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「より安全で良質な同種骨を供給するための社会基盤整備」
分担研究報告書

ボーンバンクネットワーク構築における拠点バンクの役割

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＜研究要旨＞
1953年に本邦初の骨バンクが天児により設立された。しかしその後、本邦における骨バンクが発展しているとは言い難い状況である。2010年7月の改正臓器移植法施行後、各組織移植分野にて提供数が増加する中、骨提供に至っている例はまだ出てきていない。原因のひとつに骨摘出チームが全国的に展開されていないことがある。日本組織移植学会のレジストレーション結果と、同学会認定組織バンクである北里大学骨バンク、東海骨バンクの実績をもとに、ボーンバンクネットワーク構築における今後の役割を検討した。

A．研究目的

本邦初の骨バンクは1953年に天児によって設立された。しかしその後、残念ながら欧米と異なり本邦における骨バンクが発展しているとは言い難い。

日本組織移植学会認定組織バンクである北里大学骨バンク、東海骨バンクの活動状況を中心に、同種骨移植と他組織移植分野を比較、検討し、今後のボーンバンクネットワーク構築に向けての方向性を考察した。

B．研究方法

日本組織移植学会のレジストレーション結果と、北里、東海両骨バンクの摘出・供給状況を調査し、今後の活動の可能性を検討した。

C．研究結果

北里大学骨バンクと東海骨バンクより1997年から2010年までに、全国28都道府県、64施設に2928回骨組織を供給している。

日本臓器移植ネットワークの調査によると、改正臓器移植法施行前1年（2009年6月~2010年6月）と試行後1年（2010年7月~2011年7月）までの臓器移植提供数は5件から66件と大幅に増加している。

脳死臓器提供事例における組織提供数については、2009年は臓器提供7件のうち組織提供数が7件（うち骨提供1件）、7月より改正臓器移植法が施行された2010年は臓器提供32件のうち組織提供数が16件、2011年は7月までの約半年で、臓器提供28件と増加したことにともない組織提供数も12件に増加している。

2010年7月の改正臓器移植法施行後、骨以外の各組織移植分野においては着実に提供数が増加しているが、骨移植においては提供がない状況である。その理由には、骨摘出チームが全国的に編成されていないことが考えられる。

日本臓器移植ネットワークの調査によると、脳死後に臓器提供をしてもよいと回答している人は2006年41.6％であったが、2008年43.5％に増加し、提供したくないと回答している人は2006年の27.5％から24.5％に減少している。臓器提供者が増加するということは、骨を含めた組織提供者が全国各地に増えることを意味している。

前述のとおり、すでに骨組織は全国各地に供給されており、また全国で発生する可能性のある骨提供者の意思を尊重するためにも、全国に骨摘出チームを編成すべきである。

D．考察

骨摘出チームの全国展開に向けては、日本組織移植学会にて、従来の組織バンク認定制度に新たな枠組みとして、学会ガイドラインに準拠し組織移植も行うが、同種骨の保存・管理、シッピングを行わず、認定コーディネーター不在でも活動できる「プロキュアメン

トセンター」を設立、認定する動きが出てきている。これは、従来バンクに比べ設立を容易にし、かつ学会ガイドラインを準拠することにより、無認定バンクを増加させるよりは質的コントロールをしやすくすることを目的としている。この新規枠組みのバンクを全国展開させることができれば、関東と東海エリアの一部でしか非生体骨の採取を行っていないという理由で認められていない同種骨の摘出・処理・保存にかかる費用の保険収載が、皮膚・角膜など他組織移植分野と同様、認められる可能性が高くなる。また、整形外科医のコンセンサスを得、非生体ドナーからの正しい同種骨摘出方法を広めていくことと、プロキュアメントセンター設立とその認定を目的として、現認定バンク2施設を中心とし講演会を開催することを検討している。

矢野経済研究所の調べでは人工股関節置換術、人工骨頭置換術は年間40,000例になるといわれており、また日本整形外科学会インプラント委員会の調査ではその10%が再置換術である。その多くはプレート状の同種皮質骨を必要とし、骨移植なくして再建不可能な症例である。日本整形外科学会移植・再生医療委員会の調査では、非生体ドナーからの同種骨組織を利用したことがある施設は、2000-2004年は7.7%であったが、2005-2009年では11.6%と増加してきている。人口高齢化により、今後同種骨を必要とする症例はさらに増加すると考えられる。

E．結論

日本における組織提供者数は年々増加してきており、認定組織バンクより供給される組織数も増加している状況である。同種骨移植分野は、他組織移植分野に比べ、全国展開されておらず、保険収載もされていないなど遅れを取っている状況であり、今後増加するであろう同種骨移植を必須とする症例に対応するためには、全国で発生するドナーに対応し、同種骨が全国に供給できる体制を整備しなくてはならない。適正かつ公平に同種骨を採取、処理、保存、シッピングするシステムを整えていく必要があると考える。

F．健康危険情報

特になし

G．研究発表

特になし

H．知的財産権の出願・登録状況

特になし。

Ⅲ．　研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Gie GA et al	Impacted cancellous allografts and cement for revision total hip arthroplasty.	J Bone joint Surg	75-B	14-21	1993
Sloof TJJH et al	Acetabular and femoral reconstruction with impacted graft and cement.	Clin Orthop	324	108-115	1996
坂野真士、長谷川幸治	骨バンクー生体ドナーからの骨頭採取・保存・供給"Bone Bank Network".	別冊整形外科	47	59-65	2005
	整形外科移植に関するガイドライン、冷凍ボーンバンクマニュアル、処理骨作成マニュアル（脱脂・凍結乾燥）	日整会誌	73	43-70	1999
	切除大腿骨頭ボーンバンクマニュアル（生体ドナー）	日整会誌	74	52-55	2000
	Bone Bank Network 規約	Bone Bank Network Living Donor からの同種骨移植	Version2	1-3	2002
長谷川幸治ら	骨バンクネットワークの運営と問題点	日本人工関節学会誌	37	184-185	2007
松岡篤史ら	バーコードシステムによる同種骨管理	日本人工関節学会誌	40	532-533	2010
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Galea G et al	Supply and demand of bone allograft for revision hip surgery in Scotland.	J Bone Joint Surg	80-B	595-599	1998
坂野真士ら	同種骨移植のためのBone Bank Network.	日本人工関節学会誌	31	303-304	2001

Ⅳ．　研究成果の刊行物・別刷

IMPACTED CANCELLOUS ALLOGRAFTS AND CEMENT FOR REVISION TOTAL HIP ARTHROPLASTY

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We report the results of using impacted cancellous allografts and cement for fixation of the femoral component when revision arthroplasty is required in the face of lost bone stock. In 56 hips reviewed after 18 to 49 months there were few complications and a majority of satisfactory results with evidence of incorporation of the graft. Further study and review are necessary, but the use of the method appears to be justified.

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Much early and some recent experience of using cement to fix the femoral component in revision arthroplasties has given little grounds for optimism concerning longer-term results (Hunter et al 1979; Amstutz et al 1982; Kavanagh, Ilstrup and Fitzgerald 1985; Pellici et al 1985; Strömberg, Herberts and Ahnfelt 1988), but other authors have reported better outcomes (Schüller, Marti and Besselaar 1988), especially when using modern cementing techniques (Rubash and Harris 1988). Young patients (Strömberg et al 1988) and those with poor bone stock present especially difficult problems. Kershaw et al (1991) and Atkins (personal communication, 1992) reported that cemented revision into poor bone stock was associated with a failure rate six times higher than revision into normal or reduced bone stock. Repeated revision surgery using cement has an especially poor outcome (Retpen et al 1992).

Hungerford and Jones (1988) advised against the use of cement in *any* revisions, and Wilson (1987) suggested that femoral loosening with defective bone stock was an indication for the use of cementless revision techniques. There is little evidence, as yet, however, that 'biological fixation' by ingrowth into porous-coated, uncemented devices is likely to be any more successful in the long term (Lord et al 1988; Cook et al 1991; Galante, personal communication, 1991). The loss of bone stock secondary to the adverse effects of particulate debris and to mechanical instability of the implant is the major challenge in revision surgery.

We have already reported the preliminary results of our technique of using impacted cancellous allograft and cement (Simon et al 1991). Follow-up remains relatively short, but we are encouraged to report the method in more detail because there has been no deterioration in those cases with the longest follow-up, including three patients in whom it has exceeded five years. The method appears to yield results that are significantly different from conventionally cemented revisions.

It is based on the application to the femur of the techniques described by McCollum (1978, 1980) and Gates et al (1990) for primary protrusio acetabuli, and subsequently modified by Slooff et al (1984) for use in revision surgery in the acetabulum. The technique developed from experience with one patient in 1985. Serious loss of bone stock at a femoral revision was treated by packing the canal with allograft bone chips before inserting an Exeter long-stemmed femoral component *without* cement. Although the component migrated distally with time, the patient's symptoms were relieved and there was some reformation of diaphyseal bone. In the light of Slooff's experience in the acetabulum, it was thought that adding cement might improve the results of revision using allograft chips in the femur.

METHODS

Operative technique. The loose prosthesis is removed and all cement, debris, granulomata and fibrous membrane are completely cleared from the femoral canal which is thoroughly irrigated and occluded distally by an acrylic plug placed 2 cm distal to the most distal area of bone lysis. Any defects in the femoral cortex are covered from the outside by fine wire mesh held in position by cerclage wires. Large proximal defects may require the additional support of a reconstruction plate to hold the mesh which will constrain the grafts.

The canal is then filled, starting distally, with unwashed, cancellous allograft bone chips prepared from frozen femoral heads retrieved at primary hip arthroplasties. These are packed firmly down on top of the plug. When the level of the impacted chips reaches 8 to 10 cm below the level of the top of the greater trochanter, a trial femoral component two sizes larger than the size estimated to be correct by preoperative templating is driven vigorously into the impacted chips. The tapered femoral component forces the impacted chips firmly against the walls of the femoral canal; the oversized femoral component creates and shapes a 'neo-medullary canal' within them. The stem is then withdrawn, more chips are introduced and impacted, and the oversized stem is again hammered down into the chips. This procedure is repeated until the canal has been filled to its proximal end with impacted chips. Vigorous impaction can achieve an impressive degree of stability of the trial stem.

Trial reduction is then performed; if this is satisfactory, the trial stem is removed and the 'neo-medullary canal' is sucked dry. Antibiotic-loaded cement of reduced viscosity is then introduced in a retrograde fashion through a tapered spout from a cement gun. When the cavity has been filled, it is sealed and pressurised to force the cement dough into the graft. Pressure is maintained until the cement viscosity has risen appropriately, and only then is the new femoral component inserted. We use standard-length femoral components: no special components have yet been required. For recent cases we have used specifically designed instruments to pack the grafts and to centralise accurately the neo-medullary canal.

Postoperative care. Initially, patients were kept in bed for three weeks, but with increasing experience mobilisation has been started earlier, and depends more on the state of the acetabulum and the soft tissues. Most patients are now allowed up within two or three days, and walk with minimal weight-bearing on crutches for three months, followed by graduated return to full weight-bearing.

PATIENTS

This technique was first used in mid-1987, and by the end of 1991, it had been employed in 127 hip revision operations at the Princess Elizabeth Orthopaedic Hospital. We have studied 68 hips operated on for femoral component loosening before April 1989, to give a minimum follow-up of 18 months. The longest follow-up

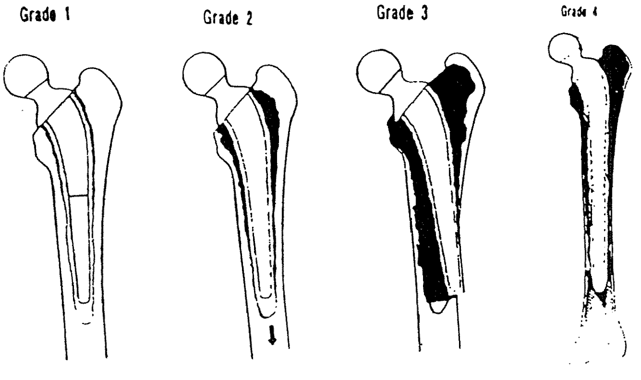

Fig. 1

The Endo-Klinik classification of loss of femoral bone stock:
Grade 1 – radiolucent lines confined to the upper half of the cement mantle; clinical signs of loosening.
Grade 2 – generalised radiolucent zones and endosteal erosion of the upper femur leading to widening of the medullary cavity.
Grade 3 – widening of the medullary cavity by expansion of the upper femur.
Grade 4 – gross destruction of the upper third of the femur with involvement of the middle third, precluding the insertion of even a long-stemmed prosthesis.

Table I. Mean preoperative and latest follow-up scores of all 56 patients on the modified Merle d'Aubigné-Postel scale

Charnley category	Pain		Function		Movement	
	Preoperative	Follow-up	Preoperative	Follow-up	Preoperative	Follow-up
A (n=11)	2.51	5.63	1.66	5.63	2.81	5.54
B (n=21)	3.72	5.89	2.50	5.05	4.05	5.65
C (n=24)	2.56	5.50	1.87	3.54	3.95	5.10

at the time of the review was 49 months, and the mean 30 months. Twelve hips were not reviewed: nine patients had died before the 18-month follow-up, one failed to attend, one had complete early failure and one sustained a postoperative fracture. The last two are described in detail below. This left 56 to form the basis of the results: 50 were reviewed clinically, five were contacted by letter or telephone, and the data of one who died after 20 months were included. All radiographs were available. There were 32 men of mean age 70.8 years (49 to 87), and 24 women of mean age 66.2 years (46 to 85). Ten patients were under the age of 60 years at the time of revision.

Five hips had undergone one previous revision, two had had two, and one hip had had three. Three hips were infected. Eleven different operating surgeons were involved; two performed 36 of the procedures, and of the other nine surgeons six were under training. The implants that were removed included 22 matt-surfaced Exeter, 17 McKee-Farrar and 6 Charnley components.

RESULTS

The patient categorised as a total failure had a preoperative fracture of the femoral shaft, distal to the loose femoral component. At revision, the surgeon elected to treat the fracture conservatively. It did not unite, and further surgery is planned. Another patient required a second revision after sustaining a fracture of the femur in a fall nine months after the original revision. This had been treated elsewhere by skeletal traction, followed by open reduction and internal fixation using a Partridge plate and bands. The fracture failed to unite and required further reduction, fixation and grafting.

All the clinical reviews were performed by one surgeon (LL), and the radiological assessments were carried out on a consensus basis by four surgeons. Loss of bone stock at the time of revision was categorised according to the Endo-Klinik classification (Engelbrecht and Heinert 1987; Fig. 1). Three hips were in grade 1, 40 in grade 2, 13 in grade 3 and none in grade 4. A number of the grade 3 cases were borderline between grades 3 and 4.

Clinical status. The Charnley modification (1979) of the Merle d'Aubigné-Postel classification was used. There were 11 hips in category A, 21 in category B, and 24 in category C. The preoperative and follow-up scores of the patients are shown in Table I.

Of the 11 hips in category A, all but two were pain-free at review, and overall pain relief has been comparable with that achieved in primary interventions using cement. Function was obviously worse in category C patients, but the general increase in level of activity of the patients has been encouraging. So far there is little evidence that the results are deteriorating with time (Table II) or that they are worse in those with more severe loss of bone stock or after repeated revisions. The average pain gradings at review for cases in the Endo-Klinik grades 1, 2 and 3 for bone stock loss were 5.66, 5.72 and 5.53 respectively.

Radiology. All radiological assessments were made by

Table II. Mean preoperative and latest follow-up scores of all 13 patients followed for more than three years

Charnley category	Pain		Function		Movement	
	Preoperative	Follow-up	Preoperative	Follow-up	Preoperative	Follow-up
A (n = 2)	2.00	6.00	1.00	5.50	4.00	5.50
B (n = 4)	2.75	5.50	1.75	5.25	4.33	5.75
C (n = 7)	2.50	5.66	2.00	3.83	4.80	5.50

Table III. Grade of initial packing and of cement filling in 56 hips

Grade	Graft	Cement
Excellent	11	16
Good	21	25
Fair	16	11
Poor	1	3
Defective	5	1
Not classified	2	0

Table IV. Later appearance of the grafts in 56 hips reviewed at a mean of 30 months (18 to 49)

Findings	Number
No change	2
Localised resorption	3
Cortical repair	3
Trabecular remodelling	13
Trabecular incorporation	12
Cortical repair and trabecular remodelling	19
Cortical repair and trabecular incorporation	3
Not classified	1

Fig. 2a

Fig. 2b

Fig. 2c

Fig. 2d

Radiographs before and after the third revision operation: preoperative (a), postoperative (b), at 13 months (c), and at 28 months (d). There is cortical reconstitution in zones 2 and 3 on the 13-month film which is more evident in the 28-month film. The stem subsided about 3 mm into the cement mantle during the first 13 months but there was no further subsidence during the ensuing 15 months. There is no evidence of cement fracture, and no radiolucent lines at the cement-bone interface.

zones, using the classification of Gruen, McNeice and Amstutz (1979). The interpretation of the radiological appearances in some of these cases was not easy, since the technique produces unfamiliar changes (Figs 2, 3).

We tried to assess the efficiency of initial graft packing and cement filling in the postoperative films using the six grades, shown in Table III. We graded the later appearances of the grafts under seven headings, as shown in Table IV, using the predominant appearance in the zonal analysis of each case. These headings are empirical, since there is no proof, for example, that the radiological appearance categorised as showing trabecular incorporation, actually means that trabecular incorporation has occurred. Trabecular remodelling, however, was frequently visible on radiographs (see Fig. 3c), as was cortical repair (see Figs 2c,d).

The presence or absence of radiolucent lines was recorded at the interfaces between the graft and the host, and between the graft and the cement, on the zonal analysis of all 56 hips. The result is expressed as the percentage of the interfaces occupied by radiolucent lines (Table V).

The incidence of radiolucent lines was remarkably low. In the 13 hips followed for over three years 71.4% of the zones showed no lucent lines, and only 2.2% of the zones showed complete lucent lines of 1 mm or more in width. None of these 13 hips showed any radiological deterioration during the most recent year of follow-up, and eight have shown continued improvement.

Subsidence. The femoral components were all of the Exeter design: they were polished, totally collarless, and double-tapered, with the capacity to subside *within* the cement mantle without damaging the cement-bone interface (Fowler et al 1988). We believe that this subsidence is generally accommodated by time-dependent deformation, or creep (Weightman et al 1987; Lee, Perkins and Ling 1990), and we have shown that in primary arthroplasties subsidence of this type of stem within the cement is generally self-limiting (Fowler et al 1988; Gie et al 1990).

We assessed two types of subsidence: that of the stem within the cement and that of the stem *and* the cement together, probably mainly within the allograft

Fig. 3a Fig. 3b Fig. 3c

Radiographs showing remodelling: preoperative (a), postoperative (b), and at two years (c). Aligned trabeculae are visible in all zones in the proximal femur. There is a radiolucent line at the cement-bone interface in zone 1 only. The stem has subsided about 2 mm into the cement mantle.

Table V. Incidence and extent of radiolucent lines at the graft-host and graft-cement interfaces in 56 hips

***Percentage* of interface**	**Graft-host**	**Graft-cement**
None	33	40
1 to *10*	15	8
11 to *20*	5	4
21 to *30*	0	1
31 to *40*	0	0
41 to *50*	1	2
Unknown	2	1

chips and due to slippage and further compression of the chips. Our methods of measurement have been reported (Fowler et al 1988). In those hips in which a hollow centraliser had been used, subsidence of the stem within the cement can be confirmed by repeated measurement of the distance between the tip of the stem and the bottom of the hollow centraliser. This is a device used with the Exeter femoral component to prevent end-bearing and allow the stem to subside and the taper to engage (Figs 2b,c and d). This movement is due to deeper engagement of the stem taper within the cement.

Table VI. Incidence and extent of subsidence in 56 revisions

Subsidence (mm)	Stem within cement	Cement mantle within bone
None	1	45
<1	11	3
1 to 2	22	6
3 to 4	11	1
5 to 7	7	1
8 to 10	2	0
>10	2	0

The results of subsidence measurement are set out in Table VI. In the 13 hips followed for more than three years, we detected no progression of subsidence of the stem within the cement after six months in two hips, after 12 months in two and after 24 months in six. The relationship between subsidence and the quality of graft packing and cementing is not yet clear. When graft packing and cementing are good or excellent, progressive subsidence has not been seen, but it has also been absent in some cases in which the packing and cementing have been poor. We found no relationship between subsidence of the stem within the cement and the clinical grade, as already reported for primary arthroplasties with this type of stem (Fowler et al 1988).

Only one femoral component changed alignment with subsidence, moving into a valgus position, as reported for primary arthroplasties using the Exeter stem (Fowler et al 1988). No component subsided into a varus position, probably because there can be no 'calcar pivot' effect (Gruen et al 1979) with this stem geometry.

Complications. In the 68 consecutive operations there were only seven complications which could be related to the technique. Intra-operative fractures occurred in two; these were treated by reduction and plating, followed immediately by impaction grafting and cementing. In one case the stem pierced the femoral shaft. Dislocation occurred in three arthroplasties. The one postoperative femoral shaft fracture has been described above.

No hip has yet been re-revised for aseptic loosening, and there has been no recurrence of infection in any of the three infected hips.

The major general complications in the early postoperative period were disseminated intravascular coagulation in one patient and cerebrovascular accidents in two.

DISCUSSION

Although our follow-up is relatively short, it is already clear that the postoperative course is totally different from that of revisions using cement alone. Both relief of symptoms and the functional result compare well with those of primary arthroplasty. Radiological improvement after operation is frequently remarkable: the continued improvement that is often seen contrasts with the behaviour of conventionally cemented revisions (Amstutz et al 1982; Kavanagh et al 1985; Pellici et al 1985), especially where the bone stock is poor (Kershaw et al 1991). Amstutz et al (1982) reported that two years after cemented revision, 25% of hips showed radiolucent lines extending around 100% of the interface, and that one-fifth of the lines exceeded 2 mm in width.

It is uncertain how much of the graft is replaced by living host bone. When there is much trabecular remodelling and realignment, as shown in Figure 3, it is justifiable to conclude that the bone is living: dead allograft chips could not remodel in this way. Histological examination was carried out on only one post-mortem specimen, and this was from a patient excluded from this review because his femur showed endosteal bone lysis associated with a large cortical diaphyseal defect. The same technique of impaction cancellous grafting had been used and the findings showed healing of the cortical defect by new living cortical bone, supported by living cancellous bone containing viable marrow spaces, that had been replaced by allograft chips (Ling, Linder and Timperley 1992). In the femoral canal, there were areas of direct contact between osteoid and cement. There was no continuous layer of fibrous tissue at the graft-cement interface, and only scattered islands of dead bone were present, suggesting that most of the allograft had been replaced by viable bone. These histological findings and the radiological appearances in the series that we report give grounds for cautious optimism.

The biology and biomechanics associated with this technique need considerable research and clarification. The trabecular alignment that often appears in place of the graft suggests that load has been directed through the graft during healing. This loading, and the compression of the grafts (Burri and Wolter 1977), may be important in relation to the replacement of the grafted bone and contrasts with the situation within a structural cortical allograft; the latter's stiffness must stress-protect any new bone that is formed within it.

Two other factors are probably of significance. First, the graft is 'fixed' to the composite of implant cement and metal. This must limit micromovement between the graft and the implant, and distinguishes the method from that reported by Nelson, Bulstrode and Mowat (1990), in which, in the absence of cement, the grafts were *not* fixed to the implants. Secondly, an impressive stability of the femoral component can be achieved by impaction grafting, and this is increased by using cement (Schreurs, Huiskes and Slooff 1991). Compression of the graft is further increased by the tapered wedge shape of the polished collarless femoral component, which also eliminates the calcar-pivot phenomenon (Gruen et al 1979; Timperley et al 1992). One of the authors (Linder, unpublished data 1992) has recently shown that subsidence of the polished, tapered, collarless stem, occurring within the graft and within the cement, contributes significantly to torsional stability. There is also experimental and theoretical evidence (Miles, Clift and Bannister 1990) that this type of stem geometry produces a relative increase in compression and a relative reduction in shear at the stem-cement and cement-bone interfaces, and within the cement, in comparison with a component having a textured surface. This is supported by the orientation of remodelled trabeculae that we report, and by the long-term behaviour of such stems in primary arthroplasties (Fowler et al 1988; Gie et al 1990). It is probable that these properties are of even more significance in revision procedures, although more conventional stems may well function satisfactorily when used with our grafting technique.

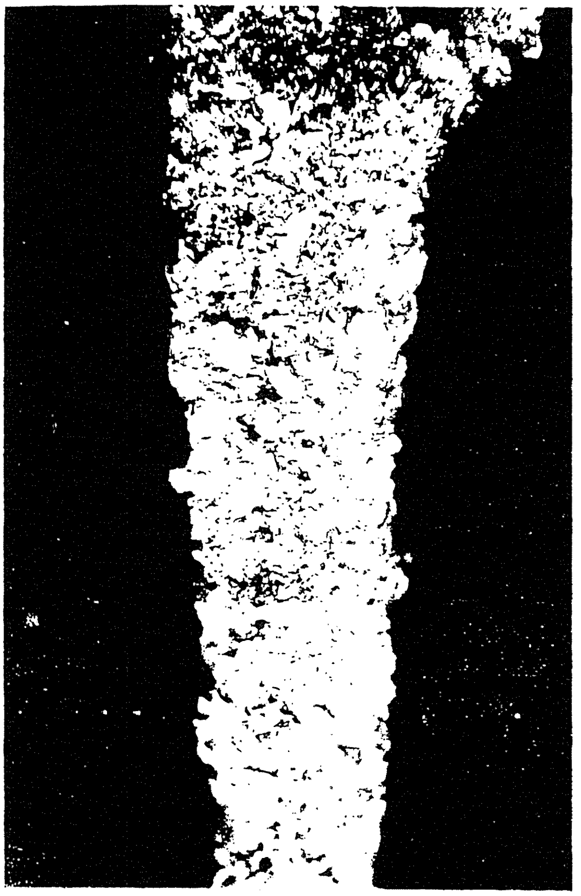

Fig. 4

Photograph of a specimen extracted from a cadaver femur after impaction grafting and cementing. The surface is entirely covered with graft, which is fixed to the cement.

Our technique is, in essence, a method of coating cement with allograft chips (Fig. 4); this concept may have other applications. Despite our relatively short-term experience, we conclude that the method shows considerable promise. It may be especially valuable when there is severe loss of bone stock.

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Acetabular and Femoral Reconstruction With Impacted Graft and Cement

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Loosening of primary cemented and noncemented components of total hip arthroplasties always is accompanied by a loss of bone stock. There are several options for reconstruction of the acetabular and femoral defects. The authors' treatment of choice is a standardized cemented revision procedure with tight impaction of morsellized cancellous autograft or allograft chips in acetabular and femoral reconstructions. In this study, the clinical and radiographic evaluation of acetabular defects reconstructed with impacted morsellized allograft femoral heads was described. A cemented cup supplemented with morsellized cancellous grafts and wire meshes in cases of segmental defects was sufficiently stable to allow for complete graft consolidation. After a mean followup of 70 months of 88 hips, 4 cases of clinical failures (including 1 infection) and 6 cases of radiologic failure of the reconstructions were observed, resulting in a failure percentage of 11.4% after 5 years. Autografts and allografts were equally effective. Because the clinical success of the technique also was supported by the results of histologic and biomechanic studies in animals, the authors were encouraged to continue this technique, not only in the acetabulum, but also in the femur.

It is generally accepted that aseptic loosening is the most common long-term complication of total hip arthroplasty. The migration of implants during loosening and procedures to remove the prosthesis and cement during revision induce significant bone destruction, resulting in enlargement of the acetabulum and widening of the femoral medullary cavity. Choices have to be made regarding the reconstruction of the bone stock loss, how to repair the anatomy of the acetabulum and femur, and how to achieve direct postoperative functional stability of the revised total hip.

The use of bone grafts in orthopaedic surgery is described extensively in the literature and is generally accepted as a reconstructive technique.[1,3,10,13,14,25,27] Regardless of the type of graft used, essential factors that influence the incorporation process are the stability of fixation, the amount of contact between host and graft, the strain pattern within the graft, and the degree of antigen matching. However, the size of the graft has also been found to play an important role in the graft incorporation process.

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The revascularization of graft bone is essential for successful bone incorporation. In cases of allograft bone, the host contributes all vascular and cellular elements required for incorporation of the graft. However, revascularization may differ among different types of graft. In theory, a cancellous graft allows rapid vascular invasion and should therefore enable a more rapid, complete, and uniform incorporation without mechanical weakening, as compared with the incorporation of solid cortical graft. Clinical studies of massive structural trabecular allografts[15] used in revision or tumor surgery[8] showed that the incorporation of these structural cancellous autografts and allografts is in many cases confined to the outer few millimeters, leaving a more centrally located permanent necrotic core, which in time may cause failure of the graft.

The authors have found that grafting with impacted allograft chips does not have the drawbacks of structural allografts. Since the late 1970s, impaction grafting combined with cement fixation of the prosthetic components has been their treatment of choice for restoring bone stock on the pelvic side and since the 1980s also on the femoral side. In 1984, their clinical experience was published[23] with a modification of the techniques developed by Hastings and Parker[16] and McCollum et al.[17] Morsellized allografts were used, and these chips were impacted tightly in the enlarged acetabulum. In cases of segmental medial and peripheral defects, containment was effected by reconstructing these defects with metal meshes, which resulted in direct initial stability of the reconstruction.

This reconstruction method was modified in close cooperation with Prof. Ling and Dr. Gie from Exeter (United Kingdom) and with representatives from Howmedica International for the clinical application in the femur to restore the femoral bone stock deficiencies after loosening of femoral components of total hip arthroplasty.[11,12] The initial clinical experience with the reconstruction method in the femur was reported in 1991 by Simon et al.[22] In the same year, Schreurs et al[20,21] showed experimentally the increased stability of the femoral component obtained by combining the use of impacted graft and cement.

In the current study, the authors presented their 5-year followup of acetabular revisions of reconstructions with morsellized chips, wire meshes, and cement as well as a short-term followup of a few femoral revisions.

MATERIALS AND METHODS

Between January 1979 and January 1988, 91 cemented revision hip arthroplasties in 83 patients were done at the authors institution with the acetabular reconstruction technique with impaction grafting, wire meshes, and cement. The indications for surgical intervention were clinical and radiographic loosening. All patients reported pain and functional disability. Patients were excluded from the followup study if the revision procedure was done without bone grafts or if solid bone grafts or a metal acetabular reinforcement ring had been used.

Acetabulum

In the first half of 1990, all patients eligible to participate in the study were invited for a clinical and radiographic examination by 2 of the authors (T.J.J.H.S. and J.W.S.). Seven patients (7 hips) had died of causes unrelated to the revision procedure. One patient (1 hip) was lost to followup. Most patients were followed yearly, thus their records and radiograph results from previous visits could be evaluated. Finally, 80 patients (88 hips) entered the study with an average followup of 70 months (range, 24–132 months). The average age at the time of revision was 62 years (range, 33–89 years).

Femur

Between March 1991 and November 1992, 10 cemented revision arthroplasties were done with reconstruction of the femoral canal by means of impacted morsellized allografts and cement. In 9 of these cases, the acetabulum and impacted allografts were reconstructed simultaneously. All of the patients' records were reviewed. The mean followup time was 24 months (range, 14–34 months) (see Table 1). Seven of the patients were women and 3 were men, and the mean age at the time of revision was 64 years (range, 35–76 years).

TABLE 1. Summary of Results of Femoral Revision with X-Change Revision System

Case No.	Age (years)	Gender	Length (cm)	Weight (kg)	Side	Original diagnosis	No. of Earlier Revisions	Implant Removed (type)	Followup After Revision (months)	Endo-Klinik Classification	Preoperative Harris Hip Score	Postoperative Harris Hip Score	Complications
1	76	F	162	60	R	Osteoarthritis	1	Lubinus SP2	34	3	56	76	Fracture 23 months postoperative
2	35	F	165	78	R	Osteoarthritis	1	Müller curved stem	29	2–3	59	101	
3	67	M	190	84	R	Osteoarthritis	0	Unknown	27	3	47	96	
4	66	F	162	60	R	Rheumatoid arthritis	1	Müller straight stem	27	2–3	—	—	Fracture 4 months postoperatively
5	69	M	178	67	L	Osteoarthritis	2	Müller straight stem	26	2–3	34	97	
6	70	F	158	62	R	Osteoarthritis	2	Wagner long stem	22	4	24	97	
7	65	F	167	79	R	Osteoarthritis	0	Charnley	22	3	36	90	Femoral fissure operation
8	69	M	180	80	L	Osteoarthritis	1	Lubinus SP2	18	4	59	97	
9	71	F	165	58	R	Rheumatoid arthritis	0	Müller curved stem	18	2–3	37	95	
10	52	F	158	73	R	Osteoarthritis	0	Müller curved stem	14	1	58	[illegible]	Perforation sha at operation

The acetabular defects were classified on the basis of the preoperative and immediate postoperative radiographs and the operation charts. The American Academy of Orthopaedic Surgeons' classification for acetabular defects according to D'Antonio et al[5] was used. In the femoral reconstruction group, the defects were assessed according to the Endo-Klinik classification.[7] The data of the acetabular defects in this group were not included in the current study. Early in the series, bone grafts were taken from the iliac crest as autografts and sometimes combined with allografts. Most of the grafts were deep-frozen femoral head allografts from the hospital bone bank. Allografts were used in 65 hips. The grafts were prepared with a rongeur during surgery. The chip size was substantial (1 cm^3), compared with the smaller-milled chips used for femoral reconstructions. The amount of the graft used varied from 1 to 3 femoral heads per patient depending on the severity of the acetabular defect. For all patients, the hip joint was approached by a posterolateral incision, and the exposure was combined with a trochanteric osteotomy in only 3 cases. The proximal part of the femur was exposed and mobilized carefully and extensively before the hip was dislocated. The entire socket of the acetabulum was exposed, from the transverse ligament to the superior margin and from the posterior wall to the anterior wall. After being tested for loosening, both components were extracted from the cement mantle. After removal of the socket and all of the cement, the fibrous interface was separated from the thin, irregular acetabular wall by means of sharp spoons. Removal of this layer led to abundant bleeding of the often sclerotic bone. At least 3 specimens were taken from the interfacial fibrous membrane for frozen sections and bacterial cultures. After these tests were performed, a perioperative prophylactic antibiotic regimen was started. The wall and floor of the cavity were examined to establish their integrity and bone quality and to detect any hidden defects. Reconstruction was directed to the closing of the medial and peripheral segmental acetabular rim defects with a metal-wire mesh. In this way, the segmental defects became a cavitary defect. This defect was filled with firmly impacted morsellized cancellous allografts, and the graft surface was covered by a second metal mesh. A polyethylene cup was cemented directly onto this reconstruction (Figs 1, 2). Care was taken to re-

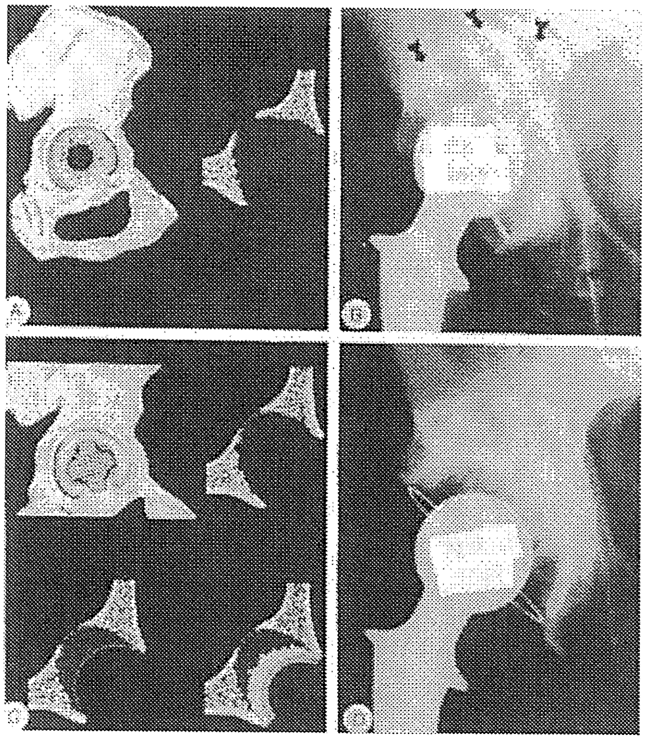

Fig 1A–D. (A) Schematic drawing of a medial defect, a perforation of the acetabular medial wall (P). (B) Radiograph of a loose acetabular cup that migrated upward, leaving a gap at the site of the teardrop (lower arrows). The loosening process also has created bone loss in the acetabular roof (upper arrows), which is called a medial segmental and cavitary defect. (C) Schematic drawing of the reconstruction technique showing the closure of the medial defect with a metal mesh (M) and the impacted morsellized chips (dotted area) filling the defect. The layer of chips was covered by a second mesh (M), and a cup was cemented in place. A new acetabulum of a desired size is created in the anatomic position near the teardrop. (D) The 5-year followup radiograph of the same patient after the acetabular reconstruction (Modified with permission from Slooff TJJH, Schimmel JW, Buma P: Cemented fixation with bone grafts. Orthop Clin North Am 24:667–677, 1993).[24]

pair the hip by packing as much graft material as necessary until the socket was brought down to the level of the transverse ligament, which is the anatomic location of the acetabulum, but with a graft thickness of at least 5 mm.

On the femoral side, all of the bone cement and debris was removed with chisels and curettes. The canal was irrigated by means of pulsatile lavage. Segmental defects of the femoral tube were repaired with wire mesh to contain the graft (Fig 3). For facilitation of accurate and vigorous packing of the graft, special instruments were developed jointly at the Universities of Exeter (United Kingdom) and Nijmegen (the Netherlands) and in close collaboration with Howmedica International (United Kingdom). This technique was described extensively by Gie et al[11,12] and by Schreurs et al.[19–21]

Postoperative treatment included anticoagulation therapy for 3 months and systemic antibiotic therapy for 24 hours. Indomethacin was administered for 7 days to prevent heterotopic ossification. Passive motion exercises were started 24 hours after the operation, partial weightbearing after 6 weeks, and full weightbearing after 3 months.

All patients were seen in the authors' outpatient department 6 weeks, 4 months, 1 year, and 2 years after the operation. Harris Hip Scores were estimated before and after surgery by interview and examination. All preoperative and postoperative radiographs were examined and graded consensually by 2 surgeons and a radiologist. Preoperative radiographs were graded according to the Endo-Klinik classification in case of femoral bone stock loss.[7] Acetabular defects were classified as segmental or cavitary according to D'Antonio et al.[5] Radiographs were used to evaluate consolidation and incorporation of the graft, migration measurement, and the occurrence of radiolucencies. Consolidation was defined as the presence of clearly delineated trabecula crossing the graft-host junction. Graft incorporation was assessed according to the criteria of Conn et al[4] and was considered to be incorporated when an identical radiodensity of the graft and host bone, with a continuous trabecular pattern throughout, existed. Migration of the cup was established with digitization of the serial radiographs. Reliable, reproducible measurements were done on the monitor (Fig 4). The position of the socket was determined by the metal wire, and

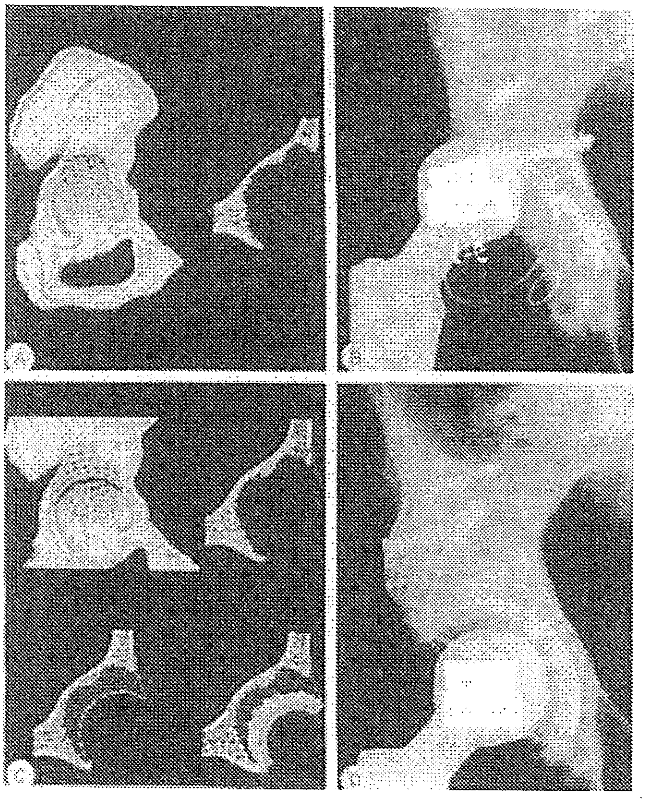

Fig 2A–D. (A) Schematic drawing showing the acetabular rim defect anteroposteriorly and cross-sectionally. A combined segmental and cavitary defect exists. (B) Radiograph of a failed acetabular rim reconstruction with a solid structural graft and screw fixation. The result is visible: a segmental defect in the acetabular wall, a broken prosthetic cup, and a luxated femoral component. (C) Schematic drawing of the reconstruction. The acetabular rim is reinforced with a metal mesh (M) and the defects are filled with impacted morsellized grafts (dotted area). (D) Direct postoperative radiograph showing the reconstruction with the acetabular component at the anatomic site near the teardrop (Modified with permission from Slooff TJJH, Schimmel JW, Buma P: Cemented fixation with bone grafts. Orthop Clin North Am 24:667–677, 1993.[24]

the cup was measured relative to Kölher's line and the teardrop line. Radiographs were digitized (TEA Image Manager System, DIFA Measuring Systems Ltd, Breda, the Netherlands), and a computer program was developed. This program allowed for reproducible measurements to be made according to a coordinate system applied in each radiograph. In each radiograph, the magnification factor was determined based on the prosthetic head of 32 mm, which was used for all patients. The Köhler line was chosen as the Y axis, and K was the line along the medial aspect of ilium and ischium. The line T, running perpendicular to the line K and tangential to the inferior aspect of the teardrop, was chosen as the X axis. As a reference point on the acetabular cup, the center of the projected elliptical image of the metallic ring at the periphery of the cup was chosen. This point, c, which was considered to be the center of the cup, was determined through bisection of the long axis a–b of the projected ellipse. The angle between the long axis of the ellipse and the line T was defined as the inclination angle and was measured in each radiograph.

Subsidence of the stem within the bone cement was estimated as described by Fowler et al.[9] Subsidence of the stem-cement mantle relative to the cortical bone was also estimated. Radiolucency at the graft-cement interface was assessed according to the criteria of DeLee and Charnley.[6] Cups with continuous radiolucent lines thicker than 2 mm in all 3 segments were considered to be loose.

RESULTS

The results of the femoral revisions were preliminary and are described in the Discussion section.

At the time of the study, 4 acetabular components had been revised because of recurrent infection in 2 cases and aseptic loosening with migration in 2 cases. The postoperative Harris Hip Score averaged 87 points and, compared with the average preoperative score of 44 points, showed that the clinical results improved after the reconstruction. Consolidation

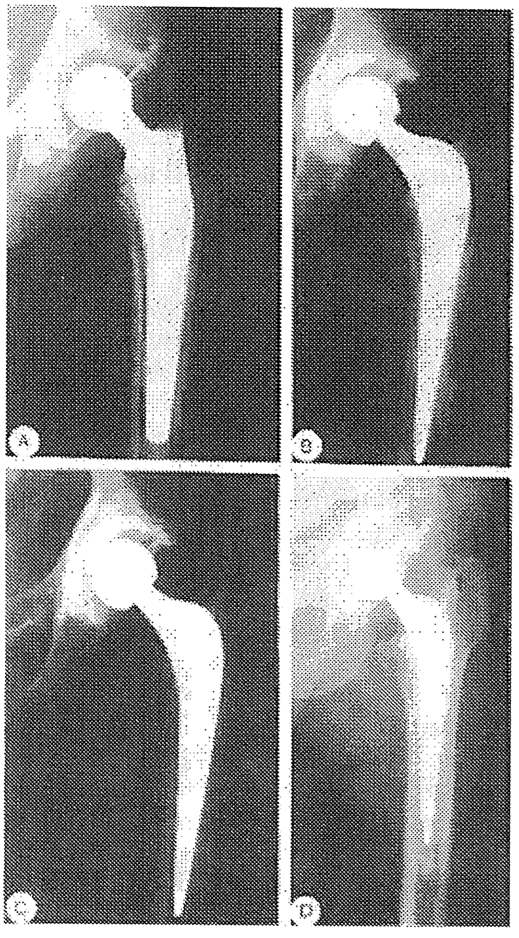

Fig 3A–D. Revision of an acetabular and femoral loosening of a straight-stem Muller prosthesis. (A) The preoperative situation. Moderate migration of the cup with radiolucent lines in all 3 segments. Around the stem a clear radiolucent lining is visible around the cement mantle. (B) Radiograph done immediately after the revision with the impacted morsellized chips in the acetabulum and femur. The X-Change Revision System and the Exeter Hip System were used. (C) Radiograph 1 year after surgery. Neither migration nor radiolucency is visible. (D) Radiograph 2 years after surgery. The position of the cup is the same as it was immediately after surgery. No migration has occurred. Signs of remodeling of the impacted graft are visible at the femoral side.

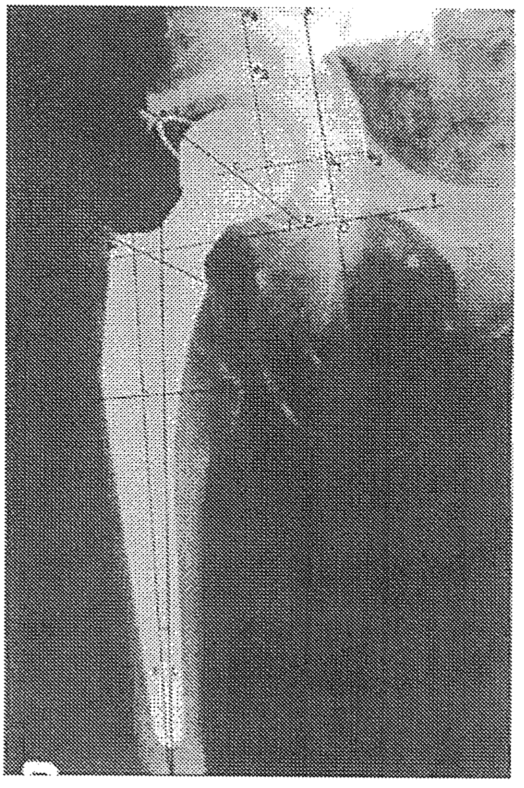

Fig 4. Radiograph with coordinate system for measurement of subsidence. See text for explanation of the lines and symbols.

of the graft, which involves union of the graft to the host bone, was complete in all 88 hips. Signs of incorporation were difficult to assess because of the irregularities at the graft-cement interface. Eight acetabuli showed incomplete graft incorporation: 2 cups had remained stable during the followup period; 5 cups had migrated with partial graft resorption but were clinically asymptomatic; and 1 cup had been rerevised because of progressive loosening. Migration occurred in the 5 cups with incomplete graft incorporation. These cups were considered to be radiographically loose. One cup showed progressive continuous lucency with evident signs of incomplete graft incorporation, although migration had not occurred in this case. Clinical failures were seen in 4 cases and radiographic failures in 5 cases because of migration of >5 mm (4 cases) and continuous lucency thicker than 2 mm (1 case). The overall success rate was therefore 78 of 88 hips (88.6%).