BMJ

LONDON, SATURDAY 10 OCTOBER 1992

Helmets for pedal cyclists

They reduce the numbers of head injuries

Debate about the benefits of helmets for pedal cyclists continues,[1-7] and the main arguments are summarised on pages 881-3.[8 9] Helmets are advocated by the Department of Transport,[10] the Parliamentary Advisory Council for Transport Safety, many health promotion and accident prevention agencies, and substantial numbers of health professionals.[11 12] With the exception of organisations representing racing cyclists, British cycling organisations remain neutral or unenthusiastic about helmets.[13 14] Some cyclists object to wearing helmets on the grounds that it infringes personal freedom; others believe that as motorists cause most of the accidents involving cyclists it is they who should be penalised not cyclists.

Although some consensus has been achieved on the best ways to approach cycle safety, progress towards this goal has been slow. Most interested parties agree on the need for improved road engineering methods; traffic calming devices; more cycling facilities, especially those that separate cyclists from other vehicles; and better education of all road users, particularly motorists, about cyclists' special needs.[5 10 13 15]

Disagreement still exists about the degree to which more widespread wearing of helmets would improve cycle safety. Parts of the cycling lobby point out that helmets fail to protect all the head, do not fully protect the head in direct impact crashes at high speed and, most of all, do not prevent accidents from occurring.[13]

Some people have suggested that evidence reporting a lower risk of head injuries in cyclists wearing helmets[16] is flawed because such cyclists may be more cautious.[9 17] Formidable problems exist in trying to resolve this issue: studies would have to compare the outcomes for cyclists with and without helmets who had previously been matched for "risk taking behaviour."

Meanwhile, research already completed goes some way to answering basic questions asked about helmets. Could they give any protection in cycling accidents that involve another vehicle, such as a car or a lorry, in which an unhelmeted rider would be expected to die from a head injury? The answer would seem to be no: according to the foreword to the British Standard specification for pedal cycle helmets,[18] they are not designed to cope with an accident involving another vehicle. A recent report on the protective capabilities of bicycle helmets also conceded their failure to protect the head in a direct impact at high speed.[6] Nevertheless, American reports have suggested that up to 70% of fatal crashes involving head injury are potentially survivable.[7 19]

In less serious accidents does wearing a helmet give greater protection from head injury than wearing no helmet at all? Here reports are more optimistic, most providing evidence of the benefits of wearing a helmet.[2 5 6 8 16]

The pro-helmet lobby has therefore concentrated its efforts on flagging up the growing body of evidence that helmets reduce the chances of death and serious head injury in accidents. It has emphasised helmets' potential for minimising the number of head injuries in children, though the potential fallibility of helmets in certain types of accident is sometimes passed over. As at least half of all accidents to younger children do not involve another vehicle,[5] helmets' decreased effectiveness in high speed impacts is compensated for by the protection they afford in the more common solo accidents experienced by children, many of which involve the head. Given the slow progress towards improving cycling facilities, pro-helmeteers have been promoting good quality cheap helmets as a secondary safety measure. If more riders wore helmets the costs of cycling accidents would fall, though by less than would follow large scale engineering changes.[20]

Meanwhile, helmets have improved in design and availability. The British Standard specification for cycle helmets, BS 6863, which has undergone minor revisions,[18 21] will be superseded by a European Standard next year. Approved helmets are likely to offer better protection because they will be tested from rigs with higher drops.

Cycle helmets, once scarce, may now be found in most cycle shops and many large chain stores. Sales have risen dramatically since many authorities introduced low cost programmes. In Sheffield's scheme the local authority's road safety unit buys helmets in bulk and sells them at prices well below those found in normal retail outlets. Many other local authorities have followed suit, as have voluntary agencies and schools. The Scottish Road Safety Campaign will supply low cost cycle helmets to any child in Scotland and will also respond to requests from anyone in the rest of Britain.[11]

Supplying helmets is the first step in any campaign; persuading people to wear them is the next. Here the media can help. As well as television programmes other successful initiatives have included competitions featuring cycle safety or offering helmets as prizes.

Much progress has been made, both in the wider provision of good quality helmets and in the greater commitment by voluntary and statutory agencies to promoting helmet wearing. Britain, however, still has a long way to go to reach the rates of helmet wearing in some parts of the United States and

Australia. After legislation, rates of helmet wearing by children have risen to 47% in parts of Maryland, United States, and 80% in Victoria, Australia.[22]

What can doctors do in Britain to encourage more children to wear helmets? District health authorities can work with local authorities to establish coordinated strategies to reduce cycling accidents. School cycle safety programmes and low cost helmet schemes have already been established in many parts of the country. Health authorities have cooperated successfully with road safety units, education authorities, schools, and voluntary and commercial organisations to get these schemes going. Doctors should encourage these initiatives, particularly low cost helmet schemes. Helmets bought in bulk cost less than £20 each, surely cheap at the price.

HELEN R TRIPPE

Senior Registrar in Public Health Medicine,
Department of Public Health Medicine,
Southampton SO9 4WQ

1 When are cyclists going to wear helmets? [Editorial.] *Lancet* 1988;i:159-60.
2 Kraus JF, Fife D, Conroy C. Incidence, severity and outcomes of brain injuries involving bicycles. *Am J Public Health* 1987;**77**:76-8.
3 Bull JP. Cyclists need helmets. *BMJ* 1988;**296**:1144.
4 Wood T, Milne P. Head injuries to pedal cyclists and the promotion of helmet use in Victoria, Australia. *Accid Anal Prev* 1988;**20**:177-85.
5 Mills PJ. *Pedal cycle accidents, a hospital-based study*. Crowthorne: Transport and Road Research Laboratory, 1989. Research report 220.
6 Mills NJ. Protective capabilities of bicycles helmets. *Br J Sports Med* 1990;**24**:55-60.
7 Sacks JJ, Homgreen P, Smith S, Sosin DM. Bicycle-associated head injuries and deaths in the United States from 1984 through 1988. How many are preventable? *JAMA* 1991;**266**: 3016-8.
8 Illingworth C. Do cycle helmets prevent serious head injury? The argument for helmets. *BMJ* 1992;**305**:882-3.
9 McCarthy M. Do cycle helmets prevent serious head injury? Cycling without helmets. *BMJ* 1992;**305**:881-2.
10 Department of Transport. *Children and roads, a safer way*. London: DoT, 1990.
11 Child Accident Prevention Trust. *Low cost cycle helmet schemes*. London: CAPT, 1992.
12 Bouvier R. Bicycle accidents in childhood: social and preventive aspects. *Aust Fam Physician* 1984;**13**:287-9.
13 Cyclists Touring Club. *The cycle helmet and real road safety. Information sheet*. CTC, 1991.
14 Cyclists Touring Club. *Cycle Digest* 1991; Spring.
15 Hillman M. *Cycling and health: a policy context. Papers from a conference entitled "cycling and the healthy city."* London: Friends of the Earth, 1990.
16 Thompson RS, Rivara FP, Thompson DC. A case-control study of the effectiveness of bicycle safety helmets. *N Engl J Med* 1989;**320**:1361-7.
17 Godlee F. Transport: a public health issue. *BMJ* 1992;**304**:48-50.
18 British Standards Institution. *BS 6863: 1989*. London: BSI, 1989.
19 Fife D, Davis J, Tate L, Wells JK, Mohan D, Williams A. Fatal injuries to bicyclists: the experience in Dade County, Florida. *J Trauma* 1983;**28**:745-55.
20 Department of Transport. *Road accident costs 1990*. London: DoT, 1991. (Highway economics notes No 1.)
21 British Standards Institution. *Amendment No 1 to BS 6863: 1989*. London: BSI, 1991. (AMD 6954.)
22 Coté T, Sacks JJ, Lambert-Huber DA, Dannenberg AL, Kresnow M, Lipsitz CM, *et al*. Bicycle helmet use among Maryland children: effects of legislation and education. *Pediatrics* 1992;**89**:1216-20.

Transferring myoblasts in Duchenne dystrophy

Clinical results are disappointing

After the isolation of the Duchenne gene and the characterisation of its protein, dystrophin,[1,2] there was a wave of understandable enthusiasm that this would open the way for treatment. Such optimism underestimated the technical hurdles to be overcome.

Given the large size of dystrophin (over 400 kD) and its intimate connection with the muscle membrane, replacing the deficient protein or finding some biochemical means of compensating for its (not fully understood) function seemed unlikely. The alternative approach of gene therapy also posed major hurdles—handling a gene with over 2 million base pairs was way beyond the capacity of vectors such as retroviruses. There was the additional problem of how to target the gene or its product to the widely distributed musculature.

Somatic cell therapy seemed to offer a possible shortcut for delivering the normal gene or its product direct to the muscle. It entailed transplanting normal muscle cells directly into the diseased muscle with the aim of fusing donor to host myoblasts. (These are normally quiescent in muscle until activated to proliferate, divide, and fuse.) This would then produce a mixture of dystrophin positive and dystrophin negative fibres, comparable to the heterozygote female carrier of the Duchenne gene.

The discovery of several animal models of Duchenne dystrophy boosted this research.[3,4] With the impetus and financial support of the Muscular Dystrophy Association of America several North American units opted for direct experimental studies in humans to assess the benefits of transferring myoblasts.[5] In the most comprehensive study to date Karpati and colleagues in Montreal recruited into a double blind study eight young boys with Duchenne dystrophy, all of whom had a deletion in the gene and no dystrophin in their muscles. Ten million cultured myoblasts from the father's muscle were injected into multiple sites in one biceps and a control injection was made into the other biceps. Immunosuppression was provided with cyclophosphamide. The power of the muscle was assessed by sequential myometry and the dystrophin status of the muscle by repeat biopsy. All patients have now been followed up for a year, and Karpati presented the preliminary data at a recent workshop.[6] No significant differences were found between the two sides either clinically or in the presence of dystrophin.

In an uncontrolled study Tremblay's group injected myoblasts into several different muscles in four non-ambulant patients with advanced Duchenne dystrophy.[7] Meticulous attention was paid to histocompatibility of the donor and recipient for HLA classes I and II-DR; no immunosuppression was used. In one case the donor was a brother; in the other three cases the donors were sisters, including one Duchenne carrier. Three of the four patients developed antibodies against the donor's myotubes. Muscle biopsies of the injected tibialis anterior showed some degree of dystrophin immunostaining in three cases and in the contralateral uninjected muscle in only one case.

Law and colleagues injected 8 m cultured myoblasts obtained from a 1 g biopsy from the patient's father or brother into the extensor digitorum brevis muscle of three boys with Duchenne dystrophy.[8] A comparable volume of carrier fluid was sham injected into the other side; in two of the patients this was double blinded. After three months twitch tension increased in the myoblast injected side and decreased in the sham injected side; open biopsy showed dystrophin only on the side injected with myoblasts.

Fired by the success of this limited series, Law established a Cell Therapy Research Foundation and proceeded to his phase 2 therapeutic trials of myoblast transfer into several major muscles in Duchenne dystrophy. This group recently reported the results of a three month follow up on 18 of their 21 cases, which included their three original patients.[9] Five billion cultured, normal myoblasts were transferred by 48 intramuscular injections into 22 major muscles of both lower limbs. Immunosuppression was provided by cyclosporin. Dynamometric measurements of the isometric tension in the knee flexors, knee extensors, and plantar flexors before and