Clinical and Radiographic Investigation of Bone Defects Following the Application of a Collagen Matrix

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Summary

Large bone defects of the jaw have, so far, been filled with various types of bone implants, mainly synthetic nonresporative aloplastic implants (hydroxilapatite). As we have data only for two types of resorptive xenogenic bone implants, the purpose of this investigation was to examine resorption and osteoinductive capability of OSTEOVIT as a material for filling bone defects after removing large cysts (more than 20 mm in diameter) and after apicectomy of the tooth, where more than 1/3 of the tooth has no strong bone bases.

Osteovit is a collagen matrix of calf spongiose consisting of porous collagen purified of antigens, fats minerals, enzymes and all other noncollagen materials.

Forty-one patients, 9 female and 32 male aged 15-54 years were included in the investigation Nineteen of them had a clinical diagnosis of OPC and 22 a clinical diagnosis of cysts radicularis. All patients had a indication for apicectomy indicating that they had bone defects larger than 20 mm in diameter or destructive alveolus along more than 1/3 of the tooth root.

The results are shown on the basis of a clinical follow up and radiographic examination 6 months, 1,2,3 and 4 years after surgery. If, in some cases, a fistula was found during the postoperative follow-up the treatment was recorded as clinically unsuccessful. Success on the basis of radiographic criteria was also evaluated. First we classified defects into periapical (circumscriptive) and those along the tooth root and than divided the rays into two groups.

Unfortunately results for only for 22 patients were abtained and the others were excluded from the investigation because of incomplete follow-up.

With regard to total success, according to clinical criterium, 20/22 patients had good clinical diagnosis, i.e. 91%. By radiographic analysis we found complete healing in 13/22 patients or 59%. We also analysed results according to the localization of the periapical change. It was concluded that patients with circumscriptive changes were 88% clinically successful while those with a defect along the tooth root were 93% clinically successful.

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According to the results of this investigation it can be concluded that OSTEOVIT is a very good resorptive material for filling bone defects and with OSTEOVIT it is possible to widen indication for apicotomy to include cases where more than 1/3 of the tooth has no strong bone base.

Key words: *colagen matrix, bone defects.*

Introduction

Today, the surgical profession in the field of modern medicine and dentistry, cannot be imagined without the use of alloplastic materials for reconstruction and replacement of removed bone tissue. The aim of scientists is to discover a material, which, after implantation in bone defects, would stimulate the formation of bone, form a firm connection with the base and have the characteristics of bone (1). During the last few years the use of biocompatible synthetic materials, which have an osteoinductive effect, has become increasingly more frequent.

In 1968 Kramer and co-workers (2) classified implants for filling bone defects into four basic groups:

1. *Autologous* (autogenous) bone implants - transplanted from one place to another on the same individual (cortical bone, bone marrow, cartilage).
2. *Homologous* (allogenous) bone implants - transplanted from one individual to another of the same species (freeze-dried cortical bone and bone marrow, freeze-dried and decalcified cortical bone and bone marrow, combination of dried allogenic and autogenous bone.
3. *Xenogenic* (heterogeneous) bone implants - transplanted from an individual of one species to an individual of another species (endobon, bio-oss, bio-plant, kiel-bone, knee-cap, osteovit).
4. *Alloplastic* (synthetic) bone implants - artificial materials (collagen fibres, glass ceramics, hydroxylapatite, tricalciumphosphate).

Several papers have been published evaluating the healing of bone following apicotomy (3,4,5). On the basis of radiographic follow-up and criteria established by Molvan and co-workers in 1987 (6), four kinds of healing of the periapical region after apicotomy, are differentiated.

1. Complete healing
2. Incomplete healing
3. Unreliable healing
4. Unsatisfactory healing

In the field of bone surgery efforts are being made to discover a material which could substitute bony tissue. Such material should have osteoinductive or osteoconductive properties. At present, morphogenetic protein is closest to such an ideal material, although it is still not in everyday use. Apart from other alloplastic materials OSTEOVIT is in use today in bone surgery.

Osteovit is a collagen matrix of calf spongiose from which, by a special process, antigens, fats, minerals, enzymes and other noncollagenous elements are removed. It has exceptional tissue tolerance, and resorbs with phagocytose within six months after implantation into the bone defect, and the time of resorption depends on the localisation, quantity of implanted material and mechanical causes. Osteovit stimulates osteogenesis in the bone cavity and in the soft tissues it is substituted by connective tissue. The aim of this investigation was to assess the value of collagen matrix of calf spongiose (OSTEOVIT) as a material for filling larger bone defects, and to determine the success of implantation with regard to the time elapsed after surgery and the type of bone defect.

Material and methods

The investigation included 41 patients (9 female and 32 male) aged from 15 to 54 years. Nineteen

patients had a clinical diagnosis of ostitis periapicalis chronica and twenty-two a clinical diagnosis of cystis radicularis. Results were obtained for only 22 patients, as the others were excluded from the investigation due to incomplete follow-up. All the patients had wide indication for apicotomy, i.e. they had bone defects larger than 2 cm in diameter, or destroyed alveolus along more than one third of the tooth root. Several pathological changes were found in the upper jaw of 32 patients, and in the lower jaw of 9 patients. All patients underwent surgery in the Department of Oral Surgery, School of Dental Medicine, and in the Clinic of Maxillofacial and Oral Surgery in Zagreb, during the period from 1990 to 1994.

Results

Results are presented on the basis of a clinical follow-up and X-rays performed after 6 months, one, two, three and four years following surgery. Cases in which a fistula was diagnosed during the postoperative follow-up were recorded as clinically unsuccessful treatment. Success was also assessed on the basis of radiographic criteria, by first classifying defects into periapical (circumscriptive) defects and those located along the tooth root, and dividing them into two groups.

Criteria for radiographically complete healing: lamina dura visible along the whole of the tooth root, can be slightly enlarged, or with a defect of up to 1 mm. This category also includes cases with newly formed bone, but of less intensity than the surrounding healthy bone, and cases with completely new bone formation, but without visible lamina dura on the apex of the tooth root.

Criteria for radiographically incomplete healing: periapical transparency visible in contact with the tooth apex or independently in the newly formed bone, which is considered to be scar reparation.

A total of 41 patients underwent surgery during a period of four years, of which the results of only 22 patients were available, while the remaining patients were excluded from the investigation due to incomplete follow up (Table 1).

An analysis of the overall success, according to clinical criteria, showed 20/22 patients had a normal clinical finding, which is 91% success. In two patients a fistula was clinically diagnosed, and they were clinically assessed as failure. Analysis of X-rays determined complete healing in 13/22 (59%) patients and incomplete healing in 9/22 (41%) patients. No case of radiographically unsatisfactory healing was determined.

The results were also analysed with regard to the period of time elapsed after the surgery (Table 2).

Four years following surgery a normal clinical finding was determined in 2/3 (66%) patients. None of the patients who underwent surgery in 1991 reported for a check-up and thus there is no group with a three-year follow-up. Two years following the surgery only one of the four patients was examined, in whom a normal clinical finding was found. The best results were observed in the groups with one-year follow-up after surgery and six months after surgery. One year after surgery 11/12 (92%) patients had a normal clinical finding. Normal clinical finding was determined in all six patients during a check-up six months after surgery. Results were also analysed with regard to the localisation of the periapical changes. Operations were performed on eight patients with circumscriptive periapical changes and 14 patients with a defect along the tooth root (Table 3).

Clinical success was determined in 88% of patients with circumscriptive changes and complete healing was determined radiographically in 75%. Clinical failure was determined in 1/8 patients, and incomplete healing was determined radiographically in 2/8 patients. Clinical success was determined in patients with a defect along the tooth root in 13/14 patients (93%), and only one patient had a clinical fistula. Complete healing of the defect radiographically determined in 50% of patients, and the same percentage of incomplete healing (Figure 1 and 2).

In order to establish whether the success of surgery depends on certain characteristics of individual patients, univariate methods of statistical analysis were applied. Correlation of the results with regard to the age and sex of subjects was determined, clinical success and radiographic success independently. Correlation was also investigated between the clinical diagnosis and localisation of pathological changes with certain characteristics of the subjects.

Fisher's exact test was used to test the difference in success, for category variables, instead of the usual X 2-test, because of the relatively small number of patients in the examined groups. For continuous variables, the age of patients, non-parametric "Wilcoxon rank sum" test was used.

Results of the analysis showed that clinical success, i.e. 20 successfully recovered patients out of 22 (90.9%), did not statistically depend on any one characteristic of the patients. This is more likely be a consequence of the small number of patients than the complete lack of dependence (of surgical success) on the analysed variables.

Analysis of radiographic success showed that it depended significantly on the patient's sex; 16.7% successfully treated female patients compared to 75.0% successfully treated male patients (p=0.023). Although marginal, the significance of the role played by diagnosis, with regard to radiographic success was observed. Success in patients with a diagnosis of OPC was 42.9 %, and in those with CYS 87.5 % (p=0.074) (Table 5).

Although not statistically significant, difference in the success of OSTEOVIT application was observed, depending on which jaw was in question. With regard to radiographic criteria better results were realised in the mandibula, i.e. 80%, than in the maxilla, 52.9%. Furthermore, correlation analysis (Spearman's correlation of ranks) showed correlation of radiographic success with sex (p=0.0115) and diagnosis (p=0.0421).

According to clinical and radiographic criteria a healed patient was considered completely successful. Analysis results are presented in Table 6.

When success is analysed with regard to the diagnosis, differences can be seen, although not statistically significant. Complete success depends significantly only on sex (none of the female patients were completely healed. In the case of patients with a diagnosis of OPC 35.7% were completely healed, compared to 75.0 % completely healed patients with a diagnosis of CYS.

Statistically significant dependence of recovery (both RTG or complete) on sex can be explained by the significant correlation (Spearman's correlation of ranks, p=0.03) of sex and diagnosis, presented in Table 4. All six female patients had a diagnosis of OPC, while in the male patients diagnoses were evenly distributed (50% had a CYS diagnosis, and 50% OPC diagnosis). Fisher's exact test also showed statistically significant difference in a distribution of sex with regard to diagnosis (p=0.051) (Table 7).

Discussion

The use of bone transplants is today frequently indicated in maxillofacial and oral surgery. A transplant not only accelerates post-operative recovery by shortening the healing process, but is also a good haemostatic, preventing bleeding and collapse of soft tissue in the empty space. Undoubtably, the best material for osteoplastics is fresh autologous bone (7,8,9,10), although such an intervention excludes out-patient treatment, because it involves another surgical field (hip, rib, lower leg) and increases the possibility of infection (7,8,11,12). For this reason homologous and xenogenic implants are used. During a comprehensive clinical and histological investigation of nine different types of homologous and xenogenic transplants, Heiple and co-workers came to the conclusion that freeze-dried homologous bone is the best substitute for autologous bone transplant. Many authors (13, 14,15,16,17) have reported that 40 % of bone transplants are resorbed during the first 6 months following surgery, and later 60-80% of the transplant is resorbed. Since 1983 investigations have continued of xenogenic transplants for filling bone defects. Choi and coworkers assessed the effectiveness of collagen matrix for healing peridontal defects in dogs (18). In seven hunting dogs defects were made (6x4 mm) above the upper canine, through the vestibular bone wall, and filled with collagen matrix. Contra-lateral defects served as controls. Four weeks following the surgery the dogs were sacrificed. Samples were made for histometric analysis and it was concluded that the collagen matrix neither increased the formation nor prevented healing of bone in this model. Having been thoroughly tested on animals, the composite polymer, material based on "poly (2-hydroxyetyl methacrylate)" and calf skin collagen was allowed to be used in limited clinical experiments in the Czech Republic. The obtained clinical results were presented as reports and are very encouraging for wider use of this type of biomaterial in the field of human surgery. Numerous

authors (19,20,21,22) have studied the effects of various bio-materials used in surgery for the substitution of bone. The materials used were collagen matrix of calf spongiosis (OSTEOVIT) and two kinds of hydroxylapatite (CEROS 80, OSTILIT). The results demonstrated that exposure to Osteovit increased proliferation of human osteoblasts, while Ceros and Ostilit induced a reduction in cell growth.

Results of this investigation confirm that of the use of OSTEOVIT as a resorptive material for filling larger post-operational bone defects is justified, and judging by the overall success with regard to clinical criteria, 20/22 patients had a normal clinical diagnosis, which is 91% success.

Conclusion

In conclusion it can be said that OSTEOVIT is a very good resorptive material for filling circumscriptive periapical bone defects and defects along the tooth root. If the clinical status only is analysed the results are almost identical, slightly more in favour of defects along the tooth root (93% : 88%). However, the results according to radiographic evaluation differ significantly, and are much more in favour of circumscriptive periapical bone defects (75% : 50%).

According to the results of this investigation it can be concluded that with Osteovit it is possible to extend indication for apicotomy to include those cases where more than two thirds of the tooth root lacks a firm bone base. Almost one third of patients with a defect along the tooth root have at the same time a normal clinical finding with incomplete radiographic healing. This prompts the conclusion that assessment of the failure of implant application and possibility of further surgery, can be decided solely on the basis of the clinical diagnosis.