xenografts, pig bones are the most similar to human bones among pigs, mice and rats. Therefore, pig bone is usually used as a model for studying the molecular genetics of bone-related disorder or even for xenografting. Moreover, with regard to macro- and microstructure, composition and suitability for remodeling, again pig bone is the most similar to human bone among porcine, canine, sheep, goat and rabbit.

Bone Graft Demand

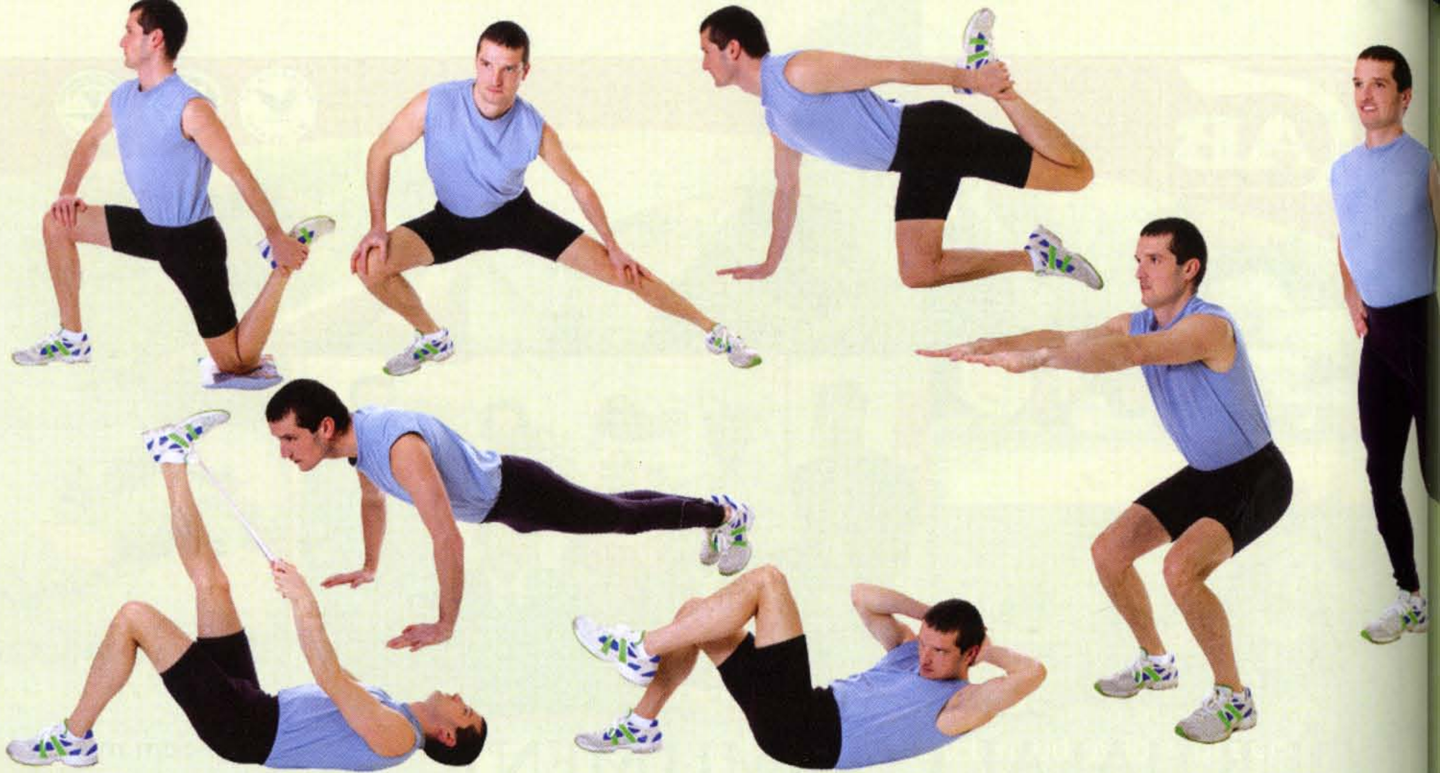
The demand for bone graft has been increasing steadily in recent years particularly in orthopedics, dental, maxilla-facial, neurosurgery



and osteoporosis. For these reasons, there is a growing need for fabrication of artificial hard tissue replacement implants. The biomaterials industry worldwide, in 1998, has an annual turnover of US$2.3 billion in the field of hard tissue repair and replacement (of a total of US$12 billion industry). There is currently a projected growth rate of 7–12% per annum for biomaterials in clinical applications.

In the U.S., 50% of women over age 50 have osteopenia, or low bone mass. Osteoporosis, which is characterized by loss of bone mass leading to increased risk of fracture, affects 8 million women and 2 million men. By 2010, 9 million and 26 million women over age 50 are expected to have osteoporosis or osteopenia, respectively. Osteoporosis-related fractures are a main cause of disability and mortality in the U.S. Approximately 1.5 million fragility fractures, which result from a fall from no greater than standing height, occur in the U.S. each year; approximately 90% of fractures that occur in the elderly are due to osteoporosis.

One in two women and one in four men over 55 will have an osteoporosis-related fracture in the remainder of their lifetime. A women's risk of hip fracture is equal to her combined risk of breast, uterine, and ovarian cancer. One half of women who sustain a hip fracture fail to return to their pre-fracture function level. Independent of bone mineral density (BMD), previous fracture is the most important risk factor for future fractures. Osteoporosis is more common in



Caucasian, Asian, and Hispanic women than in African American women. Hip fracture risk is increasing most rapidly among Hispanic women. Caucasian women 65 years or older have twice the incidence of fractures as African American women.

In Europe in 2000, the number of osteoporotic fractures was estimated at 3.79 million, of which 0.89 million were hip fractures (179,000 hip fractures in men and 711,000 in women). The total direct costs were estimated at €31.7 billion (£21.165 billion), which were expected to increase to €76.7 billion (£51.1 billion) in 2050 based on the expected changes in the demography of Europe. Whereas, The Asian Osteoporosis Study (AOS) is the first multicenter study to document and compare the incidence of hip fracture in four Asian countries.

Hospital discharge data for the year 1997 were obtained for the Hong Kong SAR, Singapore, Malaysia and Thailand (Chiang Mai). The number of patients who were 50 years of age and older and who were discharged with a diagnosis of hip fracture (ICD9 820) was enumerated. The age-specific incidence rates were deduced and were directly adjusted to the US white population in 1989. The age-adjusted rates for men and women (per 100000) are as follows: Hong Kong, 180 and 459; Singapore, 164 and 442; Malaysia, 88 and 218; Thailand, 114 and 289; compared with US white rates of 187 in men and 535 in women, published in 1989. The rates were highest in urbanized countries. With rapid economic development in Asia, hip fracture will prove to be a major public health challenge.

Maxillary fractures often result from high-energy blunt force injury to the facial skeleton. Typical mechanisms of trauma include motor vehicle accidents, altercations, and falls. With increased legislation requiring seat belt use, injuries from driver impact with the steering wheel have shifted from chest trauma to facial trauma. In the cosmetic field, facial ageing is regarded as the gravity assisted downward migration of the soft tissues of the face. Nowadays it is believed that this is not the only reason. Bones of the face also change, which causes flattening of the cheek bones exacerbating this downward movement of the soft tissues.

Bone Graft Materials

Metals have been widely used for major load bearing orthopedic applications. There are, however, various problems related to metallic materials in the human body due to corrosion, wear, and/or negative tissue reaction. Almost all metallic implants are encapsulated by dense fibrous tissue, which prevents proper distribution of stresses and may cause loosening of the implant.

If the material is toxic, the surrounding tissue dies; if the material is non toxic and biologically inactive (bioinert), a fibrous tissue of variable thickness forms; if the material is non toxic and biologically active (bioactive), an interfacial bond forms. High biocompatibility property of the material is also necessary. Generally speaking, biocompatibility denotes acceptance of the implant to the tissue surface. This broad term includes also non-toxic, non- carcinogenic, chemical inertness, and stability of the material in the living body.

In the preceding paragraphs pig bone has been identified to be the most similar to human bone. Although this may be generally good news to customers/patients that require bone-graft implantation to treat and replace bone-related disorder, pig-based xenografts will raise issues among Muslim customers/patients since these implants may deem haram or doubtful for Muslims. A substitute bone-graft implantation acceptable and halal for Muslims is needed. Fortunately, there is a synthetic bone with the highest bioactivity and biocompatibility, and resembles the human bone. This synthetic bone is based on calcium-phosphate ceramic material called hydroxyapatite (HA). This synthetic bone resembles the human bone because the human body consists of 60~70% HA. The HA phase can be developed from lower grades of many calcium-phosphate based materials. For instance, a di-, tri-, and tetra-calcium phosphate can be mixed to be transformed into HA, even in vivo test implantation.

For convenience, a synthetic body fluid, which resembles the composition of the human blood plasma, is deployed to study the material reaction under the fluid system. Metastable synthetic body fluid has been proven to facilitate the spontaneous generation and growth of bone like calcium apatite. The presence of this layer formed by a biomimetic process was proven to promote in vitro cell differentiation and induce osteogenic cell differentiation and subsequent bone matrix apposition, which allows a strong bond to the bone.

HA has been widely applied as bone substitutes. Research and development work at the International Islamic University Malaysia based on HA for the development of artificial bone grafts are progressing well. Together with β-tricalcium phosphate, the other type of calcium-phosphate derivatives, they have been, for nearly three decades, the most extensively used substitution materials for artificial bone grafts. This bioceramic family can be introduced in various forms including cement, powder or granule, dense, or porous.

Results from the application field has been very promising, for instance, in craniofacial reconstruction there was no infection observed except at unclean areas and it is a technical problem rather than the implant material, and the infection problems were successfully treated with a systemic antibiotic and/or hyperbaric oxygen therapy. Results on histological analysis of osteoconduction in vivo of porous HA showed that within six weeks after implantation mature bone ingrowth was observed in the entire parts of the porous HA, followed by an increase in compressive strength of the porous. Bone tissue regeneration can also be conducted using carrier-scaffold system using biologically active bone morphogenetic protein as the carrier.

Concluding Remarks

The encouraging and promising developments of synthetic bone will cater for the needs of patients/customers who have ethical and/or religious reasons to refuse animal body parts to be in their body!