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Legislation on hip prostheses?

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The EEC is striving to establish a single common market in 1992 without trade barriers between member states. This also has implications in terms of acceptance requirements for medical appliances: from 1992 on, an appliance admitted to the market in one member state will have to be accepted by all the other member states without additional requirements.

Acceptance of medical appliances, unlike that of pharmaceuticals, is at this time hardly subject to legislation in The Netherlands. In view of EEC guidelines, this will have to change. Measures to be taken will be more stringent as to risk to the patient increases. Considerations focus on a classification of "risk classes" comparable to the system used in the USA by the FDA.

Proposals so far made envisage classification of orthopedic implants in the medium risk class. Measures to be taken for that class will mostly focus on testing the production process used by the manufacturer. A so-called premarket approval will not be required for these products. The question arises whether these measures—arising from economic considerations—do in fact adequately guarantee the patient's safety.

In an effort to answer this question, an investigation was instituted into quality control for orthopedic implants, more specifically hip prostheses. The purpose of the investigation was to establish the cause of quality problems in hip prostheses, and whether or not legislation would be an effective way to ensure adequate quality of hip prostheses, as measured by their life span outside the body. Loosening is the principal complication abbreviating this life span, and loosening is influenced by three factors: product, expert surgical skill, and patient.

By a study of the literature and by interviews of surgeons as well as representatives of the industry, an attempt was made to identify the principal quality problems. These problems were arranged in a so-called life-cycle model in order to make the "problematic life phases" of a hip prosthesis more surveyable.

The findings show that problems are more likely to develop during the following phases: design, experimentation, acceptance for use, and application.

It looks as if the measures envisaged will only marginally counteract these problems. Moreover, the legislator's view is that the quality of health care is primarily the responsibility of those providing that care.

The conclusion must be that self-regulating activities with emphasis on the "problematic life phases" should be initiated and stimulated by the medical profession. Legislative measures creating conditions might play a role in this context. Activities should focus in particular on examination of new designs, acceptance for use, central registration, and training/expert skill.

The value of CT-discography in determining indications for percutaneous nucleotomy

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Percutaneous nucleotomy was evolved towards the end of the 1970s and initially involved manual removal of nucleus pulposus tissue with the aid of a forceps. In 1985, Onik introduced the procedure of "automated percutaneous lumbar discectomy," which proved to have a low rate of complications and a high success rate. Since February 1988, we have used this technique in treating patients with a slipped disc. The results obtained in the first 40 patients thus treated were analyzed with special reference to the value of CT-discography in determining the indications for the operation.

Material and method: A CT-discogram was always obtained prior to percutaneous nucleotomy. The contrast medium distribution within the disc was recorded using the Düsseldorf Discogram Description (a modification of the Dallas Discogram Description). The most pathologic forms in this classification are divided into types VA, VB, and VC,

with type VA being a slipped disc with a broad contrast medium base, type VB one with a narrow contrast medium base, and type VC a sequestrum.

Results: A correlation was found between CT-discographic results and the success of the operation. Eleven of the 40 patients subsequently had a herniotomy performed in view of persistent or increasing complaints. Of these 11 patients, 9 had type VB! Although this was a preliminary analysis of a small series of patients, the findings seem to warrant the conclusion that CT-discography is indispensable in determining indications for percutaneous nucleotomy.

In vitro culture of mature human perichondrium

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Repair of defects in cartilage has so far been difficult. It has been demonstrated both in vivo and in vitro that immature animal perichondrium is capable of forming cartilage with hyaline characteristics. Whether this also applies to mature human perichondrium is not actually known. Because human cartilage is much thicker than animal cartilage, the ability to form cartilage is also important. The possibility as well as the ability of mature human perichondrium to form hyaline cartilage was histopathologically evaluated in an in vitro model. Cartilage formation was observed after no more than 7 days' culture, and after 10 days the thickness of the newly formed cartilage was about 300 µm. The newly formed cells presented the appearance of healthy cartilage cells.

The findings warrant the conclusion that mature human perichondrium shows a marked ability to form hyaline cartilage in vitro.

Perichondrium transplantation to repair cartilage defects of the knee

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Ten patients (9 males and 1 female averaging 31 years of age) were selected for this procedure after arthroscopy. The more frequent preoperative symptoms were pain on motion (9), hydrops (8), pain at rest (7), and screw-down complaints (6). Causes of the 12 cartilage defects were trauma (6), osteochondritis dissecans (2), patellar chondromalacia (2), and chondrocalcinosis (2). Their locations were patella (4), medical femoral condyle (7), and lateral femoral condyle (1).

Operative procedure: arthrotomy via a medial Payr incision; reaming of defect down to subchondral bone; transverse incision over the costal arch; dissection of a flap of perichondrium; application of a fibrin line followed by insertion of the perichondrial graft into the defect, with the chondral side of the graft turned towards the joint.

Postoperative management: Plaster-of-Paris splint (2 weeks) and motor sled (2 weeks). Walking without weight bearing up to 3 months after the operation. Arthroscopy 3–12 months after the operation revealed a completely filled defect (tissue resembling cartilage) in 11 of the 12 instances.

At follow-up after 1 year, 8 of the 10 patients were entirely free from symptoms; there was complete restoration of function in all the cases. The mean preoperative knee score (Ranawat) of 69.9 had increased to 87.8.

Conclusion: Perichondrium transplantation to repair cartilage defects of the knee gives excellent biological and functional results.

Long-term results of chemonucleolysis

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A consecutive series of 200 patients treated by chemonucleolysis for slipped disc was studied prospectively. The effect of chemonucleolysis and the actual condition of the patients at two follow-ups were studied by questionnaire some 2.5 and 7 years after chemonucleolysis. At the first follow-up, 173 patients were submitted to physical examination and radiography. Five patients died in the course of time. At the first follow-up, 76 percent of the patients were in a satisfactory condition in terms of their back problem and its consequences. At the second follow-up, the situation was similar, but 9 percent reported more complaints, and 8 percent fewer complaints. Twelve patients were treated by an operation in view of persistent symptoms or an early relapse, but their condition usually remained unsatisfactory. In view of a recurrent slipped disc, 13 patients submitted to a second chemonucleolysis or discectomy after an asymptomatic interval of at least 3 years, and their condition usually remained satisfactory. The effect of chemonucleolysis proved to be sufficient in 70 percent and insufficient in 30 percent of the cases. The results were best in adolescents (100 percent success) and in males aged 20–30 years (93 percent success). The poorest results were observed in females aged 30–40 years (45 percent success) and in patients already on a disability pension before treatment (15 percent success).

The more evident the radicular symptomatology prior to treatment, the better were the early and late results. No correlation was demonstrable between chemonucleolysis effect and number of discs injected or degree of disc narrowing observed.

Long-term mild-to-severe back symptoms and ischialgia were common, but according to the literature not more common than after operative or conservative therapy. These long-term complaints probably had little to do with the chemonucleolysis, but could in part be due to progressive degenerative changes.

Can sonography replace radiography in the diagnosis of congenital dysplasia of the hip?

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Sonography of the hip is being used increasingly in examining patients suspected of congenital dysplasia of the hip (CDH). The trend is to use sonography to replace conventional radiography. The two methods were compared in 255 patients (510 hips) referred to the orthopedic surgeon with suspected CDH.

The positive predictive value of sonography was found to be 87 percent, versus a negative predictive value of 99 percent (respective ranges 78–95 and 99–100 percent). Specificity was high: 98 (97–99) percent. Sensitivity was 95 (90–100) percent. The conclusion is that sonography, if it gives no abnormal result, can replace radiography for infants aged at least 3 months. For infants below this age, the examination should be repeated at 3 months. Abnormal sonographic findings always indicate the necessity of radiography.

Factors determining the success of an acromioplasty according to Neer

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Acromioplasty results are often unpredictable. For a better understanding of prognostic parameters, 36 patients treated by acromioplasty were studied in retrospect. Of the 38 shoulders treated, 31 were examined, while information on the remaining 7 was obtained by telephone or correspondence. The follow-up averaged 24 (2.5–57) months. Results were favorable in 27 instances, moderate in 9, and poor in 2. Age proved not to influence the results, but sex did: four fifths of the males and three fifths of the females. The dominant side was most often involved, but acromioplasty on the nondominant side scored better. Good results were generally obtained in impingement stage III and posttraumatic impingement. Occupation played an important role: the 11 poorly scoring shoulders were all in the group of patients doing heavy work. Only 3 of these returned to their former occupation (versus 11 of the other 12 patients). Preoperative limitations of shoulder function (16 cases) did not preclude a good result (14 cases). Radiography revealed in most cases lesions related to impingement. In the case of acromioclavicular arthrosis, omission of a lateral clavicle resection led to a poor result. A positive impingement injection test predicted a good result in 27 shoulders. The approach to the coracoacromial ligament (cleavage or resection) was of no influence. Omission of an acromion resection in stage II impingement did not affect a good result in 7 of the 9 cases. A favorable outcome was observed in 6 of the 8 instances of cuff rupture . The shoulders with a follow-up of at least 1 year scored favorably in four fifths of the cases; 5 of the 11 unsatisfactory shoulders had a follow-up of less than 1 year.

Discopathy developing after intercorporeal spondylodesis: A long-term follow-up and matched-pair study

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There is no consensus about the question whether spondylodesis in the long-term predisposes to accelerated development of a discopathy in adjacent segments. It has been previously demonstrated that even long after successful ventral spondylodeses for spondylolisthesis no significant increase in discopathies of adjacent segments occurred. In this study, however, no control group was involved.

In a retrospective study of 16 patients treated by intercorporeal spondylodesis of L4–5 and/or L5–S1 during the period 1962–1966, the development of discopathies was studied in 1983 (after a mean follow-up of 17.5 years) on the basis of lateral radiographs in flexion and extension. The mean age at operation was 35 years; that at follow-up was 52 years. Discopathy parameters studied were those developed by Farfan (1973), Van Akkerveeken (1979), and Nachemson (1981). For each patient, moreover, a sex- and age-matched test subject without chronic back symptoms was selected in whom the presence/absence of discopathy at a lumbar level was examined using the same radiographic parameters.

In the longitudinal study of the patient group, only 12 of the 30 segments compared developed signs of discopathy and/or instability up to 1983. The long follow-up made it possible to distinguish four different developments in the patient groups: (1) a stable segment became unstable; (2) an unstable segment remained unstable; (3) an unstable segment became stable; (4) a stable segment remained stable (4, 4, 8, and 14 cases, respectively).

In this group, only a small number of segments showed progression of instability. In this phase only four segments

developed a discopathy expressed as reduced disc thickness (Farfan 1973).

In the matched-pair study, 43 segments in both groups were compared. At the time of the last examination, signs of discopathy and/or instability were observed in 17 segments in the patient group versus 21 segments in the control group.

The conclusion was that even after a long time patients with a ventral spondylodesis did not show a higher frequency of discopathy and/or instability of adjacent segments than was found in an age- and sex-matched control group.

Implantation of an isoelastic RM prosthesis in congenital dysplasia of the hip with painful high dislocation

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Uncemented hip replacements of the isoelastic type (RM prostheses) have been in use at our hospital since 1981. Fourteen patients with congenital dysplasia and painful high dislocation of the hips were treated by reconstruction and distalization in one session. The mean duration of the operation was 60 min. The immediately achieved lengthening averaged 3.5 cm (achievable only after dissecting the adductor, iliopsoas, gluteus, and exorotator muscles from their origins and lengthening them). The mean age of these patients was 37 years. At follow-up after an average of 3 years, all the patients expressed subjective satisfaction. The Merle d'Aubigné pain score was 6 in 12 cases and 5 in 2 cases. In no case was postoperative mobility less than that before the operation. In a few cases a very narrow femoral shaft made it impossible to insert the femoral part of the RM prosthesis; in these cases a CDH prosthesis according to Müller was used. The cup component of the RM prosthesis was used in all the cases. So far, no loosening or other complications have occurred. In these relatively young patients, the isoelastic prosthesis has to date produced satisfactory results.

Weight-bearing talocrural arthrodesis

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Some 30 different techniques of talocrural arthrodesis have been described. Most of these do not permit weight bearing until a late stage. We developed an immediate weight-bearing modification of the distraction-compression technique with two crossed traction screws for internal fixation. During the period 1987–1988, this technique was used in the treatment of 12 patients with a mean age of 60 (32–76) years. The operative indication was rheumatoid arthritis in 5 cases, poliomyelitis in 3, and posttraumatic arthrosis in 4. Three patients had undergone three previous arthrodeses; 1 patient showed a pseudarthrosis after talocrural arthrodesis. Complete weight bearing was possible after an average of 3.5 (1.5–8) weeks. Immobilization in a plaster cast averaged 10 weeks and was discontinued when radiographic signs of consolidation were observed. The mean hospitalization was 3.5 weeks. The follow-up period averaged 18 (6–38) months. Five patients were able to walk unaided, and 5 needed a cane; 1 female patient developed pseudarthrosis.

Conclusion: Our modification of the distraction-compression technique of talocrural arthrodesis permits weight bearing in an early stage and gives satisfactory results.

Visco-elastic behavior of acrylic bone cement and ways to influence its apparent viscosity

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Immediately after mixture of the fluid and the powder component, bone cement behaves like a fluid and shows the corresponding time-dependent viscous properties. After setting, a solid with elastic properties remains. During the setting time the cement shows so-called visco-elastic behavior. These two properties have been measured separately by means of oscillating rheometry applied to several cement types. It was found that viscosity predominates during application, whereas the elasticity modulus does not increase markedly until the end of the setting phase.

Combined measurements of visco-elastic behavior are possible with the aid of shearing tests, whose outcome is interpreted as "apparent viscosity." The changes in this apparent viscosity seem highly dependent on the type of cement involved. On this basis a distinction can be made between low-, medium-, and high-viscosity cement types. Ten types of cement were tested at a shearing speed of 0.36 s^{-1}, and classified as follows: high-viscosity cement suitable only for manual application: Palacos R and CMW1; medium-viscosity cement suitable for both manual and syringe application: Palacos EMD 52-521 and 42-522, Sulfix-6, Surgical Simplex RO, Zimmer Traditional and CMW3.; and low-viscosity cement suitable only for syringe application: Zimmer LVC and Cerafix.

The apparent viscosity of bone cement largely determines the depth of penetration of pressurized cement and the force required for insertion of a prosthesis. A higher shearing speed and a lower environmental temperature lead to reduced apparent viscosity. A higher shearing speed reduces the viscous component while leaving the elastic component unchanged.

A lower environmental temperature decelerates the process of chemical polymerization, thus significantly increasing the duration of the application phase, but also the total setting duration.

Operative treatment of Scheuermann's kyphosis

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The results of various operations to correct Scheuermann's kyphosis were studied in retrospect, analyzing clinical and radiographic data on 59 patients from six different hospitals. The results of an enquiry by questionnaire were considered as well.

We compared the results in 30 patients treated by anterior release and spondylodesis using the Slot–Zielke instrumentarium (ARSZ), 18 treated by Harrington spondylodesis (HS), and 11 treated by anterior release combined with Harrington's spondylodesis (ARHS).

The mean follow-up period was 3 years. The mean preoperative kyphosis angle was 75°. Both immediately after the operation and at the last follow-up, correction of the kyphosis reached the highest rate in the ARHS group: 46 and 37 percent, respectively. At the last follow-up the correction results of the HS and ARHS group were comparable: Loss of correction reached the highest rate in the HS group: 14 percent. Instrumentation complications were observed with all the operative procedures and mainly consisted of rod and screw breaks and loosening of hooklets. Septic complications in 2 cases were effectively controlled. The only major neurologic problem was a winged scapula resulting from a lesion of the long thoracic nerve.

Neurovascular lesions caused at arthroscopy of the elbow

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Introduction of an arthroscope into the elbow joint entails a risk of damage to neurovascular structures. The literature shows that neurovascular lesions are much more common after arthroscopy of the elbow than after arthroscopy of the knee.

For better assessment of the risk of neurovascular damage, arthroscopy of the elbow was performed on 5 cadavers. Three approaches were used: posterolateral, anterolateral, and anteromedial. For the anterolateral and the anteromedial approach, the site of entry chosen differed or that usually indicated in the literature. After the arthroscopy the distance between the arthroscopy tract and various neurovascular structures was measured. After an anterolateral approach the smallest distance measured to the radial nerve was 10 mm. After an anteromedial approach the distance between the arthroscopy tract and the median nerve was 12 mm.

It is advised that for arthroscopy of the elbow the approaches should be chosen carefully and carried out in a standardized fashion in order to reduce the risk of damage to neurovascular structures.

Patellectomy for comminuted patellar fractures

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In the case of a severely comminuted patellar fracture, it is technically difficult or even impossible to achieve stable osteosynthesis. The alternative is the removal of all the loose fracture fragments and reinsertion of the extensor apparatus. During the period 1974–1988, 46 partial and 13 total patellectomies were performed as primary operations.

In a retrospective study the clinical and radiographic results of 33 partial and 11 total patellectomies were evaluated after a mean follow-up of 7 years. In most cases the function of the hamstrings and quadriceps muscles could be objectively assessed with the aid of the Cybex isokinetic dynamometer. Most patients treated by (partial) patellectomy were asymptomatic and totally unrestricted in day-to-day and athletic activities. Seven patients complained of some slight pain, while others complained of pain interfering with day-to-day activities. The mean Lysholm score was 92.9. Some restriction of knee function was reported by 5 patients (slight in 4 cases and moderate in 1); 28 patients reported unrestricted function. A striking finding was the valgus instability of 9 knees (not causing complaints).

All the patients showed some quadriceps atrophy with objective loss of strength; in 8 cases atrophy and loss of strength were pronounced. Quadriceps atrophy was most marked after total patellectomy. Patellofemoral arthrosis was observed in 9 cases and gonarthrosis in 3.

Conclusion: The clinical results many years after (partial) patellectomy performed primarily for comminuted patellar fractures are excellent. Whenever a comminuted patellar fracture cannot (or only with great difficulty) be effectively treated by exercise-stable osteosynthesis, partial or (if necessary) total patellectomy is a valuable alternative.