



Safer surgery with biodegradable implants

Demonstration **BMH4-CT98-3892**

A remarkable deformity: the face of this six-month-old girl was repaired by cutting and repositioning the bone in the centre of the face. Bone fragments were fixed using bioabsorbable plates and screws made from polyglycolic acid (PLGA)

Craniofacial syndromes are rare but disfiguring or incapacitating conditions caused by malformation of the skull and jaw bones. Although virtually untreatable less than 30 years ago, they can now be corrected by surgery involving the implantation of plates, wires and fixing screws. But the metallic implants generally employed to date have to be removed later on – and they can sometimes migrate to the interior of the skull, possibly causing brain damage. In Biocranio, a demonstration project funded under the EU's BIOMED programme, a Finnish SME worked together with the University of Oulu and craniofacial centres in several countries to evaluate the use of biodegradable polymer implants. These implants, which reduce the need for invasive surgery, cut costs and minimise the risk to patients, have since sold round the world.



Although it appears to be one large bone – nature's own crash helmet to protect our brain – the skull is actually made of several bony plates connected together at joints known as 'sutures'. To allow for the normal growth of the brain and skull in early life, the sutures of an infant's skull are not joined at birth. The individual plates can thus expand to accommodate the increasing brain volume. New bone is added at the sutures, until growth stops and adjacent cranial bones fuse together. If this fusion occurs prematurely, skull growth is restricted and the head assumes an abnormal shape. Repairing such anomalies involves surgery to correct the bones and fix them in place. The ideal time to perform these interventions is in the first year of life. Later, problems can arise in the face, where a lack of forward growth may give rise to dental and jaw disorders, as well as to breathing problems.

Natural materials, cheaper treatment

At present, surgically corrected cranial bones are fixed in their new positions by means of metal plates, screws and wire. These inhibit skull growth, and can interfere with X-rays, computerised tomography (CT) scans or magnetic resonance imaging (MRI). Moreover, it often requires a further operation to remove them. And alarmingly, the currently available metal fixing devices have been found to migrate to the inside of the skull, presenting a risk of brain damage.

Implants made from biodegradable materials that are eventually absorbed by the body are already proven to work in fields such as the treatment of sports injuries. The polymers from which these are made derive from naturally existing molecules that the body itself produces and in turn degrades or consumes through hydrolysis and the action of enzymes. Hydrolysis occurs when water breaks down the molecular chains of the polymer which are subsequently metabolised in the cells into basic components such as water and carbon dioxide, which are then expelled naturally from the body. By eliminating the need for a second operation for implant removal, this can typically reduce the cost of treatment by around a quarter. However, before such devices could be adopted for the treatment of very young children – particularly in the critical area of the brain – extensive study and testing needed to be undertaken.

Objectives exceeded through co-operation

Craniofacial syndromes are rare – they occur in fewer than 16 children per million. Given this limited number of subjects, information from different centres had to be pooled to achieve the critical mass needed to work on improved techniques. Co-operation at a European level was also essential because no single country has experts in all of the fields involved.

The 45-month Biocranio project therefore assembled a consortium co-ordinated by the University of Oulu, and including the Finnish manufacturing SME Bionx Implants, together with universities and hospitals from Austria, France, Sweden and the



This acrylic model of the skull was made using a three-dimensional CT scan and used to plan how corrective surgery would be carried out



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United Kingdom. It was able to benefit from long-standing European expertise in developing biodegradable materials for surgical use – and in particular from some of Bionx's patents on ways of making bioabsorbable materials much stronger. The initial objectives of Biocranio were to develop and produce new prototype plates, wires and 2 mm-diameter mini-screws – which would then be laboratory tested, and finally applied in a multi-centre clinical trial. In fact, the initiative achieved all of these goals, and more. It was able to make an even greater contribution to the advancement of science in the treatment of craniofacial syndromes, and to introduce further innovations that were not foreseen in the original proposal.

Additional devices resulting from the project included a 1.5 mm fixation system, plus biodegradable tacks that can be inserted into holes drilled in the bone using a special tack-shooter, without requiring tapping and tightening as is the case with screws. These are not only faster and cheaper to use, but also diminish risks to the patient. Important progress was also made in validating the use of new biodegradable implants used to lengthen bones (a process known as osteodistraction).

State-of-the-art materials

The main material employed for implant manufacture is a self-reinforced polylactide (SR-PLA). Drawing this polymer through a die at a controlled temperature causes its molecules to line up, which improves its mechanical properties, stopping it breaking during implantation and maintaining strength throughout the healing process. In a bid to minimise the chance of infectious complications, which can arise with more traditional surgery, the consortium also evaluated screws that release antibiotics as they are absorbed. Unfortunately, the formulations tested to date turned out to be weaker mechanically than standard SR-PLA, but the researchers hope to solve this problem in a future project.

This demonstration project proved the technical viability and economic advantages of the technology in a totally new application area. It has contributed to improved health care in Europe, and strengthened the competitiveness of the European health industry. And it has been a success in business terms too. The resultant devices have been marketed world-wide since the end of year 2000 and, by mid-2002, more than 8,000 implants (plates and screws) had been sold, with a value approaching €300,000.

Full Title:

Treatment of craniofacial syndromes with biodegradable plates, screws and wire

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NACE 85 Health and social work

Supporting Technologies:

0382 Medical Technology;
0498 Polymer technology,
Biopolymers

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5/98 – 1/02

References:

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BIOMED 2

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€797,000

