The Effects of Surgicel® on Bone Formation

JAMES F. NAPPI, M.D.
JAMES A. LEHMAN, Jr., M.D.
Akron, Ohio 44302

The subperiosteal implantation of Surgicel® has been advocated for the stimulation of bone formation by some authors. A clinical trial in five patients demonstrated no radiographic evidence of bone formation after 12 months. An experimental model was designed in the rabbit. This study also demonstrated no radiographic or histologic evidence of bone formation with the use of subperiosteal Surgicel®. The further use of Surgicel® for the stimulation of bone formation is not recommended.

The closure of secondary palate fistulae using bone grafts was described by Jackson (1972) and is a significant advancement in secondary cleft surgery since it stabilizes the orthodontically aligned dental arches. In 1978, we described a similar technique for the closure of secondary palatal fistulae. Since then, bone grafting for the closure of secondary palatal fistulae has become an accepted procedure with well documented results (Figure 1). It must be taken into consideration, however, that bone grafting significantly lengthens fistula closure and may add to postoperative morbidity.

"Boneless" bone grafting for the closure of the anterior cleft palate defect was introduced by Skoog (1965), using a periosteal rotation-flap. In 1967, Skoog published his results on boneless bone grafting using subperiosteally placed Surgicel®, which he felt contributed favorably to new bone formation. Both of these technics were performed at the time of the primary lip repair. Thilander and Stenstrom (1970) described new bone formation with the use of Surgicel® in experimentally created premaxillary bony clefs in guinea pigs. They felt that Surgicel® produced a better response than other implanted sub-

stances utilized in their study. In 1974, they reported good results with this procedure in a series of patients. It should be noted that the periosteal flap is also a common factor in all of these reports.

In a search for an alternative method to bone grafting in the treatment of anterior palate fistulae, Surgicel® was placed between the periosteum of the oral and nasal closures in five selected patients between five and eight years of age. All of the patients had moderate palatal fistulae and did not require palatal expansion. The fistulae were all successfully closed, but follow-up between six and 12 months failed to demonstrate any radiographic evidence of bone formation (Figure 2). Because of this, we decided to re-examine the effects of Surgicel® upon bone formation implanted subperiosteally.

Methods

Various methods were considered in order to create an experimental model that would resemble the situation in a repaired palate fistula. This situation consists of a bilamellar periosteal tube with membranous bone at each end. Implantation beneath just the maxillary periosteum did not meet the criteria, and a model using the subperiosteal rib resection was chosen. Subperiosteal rib resections were performed in 16 New Zealand white rabbits. The rib resections were performed in alternate ribs taking care to preserve the periosteum. Following the resection, the periosteum was closed in one rib as a control. In the second rib, the space was filled with Sur-
Surgicel® in the fashion described by Skoog and the periosseous space were filled with microfibrillar collagen (Avitene®) in an attempt to duplicate the use of collagen products described by Thilander and Stenstrom (1970). These procedures were performed with intravenous Pentobarbital anesthesia under sterile conditions.

Animals were sacrificed at one, four, and eight weeks. Radiographic examinations were performed in a standard fashion. Serial sections of the specimens were taken in a longitudinal plane to include both resected ends of each rib. Sections were then decalcified and stained with hematoxilin-eosin for microscopic examination.

**Results**

No wound healing complications were encountered in animals surviving longer than one week. Two animals expired within the first 24 hours because of pneumothorax, which was a technical complication. In addition, three animals expired within the first six post-operative days and were noted to have wound infections. Three animals were sacrificed at one week, and four animals were sacrificed at four and eight weeks respectively.

**Radiographic.** At four weeks post-operatively, there was radiographic evidence of bone formation in the control rib. There was also some suggestion of bone formation noted in the Avitene® implanted spaces. There was no evidence of bone formation in the periosteal spaces implanted with Surgicel®.

At eight weeks post-operatively, there was radiographic evidence of increasing calcification and bone formation in the control. There was also increasing evidence of calcification and bone formation in the Avitene implanted spaces. Once again, there was no evidence of bone formation in the Surgicel® implanted spaces (Figure 3).

**Histologic.** At one week post-operatively, the control demonstrated evidence of an inflammatory reaction and some resolving hematoma beneath the periosseous space at four weeks, there was definite bone formation in the subperiosteal space with bridging of the gap. By eight weeks, there was further increase in new bone formation in the subperiosteal space, and there was maturation of the bone (Figure 4).

At one week postoperatively, there was an inflammatory reaction beneath the periosteum with a moderate number of residual Avitene® particles noted in the subperiosteal space. By four weeks post-implantation, there was definite bone formation in the periosteal space with bridging of the gap. No residual Avitene® particles were present at this time. At eight weeks, increasing bone formation was noted in the subperiosteal space, although it was less extensive than that noted in the control after the same time interval (Figure 5).
FIGURE 3. Radiographic appearance at eight weeks. Avitene®-right, control-center, and Surgicel®-left. No evidence of bone formation noted in the Surgicel® space.

FIGURE 4. New bone formation and bridging of the gap at eight weeks in the control.
FIGURE 5. New bone formation with bridging of the gap at eight weeks with Avitene®.

In animals treated with Surgicel®, one week post-operatively, there was an inflammatory reaction beneath the periosteum with residual Surgicel® particles. At four weeks, there was some early bone formation at the resected ends of the rib, but the subperiosteal space was filled with a dense mass of fibrous tissue. By eight weeks, there was even more proliferation of dense fibrous tissue in the subperiosteal space without histologic evidence of bone formation except at the resected ends of the rib (Figure 6). Scattered Surgicel® particles were seen in the dense fibrous tissue at both four and eight weeks.

Discussion

Although the results of this study are available only up to eight weeks post-implantation, the clinical usefulness of the periosteal Surgicel® implantation to stimulate new bone formation, as advocated by Skoog (1967) and Thilander and Stenstrom (1970), must be reevaluated. Surgicel®, which is oxidized regenerated cellulose, is a commonly used hemostatic agent. Johnson and Johnson (1963), in their original product description, mentioned the possibility of retardation of bone regeneration at fracture sites. Engdahl (1972) found Surgicel® implantation to result in bone growth disturbances. Rintala and Kanta (1974) found no distinct difference in bone formation by periosteal flaps with or without subperiosteal implantation of Surgicel®.

Our clinical experience in a group of patients between five and eight years of age with subperiosteal Surgicel® implantation has revealed no radiographic evidence of bone formation 12 months after implantation. While there is some clinical evidence that bone formation under periosteal flaps after age six is not reliable, we found the total lack of any bone formation unusual in view of the published reports on Surgicel®. In retrospect, this is not surprising in view of the dense fibrous tissue reaction seen in the experimental animals. Bone formation comes from the periosteum and endosteal bone, and it is obvious that Surgicel® has a detrimental effect on the bone-forming capabilities of both these tissues. In the young children reported by Skoog (1965), we feel that the bone formation oc-
curred from the periosteal flap in spite of the reaction to Surgicel® and not because of it. Further support for this can be found in the reports published by Engdahl (1972) and Rintala and Ranta (1974).

Microfibrillar collagen hemostat (Avitene®) is a denatured bovine collagen, which is also used for its hemostatic properties. It was used in this study because it seemed to closely approximate the collagen substances used by Thilander and Stenstrom (1970). They reported inconsistent bone formation by this method. Avitene® is denatured to tropo-collagen during processing and has been reported to possess a lower level of antigenicity than other commonly used hemostatic agents. The formation of bone with the subperiosteal Avitene® implantation in our model at eight weeks is somewhat less than in the control but of uniform consistency. It would appear that the resorption of Avitene® has less of an effect upon the bone-forming capacity of the perios- teum and bone than does Surgicel®.

Subperiosteal implantation essentially serves as a spacer between the two periosteal surfaces. The subperiosteal implant either remains intact, if inert, or is resorbed by an inflammatory response. Either during or following resorption, the periosteum, if uninhibited, then begins to form new bone to fill the defect. Ideally, the best subperiosteal implant for stimulation of new bone formation is one which essentially serves as a spacer and is resorbed while permitting simultaneous bone formation by the periosteum and endosteal bone. Furthermore, it is not sufficient to have merely a stimulus for bone formation. It is also necessary to have a good vascular bed, for in the absence of a proper milieu the osteocytes may not be synthesized. Surgicel® clearly does not appear to be an ideal subperiosteal implant for the stimulation of new bone formation.

Summary

Subperiosteal Surgicel® implantation has been advocated in the past for the stimulation of new bone formation in cleft palate repairs. Our clinical experience with Surgicel® implantation in the subperiosteal space for stimulation of new bone formation has demon-
strated no radiographic evidence of bone formation 12 months after surgery. Our experimental model at eight weeks is without radiographic or histologic evidence of new bone formation with the use of Surgicel®. Surgicel® does not appear to be an ideal subperiosteal implant material and should probably not be used for that purpose.

References


