

В ПОМОЩЬ ПРАКТИКУЮЩЕМУ ВРАЧУ. ЛЕКЦИИ

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Bone cement and cementation technique, antibiotics and bone cement spacers: what should you know?

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Acrylic bone cement has been used successfully in orthopaedic practice for more than 50 years, thanks to the pioneering work of Sir John Charnley in the late 1950s (Charnley, 1972). The great results achieved by Charnley with the low friction arthroplasty opened the way to the work of Buchholz who, in the early 1970s, realized that bone cement could be a great material also for the delivery of drugs thus helping in the reduction of the infection rate (Buchholz, 1981).

The evolution of the cementing technique (Breusch — Malchau, 2005) and of the implant design (Scheerlink, 2006) has been the key for the success of the cemented fixation. From finger packing, with minimal pressurisation cement contamination risk (air, fat, blood), the cementing technique evolved through the use of cement guns, endomedullary plugs and pressurizers to improve cement penetration and inter-digitation. The next step was the introduction of mixing systems, a better bone bed preparation and the use of pulsed lavage in an effort to improve cement performances to guarantee a long-lasting outcome (the third generation cementing technique). The use of centralisers did further improve cement performances, making possible even cement and stress distribution (Berger, 1997).

The implant design evolution has followed two distinct philosophies: load tapers or force-closed femoral stems, designed to subside (Exeter stem, CPT stem, C-stem), and composite beam or shape-closed designs, designed not to subside (Charnley Elite, Lubinus SP2). Other important features were related to surface finish (polished or smooth/roughened) and stem geometry design (overall shape, straight or anatomical; cross-section, oval or square; collar presence; tip shape; stem length) (Scheerlink, 2006).

The combined evolution of cementing technique and implant design has been shown to produce excellent long-term outcome of cemented implants with

a survival rate exceeding 97 % at 10 years (Swedish Hip Register Report, 2004 & 2012).

According to a recent estimate (Millennium Group Survey, 2011), in 2012 more than 3 million hip and knee replacements were performed in 9 markets (UK, France, Germany, Italy, USA, Japan, Brail, China, India) and worldwide; it is estimated that this number has reached some 4.5 million hips and knees. Most of these implants are fixed using bone cement, with or without antibiotic. In Ukraine the number of hip and knees has been growing steadily, and in 2012 about 7000 implants were made.

The success and diffusion of arthroplasty do not come without problems. Revision arthroplasty is a great problem which increases the healthcare costs, and in specific revision for infection is a major problem. According to recent reports, infection is among three main reasons for revision exceeding 20 % (Bozic, 2010; NJR 2011). All in all, infection following a primary implant exceeds 2 % over a 10-year period (Ong, 2009; Kurtz, 2010). A higher rate instead is encountered when infection occurs to a revision implant.

In an effort to reduce the risk of infection, the use of antibiotic-loaded acrylic cement (ALAC) has become quite common. However not all drugs can be added to bone cement. As a general rule antibiotics shall be thermostable, water soluble, achieve a bactericidal effect. In addition they should be gradually released, with a limited inflammatory/allergic potential and should not compromise the mechanical performances of bone cement (Joseph, 2003). The industry has then further requirements, as the antibiotic shall be available in bulk, in powder form and shall be stable to sterilization and ageing. In addition the Regulatory approval path is quite long and expensive. Therefore the high costs involved in research and development, and registration along with the request for low prices

is a terrible brake for the introduction of new products (ALAC). The theory on antibiotic release from cement is still under debate, some authors favour a diffusion theory, however the majority supports the idea that release is mainly a surface phenomenon. Release is a function of liquid penetration into the PMMA matrix. As PMMA is not a porous structure, it is clear that release will be related to bulk porosity, and influenced by surface rugosity, presence of interconnecting pores and cracks. In relation to these properties we will have low and high porosity bone cements with different release performances (van de Belt, 2000).

The local release of antibiotics from PMMA is quite interesting as the antibiotic is directly delivered into the operative site, attaining very high local concentrations without any systemic side effect (Bertazzoni Minelli, 2004).

Currently, commercially available ALACs include cement with Gentamicin or Tobramycin, and cement with Gentamicin+Clindamycin, Erhthromycin+Colistin, Gentamicin+Vancomycin. Single antibiotic cement is generally used with patient at risk, but in a number of countries (Northern Europe) it is used for the fixation of primary implants as a prophylactic means to reduce infection (Espeshaug, 1997). Double antibiotic cement is instead used in established infections in one- or two-stage procedure. In two-stage procedures ALAC spacers are used. Industrially preformed ALAC spacers are also available loaded with Gentamicin or Gentamicin+Vancomycin.

The use of ALAC should be done with caution in order not to increase bacterial resistance. The most commonly used ALACs are single antibiotic cements, loaded with Gentamicin or Tobramycin. Both antibiotics belong to the Aminoglycosides family and share the same spectrum of activity without any clinical difference in terms of results achieved. ALAC use is not uniform across the world: in Mediterranean Europe ALAC is only reserved for risk patients or in revision cases, while in Northern Europe ALAC is used for the fixation of primary implants (see Swedish, Norwegian, UK and German Registers). In US, ALAC cement should only be reserved for the second stage following a septic problem; however, recent reports indicate that the use is reaching 50%. On the contrary in Japan commercial ALAC is not approved, and is prepared in the OR by the surgeon.

Tecres is an Italian company which manufactures acrylic bone cement products and is present in the market for more than 25 years. In 1986 the first bone cement was launched (Cemex Standard), which was radiotransparent and quickly followed by the radiopaque version (Cemex RX). Soon after that a high viscosity



Fig. 1. Cemex System bone cement and Gun. Powder and liquid are contained in the syringe

version (CemexIsoplastics) was introduced. In 1991 a great innovation was made by introducing the first bone cement inside a syringe device (Cemex System, fig. 1), which serves as a mixing and delivery device, preventing from microbial contamination and MMA fumes. The first antibiotic-loaded version was introduced in 1996 (CemexGenta), and recently the innovative and unique double-antibiotic version including Gentamicin and Vancomycin was launched (Vancogenx).

The unicity of Tecres bone cement comes from the formula, and in particular from the Cemex PMMA powder which, being uniform and round, allows to reduce the amount of liquid monomer (MMA) required providing the cement great advantages. Compared to competitor products, Cemex has around 30% less liquid MMA.

MMA affects the properties of bone cement. In particular MMA generates 130 cal/g, therefore the more the liquid the more the energy (heat) generated. This is the theory, which has been confirmed by testing Cemex in comparison with other cements. The uniform and round shape of the Cemex PMMA beads has made it possible to reduce the MMA amount, making the cement more compact and less porous. So the MMA reduction is the key to the advantages of the Cemex bone cement line: lower porosity; lower polymerisation temperature; lower MMA release; lower shrinkage.

Chemicophysical, mechanical and clinical testing have been performed in the most important mechanical and orthopaedic institutes and research centers in Europe and US to assess and conform the performances and quality of the Cemex bone cement line (Milan Polytechnic, Nijmegen Uni, Rizzoli Institutes, Goteborg Uni, Munich Uni, Memphis Uni, Nurnberg Uni...). As a consequence of the compactness of the Cemex powder, vacuum mixing is not necessary to achieve the best performances, as shown by published clinical data (Soderlund, 2012; Dahl, 2012).

The excellent and outstanding features have made Cemex bone cement diffused worldwide in more than

65 countries, including Europe, US, South Korea, Japan, China, India and Australia. In Ukraine Cemex was introduced starting from 2004, while only recently the Gentamicin and Gentamicin+Vancomycin versions have been registered.

Release of antibiotic from CemexGenta is comparable or even better than in competitors (Squire, 2008), and the best elution is achieved not applying vacuum (Meyer, 2011). The use of vacuum is not needed, as Cemex powder is very compact and vacuum would reduce micro-porosity producing a negative effect on release.

While chemico-physical and mechanical performances are important for any bone cement, the clinical outcome is the key to its success. Cemex clinical performances have been assessed in two RSA studies performed in Sweden and Germany. RSA (radiostereometric analysis) is a radiological technique that enables calculation of the 3D translational and rotational movements of the implant relative to the bone with high precision and accuracy and has become the gold standard for clinical evaluation of new surgical techniques and implants. RSA is part of the recommended stepwise introduction of new surgical techniques and implants (Husby, 2010). RSA utilizes modified implants with tantalum markers, and tantalum markers included inside bone and bone cement. Through a double X-ray examination repeated over time and specific software it is possible to follow the migration of the implant.

RSA studies, which are prospective and randomized, generally last 2 years: this is enough to assess the long-term performances of an implant, as the principle of RSA is that if there is a stable interface (bone-bone cement; bone cement-implant) at the beginning, the implant will be stable and will not migrate (Karrholm, 1994).

The first RSA study compared the performances of Cemex and Palacos R (vacuum mixed) used for the fixation of Lubinus SP2 stem and Lubinus cup. At 5 years of follow-up no difference was found in terms of stem migration and head penetration (wear) (Nivbrant, 2001). At 10 years instead the implants fixed with Palacos R showed a larger magnitude of rotation into flexion/extension and retroversion (Soderlund, 2012), while no difference was found in terms of 3D and proximal wear (Dahl, 2012). This means that Cemex bone cement performs as good as Palacos R, and without the application of vacuum.

The second RSA study instead compared the antibiotic version, CemexGenta and RefobacinPalacos RG, used for the fixation of the same implant (Lubinus SP2 stem). At two years of follow-up no difference in terms of stem migration was found between the two groups (Pitto, 2003). The five years of follow-up

(only patients with implants fixed with CemexGenta) showed the same type of migration found in the first RSA study (Pitto, 2007), thus indicating that Cemex and CemexGenta share, as expected, the same excellent clinical performances.

These results, along with the solid scientific background, have led to the introduction of Cemex in two very selective markets, Sweden and Norway (as documented in the well-known Registers), where only a few cements are used, i.e. those who have proven clinical effectiveness (Swedish Hip Register, Norwegian Arthroplasty Register).

As previously introduced, the great success of arthroplasty is not without problems. And orthopaedic infection is a major complication. When dealing with a chronic infection, the only way to get rid of infection is to remove the implant. This can be done in one single procedure (one-stage exchange) or in a two-step procedure (two-stage exchange). In either case, ALAC is used. Two-stage exchange with the use of a spacer is considered the golden standard treatment approach achieving an eradication rate over 90% (Romanò, 2012).

Two-stage exchange foresees a first stage in which a thorough surgical debridement is performed and an ALAC spacer is applied. The first stage is followed by an interim period of 2–3 months (or more) during which a targeted systemic antibiotic therapy of 4–6 weeks is administered. When the serological markers indicate the remission of the infection and the clinical conditions of the patient are favourable, the second stage is programmed. This consists of ALAC spacer removal, additional surgical debridement and implantation of a definitive implant (Romanò, 2012).

ALAC spacers can be hand-made in the OR or premanufactured and ready to use.

Tecres has successfully introduced, starting from 1996, preformed spacers with standardized mechanical and pharmacological performances. Such devices are available for hip, knee and shoulder prosthesis infection (fig. 2). They have been designed to maintain space and mobility, and allow partial weight-bearing (Baleani, 2003; Villa, 2007; Romanò, 2007; Logoluso, 2011). The mechanical performances are comparable to those of a primary implant (for 6 months), while the pharmacological performances allow for prompt high and effective release (Regis, 2013), with maintenance of a high antibiotic concentration over the spacer implantation period (Mutimer, 2010).

The mechanical performances are key to avoid the common complication which may occur using hand-made spacers, such as spacer breakage (fig. 3), bone defect progression, periprosthetic femoral fracture, dislocation (Jung, 2009). The pharmacological perfor-

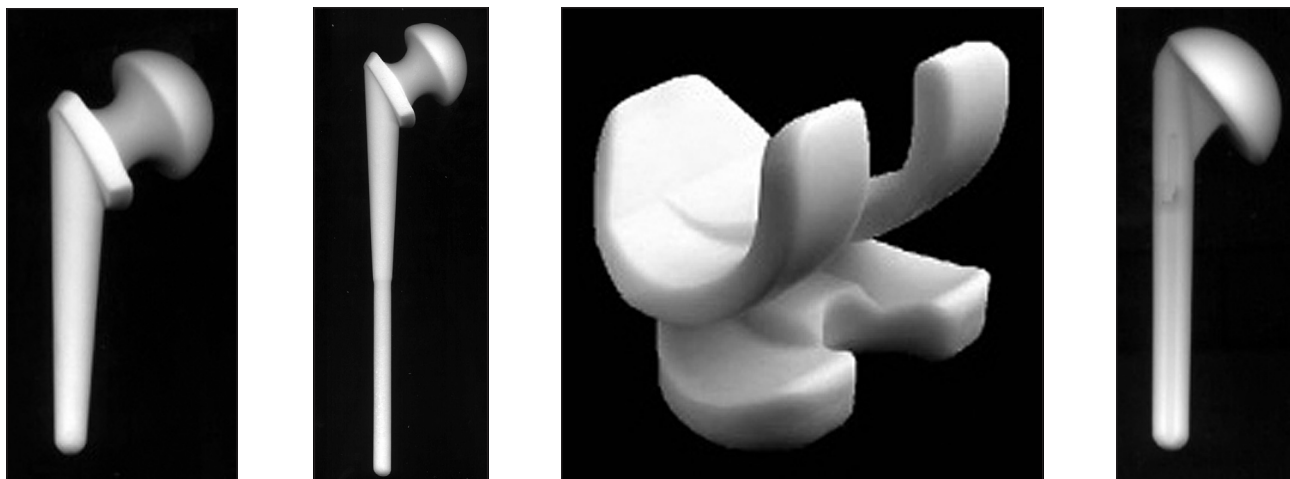


Fig. 2. Preformed hip, knee and shoulder spacers

mances instead guarantee an effective and prolonged in situ release of antibiotic, which cannot be guaranteed when making hand-made spacers in the OR (Moojen, 2008; Rogers, 2011).

Tecres preformed spacers are available with Gentamicin only (Spacer-G, Spacer-K, Spacer-S) or with the combination Gentamicin+Vancomycin (Vancogex-Space Hip & Knee). Transparents and Trials are available for the selection of the correct size. The excellent results achieved when using the preformed spacers have been published in multiple papers in peer-reviewed journals. In consideration of the large number of published papers, it is possible to make a systematic review considering only papers with more than 10 patients, with a mean follow-up larger than 1 year and limited to Gentamicin spacers (table 1). Among the 11 papers included in the review, 507 patients from 12 centres are considered. At a mean follow-up of 44 months, the eradication rate was found to exceed 94 %.

In conclusion, the evolution of cementing technique and implant design has led to excellent long-term clinical performances of cemented implants. Orthopaedic

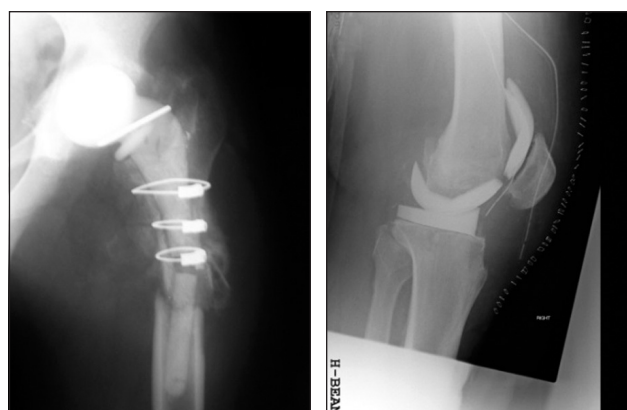


Fig. 3. X-ray showing breakage of hand-made spacers

infection is a major complication: ALAC and ALAC spacers are helpful for solving this relevant problem. Bone cement, introduced in the orthopaedic field more than 50 years ago, can be improved: Cemex is an innovative cement line and clinically reliable. Industrially preformed spacers are safe and effective in two-stage revision, ready to use and able to guarantee a high quality of life to patients.

Table 1. Summary of relevant clinical information on two-stage septic revision with Gentamicin preformed spacers

1 st Author	Journal	Pts	Type	Reimplanted Pts	Cleared at FU	Follow-up
Pitto, 2005	IntOrthop	21	Knee	19	19/19	24 (12–43)
GilGonzalez, 2010	Hip Int	35	Hip	35	30/35	32 (6–65)
Coffey, 2010	J ShoulderElbowSurg	16	Shoulder	12	12/12	18 (10–24)
Pattyn, 2011	IntOrthop	61	Hip	61	59/61	36 (9–84)
D'Angelo, 2011	MusculoskeletSurg	28	Hip	27	27/27	53 (18–106)
Romanò, 2011	BMC InfectDis	20	Hip	20	19/20	57 (24–104)
Neumann, 2012	J Arthroplasty	42	Hip	42	41/42	67 (36–120)
Romanò, 2012	Hip Int	183	Hip	183	173/183	60 (24–132)
Degen, 2012	ClinOrthopRelat Res	33	Hip	30	28/30	43 (24–70)
Wan, 2012	J Arthroplasty	33	Knee	31	28/31	44 (24–62)
Garcia-Oltra, 2012	J Arthroplasty	35	Hip	32	31/32	48 (14–85)
Total		507	–	492	467/492	44 M (6–132)
%		100	–	97	94.9/97	–

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ДО УВАГИ СПЕЦІАЛІСТІВ

ДУ “Інститут патології хребта та суглобів ім. проф. М. І. Ситенка НАМН України” проводить післядипломну підготовку лікарів-іноземців у клінічній ординатурі та у формі стажування за спеціальністю «Ортопедія і травматологія», на курсах інформації та стажування з актуальних питань ортопедії та травматології (ліцензія Міністерства освіти і науки України від 01.11.2010 р. №529881)

Курси інформації та стажування для лікарів-спеціалістів

№	Назва курсів	Керівник курсів
1	Хірургічні та консервативні методи лікування хворих з патологією суглобів	Проф. В.А. Філіпенко
2	Ендопротезування великих суглобів	Проф. В.А. Філіпенко
3	Хірургічні та консервативні методи лікування дітей з ортопедичною патологією	Д.м.н. С.О. Хмизов
4	Сколіотична хвороба, хірургічні та консервативні методи лікування	Д.м.н. С.О. Хмизов
5	Хірургічні та консервативні методи лікування хворих з патологією хребта	Проф. В.О. Радченко
6	Мануальна терапія в комплексному лікуванні хворих з патологією хребта	Проф. В.О. Радченко
7	Хірургічні та консервативні методи лікування травматичних ушкоджень кістково-м'язової системи	Проф. М.О. Корж
8	Реконструктивно-відновлювальна хірургія опорно-рухової системи в разі наслідків травм та ортопедичних захворювань	Проф. М.О. Корж
9	Лабораторні методи дослідження в ортопедії та травматології (клініко-діагностичні, біохімічні, морфологічні, імунологічні)	Проф. Н.В. Дедух К.б.н. Ф.С. Леонтєва
10	Патологія стопи, її профілактика, лікування та протезно-ортопедичне забезпечення	Проф. Д.О. Яременко
11	Немедикаментозні методи лікування в ортопедії та травматології	Проф. В.І. Маколінець
12	Лікувально-профілактичне експрес-ортезування та експрес-протезування опорно-рухової системи	Доц. О.А. Диннік І.Б. Тимченко
13	Артроскопічна діагностика та лікування патології великих суглобів	К.м.н. П.В. Болховітін
14	Хірургічні та консервативні методи лікування дітей з патологією кульшового суглоба	К.м.н. О.І. Корольков
15	Післязіометрична релаксація і масаж в ортопедії та травматології	К.м.н. В.А. Стауде