New Reconstructive Technologies in Skull Base Surgery

Role of Titanium Mesh and Porous Polyethylene

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Objective: To report on 8 years of experience with 156 titanium mesh and porous polyethylene implants used for craniofacial reconstruction after skull base surgery in 100 patients.

Design: Cohort study with a mean follow-up of 5 years.

Setting: Population based.

Patients: A consecutive sample of 100 patients treated for skull base tumors or craniofacial trauma who underwent reconstruction with 156 3-dimensional titanium mesh and/or porous polyethylene implants. A retrospective review of the Skull Base Program database, along with photographic and imaging documentation, was undertaken.

Main Outcome Measures: Rate of complications as well as the degree of functional and esthetic reconstruction.

Intervention: The reconstructive technique focused primarily on the substitution of removed craniofacial skeleton for oncologic reasons or soft tissue defects.

Results: After completion of follow-up (mean, 5 years), all 100 patients remained healed except for 7 patients (7%) with 8 implants (5%). Overall, excellent craniofacial symmetry and stability were achieved with both types of implants.

Conclusions: Immediate craniofacial skeletal reconstruction and soft tissue augmentation is feasible with 3-dimensional titanium mesh and porous polyethylene implants. The reviewed 8-year evolution in the use of these technologies (156 implants in 100 patients) highlights the excellent tolerance of these implants (5% implant complication rate) in 100 patients (7% complication rate). The few encountered complications were judged to be primarily related to the quality of the overlying soft tissue and not to the implants themselves. The advantages of using these implants for immediate 3-dimensional skeletal and soft tissue substitution, including availability, easy contouring, stability, primary healing, and tolerance of adjuvant therapy, translate to an improved function and esthetic appearance, with a better quality of life for patients.


FUNCTIONAL AND esthetic reconstruction after oncologic surgery, trauma, or repair of congenital deformity directly correlate with subsequent quality of life. However, no reconstructive step should interfere with postoperative adjuvant therapy or close tumor follow-up. Multiple reconstructive autologous tissue transfers and alloplastic materials have been available for many years, but with limitations (eg, restricted availability, difficulty with 3-dimensional contouring, and poor tissue tolerance and acceptance). Only recently have new materials become available that begin to fill the gaps of previous technical limitations. These materials include 3-dimensional titanium mesh and porous polyethylene.

I have treated 100 patients with 156 implants. The results have been very encouraging in terms of achieving functional and esthetic reconstruction as well as complete primary healing. The mean follow-up has been 5 years.

RESULTS

All patients healed primarily and remained healed for the duration of their follow-up (range, 12 months to 9 years; mean, 5 years) except for 7 patients with 8 implants: In 1 patient, the reconstructed orbit was too tight, preventing full range of motion of the eye (periorbita was resected with tumor). Revision surgery, with widening of the most posterior portion of the new orbit, reestablished full ocular range of motion in this patient. Four patients developed vascular problems at the periphery of soft tissue flaps that were used in reconstruction (3 local flaps and 1 microvascular flap) over the titanium mesh. Seven patients died of their disease. Problems with the reconstructed soft tissue, rather than the mesh itself, were judged to be the primary
PATIENTS AND METHODS

In the last 8 years, I have performed reconstruction in 100 patients (aged 7-75 years) with 136 implants consisting of titanium mesh and/or high-density porous polyethylene. Eighty-nine titanium implants were used in 88 patients (34 titanium implants were used alone in 33 patients, and the remaining 55 titanium implants were used in conjunction with polyethylene implants in 55 patients; titanium hemi-mandibles, 2.2 mm thick, with condyles were used in 6 patients, and a combination of both the titanium mesh and a titanium hemimandible was used in 1 patient; and 6 titanium mesh cranioplasties were performed). A total of 67 polyethylene implants were used in 67 patients (12 implants were used alone in 12 patients, and 55 were used in combination with the titanium implants as listed above).

All patients in whom oncologic surgery was performed (n = 84) underwent reconstruction with the use of titanium or titanium/polyethylene implants as part of single skull base surgical procedure. Twelve patients underwent reconstruction with polyethylene implants in a separate secondary procedure after an interval of several years after their initial tumor removal. These secondary procedures were performed in young patients who developed growth changes, creating asymmetry. The 4 patients with trauma also underwent the reconstructive procedure secondarily, as that reflected the timing of their referral. The histologic diagnoses of the tumors and the status of patients after 5 years of follow-up are listed in the Table. The most frequent malignant neoplasms were sarcomas, and the most prevalent benign tumors were meningiomas. The disease-specific survival rate for the group of patients who were treated for malignant tumors and who underwent reconstruction was 78%. The mean follow-up was 5 years. Skull base defects considered for reconstruction were those involving primarily the cranio-orbital region alone or those with extension into naso-orbital or orbitozygomatic areas. In such cases, the titanium mesh was used. The largest defect that was reconstructed with titanium mesh was created by resection of an extensive chondrosarcoma. Bilateral maxillectomies, including the entire palate and the pterygoid plates, were necessary to achieve oncologically clear surgical margins. The bimaxillary and palatal reconstruction was performed entirely with titanium mesh (two 9 × 9-cm mesh segments were used) with bilateral temporalis muscle transfer. The patient healed well, and the postoperative result can be seen in Figure 1. His oral function was satisfactory in terms of speech and nutrition with a diet of soft foods. A dental prosthesis with teeth, made preoperatively, could be retained with dental glue for esthetic purposes only.

The polyethylene implant was primarily used to fill the temporal fossa after temporalis muscle transfer or resection and as an adjunct to the cranio-orbital reconstruction with titanium mesh. In the group of polyethylene-only implants, there were 12 cases of facial augmentation, 1 case of total orbital reconstruction, and 1 case of cranioplasty. The facial augmentation cases involved patients who had residual deformities of the crani-orbitomaxillary region after completion of oncologic therapy, and the polyethylene implants were customized to fit the individual defects in an onlay fashion. The case of the total orbital reconstruction with polyethylene involved a patient who underwent multiple resections, photon therapy, and brachytherapy for a rhabdomyosarcoma. Eight years later, when the patient was free of disease, the cranio-orbital region was reconstructed (Figure 2).

During the preoperative assessment and planning, the degree of anticipated tissue loss is estimated from available scans, and reconstructive substitutions are planned (eg, titanium mesh, polyethylene implant, and choice of flap). After tumor resection, the surgical defect is examined and the exact loss of bone and soft tissue is determined. Any defect that is judged to eventually result in functional or esthetic deformity is considered for immediate reconstruction. Using a skull model, the titanium 3-dimensional mesh (0.3, 0.4, or 0.6 mm thick) (Leibinger, Kalamazoo, Mich; Synthes Maxillo-Facial, West Chester, Pa) is prestretched and contoured to a desired shape to approximate the surgical bony defect, with some overlap to allow appropriate fixation to the remaining skeleton (Figure 3). The mesh model, retaining its new shape, is inserted into the defect, and minor adjustments are then performed. A comparison with the opposite side of the craniocfacial skeleton is made by direct visualization and palpation; a facial bow can also be used for direct measurements of the surgically treated and the nonsurgically treated sides. In most cases, after the insertion and stabilization of the titanium mesh, a temporalis muscle is rotated into the surgical defect and around the mesh to provide “internal lining” of the titanium and to fill any dead space. Multiple absorbable sutures can help affix the muscle to the mesh. (In most patients, the temporalis muscle is large enough and can be rotated by as much as 90°. In some patients, this allows for reconstruction not only of the orbit but also of the palatal defect that often results from a total maxillectomy being performed in conjunction with orbital resection.) The overlying skin usually provides the outer coverage of the new skeletal reconstruction with the titanium mesh. If temporalis muscle is not available, a microvascular muscle flap is used. Similar surgical principles can be applied for reconstruction of traumatic defects or congenital deformities.

To minimize the temporal fossa depression that results from the muscle transfer, the temporal fossa is filled with a prefabricated porous polyethylene temporal fossa implant (Figure 4). This site-specific implant comes in 3 sizes (small, medium, and large) and is right or left sided (Medpor; Porex Surgical, College Park, Ga). Some trimming of the polyethylene implant may be necessary to ensure a good fit into the defect. One or 2 screws can be used for stabilization, either to some remaining lateral orbit or zygomatic arch, but the screw fixation is not essential. Two drains are placed in the temporal fossa and should be left in for several days, as some dead space will exist around the implant, preferentially accumulating fluid.
low for soft tissue coaptation to the underlying bone of the temporal fossa and full soft tissue coverage of the remaining mesh at the lateral orbital rim. Improvement in her nutritional status was followed by complete secondary healing without the need to remove the remaining mesh, which was supporting the eye. In the group of 6 titanium hemimandibular reconstructions, only 1 implant had to be removed owing to exposure after tumor recurrence. The remaining 5 are fully functional (the longest one, 7 years).

There were 156 implants (5% complication rate) in 100 patients (7% with complications). None of the implants were considered to be the primary causative factor in mesh exposure; the case of tight orbital fit with gaze limitation represented technical error.

There are several noteworthy observations:
• The mesh remained stable in all patients. Three patients, early in the experience, developed eventual mild enophthalmos (3 mm) without diplopia.
• No obvious clinical signs of poor tissue tolerance to titanium mesh implant were observed. Two patients underwent a second surgical procedure for tumor recurrence 2 years after the initial mesh insertion. The mesh was found to be intimately incorporated into the transferred temporalis muscle. No evidence of chronic infection was seen.
• Exposed implants do not need to be removed if soft tissue coverage can be reestablished.
• Results of the titanium cranioplasty follow-up have also been positive; the stability, lack of infection, and contour maintenance are encouraging.
• Long-term experience with the porous polyethylene implant has also been favorable. The prefabricated temporal fossa implants have provided very good contour for the temporal fossa as a replacement for transferred or removed temporalis muscle. An edge of the implant may sometimes become palpable. No soft tis-

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**Skull Base Diagnoses**

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Benign</th>
<th>Malignant</th>
<th>Trauma</th>
<th>Status†</th>
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<td>12</td>
<td>...</td>
<td>...</td>
<td>No recurrence</td>
</tr>
<tr>
<td>Fibro-osseous lesions</td>
<td>6</td>
<td>...</td>
<td>...</td>
<td>No recurrence</td>
</tr>
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<td>9</td>
<td>...</td>
<td>1 Recurrence</td>
</tr>
<tr>
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<td>...</td>
<td>8</td>
<td>...</td>
<td>2 AWD</td>
</tr>
<tr>
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<td>...</td>
<td>6</td>
<td>...</td>
<td>1 Recurrence</td>
</tr>
<tr>
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<td>10</td>
<td>...</td>
<td>2 AWD</td>
</tr>
<tr>
<td>Rhabdomyosarcoma</td>
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<td>5</td>
<td>...</td>
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</tr>
<tr>
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<td>6</td>
<td>...</td>
<td>2 DOD</td>
</tr>
<tr>
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<td>...</td>
<td>1 AWD</td>
</tr>
<tr>
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<td>...</td>
<td>...</td>
<td>4</td>
<td>Healed</td>
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</table>

* SCC indicates squamous cell carcinoma; ACC, adenoid cystic carcinoma; ellipses, not applicable; AWD, alive with disease; and DOD, dead of disease.
† After 5 years of follow-up.
‡ Small cell, not further classified.
rue errosions over the implant have been observed over the longer term. The antibiotic coverage for our skull base procedures included cefazolin sodium and metronidazole hydrochloride administered perioperatively and 3 days postoperatively.

Figure 4. A, Reconstruction of right lateral orbit with titanium mesh and temporal fossa with porous polyethylene (after resection of meningioma). B, Appearance of right lateral orbit and temporal fossa 1 year after surgery.

COMMENT

Important functional and esthetic segments of craniofacial skeleton should be considered for reconstruction after oncologic surgery or trauma or when apparent as congenital deformities. At the present time, most craniofacial skeletal defects are still being reconstructed primarily with autologous grafts, with good results despite the known disadvantages of donor site morbidity, limited supply, difficulties with 3-dimensional contouring, and variable absorption. In oncologic craniofacial and skull base surgery, there are other limitations of autologous bone grafting that need to be considered, such as significant prolongation of what is already a long operative procedure, which should be single stage, and possible dissemination of the primary disease to the donor site (although my colleagues and I have not seen a single instance of donor site tumor recurrence with the use of more than 100 microvascular muscle flaps and/or cranial bone grafts in patients with malignant tumors over the last 12 years).

Because of the need to perform an immediate functional and esthetic reconstruction in skull base procedures, my colleagues and I have been actively exploring the use of alloplastic materials for skeletal and soft tissue substitutions. The titanium and porous polyethylene were selected because of favorable laboratory and clinical experience by many authors. My use of the metallic mesh and porous polyethylene implants evolved over the last 12 years, with the gradual deployment of larger segments at more complex reconstructive sites. As the positive surgical and follow-up experience continued and the benefits to patients became obvious, the usage broadened.

The initial “standard” mesh (with straight connecting bars between the screw holes) was easy to use for primarily 2-dimensional contouring but some undesirable sharp edges/points developed when complex 3-dimensional contouring was required. This handicap was eventually overcome with a new engineering design of 3-dimensional mesh. This model has angulated connecting bars (which widen or narrow during 3-dimensional contouring, creating smooth surfaces in all dimensions) (Figure 5). As highlighted by Cutting et al, titanium as a metallic element was discovered in 1796, and various titanium implant materials have been used in orthopedics, neurosurgery, and dentistry for many years, either as prefabricated or custom-made implants.

Titanium does have some favorable metal properties: it is mechanically stable, autoclavable, compatible with magnetic resonance imaging and computed tomography, and affordable, and it exists in unlimited supply. Titanium also has acceptable tissue interaction. It is inert, noncarcinogenic, and nonallergic and is thus considered bio-compatible. This is reflected in the low risk of infection with the use of titanium mesh and the tolerance of reconstructed areas to adjuvant therapy, providing the surrounding soft tissue is adequate. The above characteristics compare well with those of other alloplastic materials. Titanium thus approximates the “ideal implant,” which needs to be inert, nontoxic, nonantigenic, noncarcinogenic and easily shaped to maintain the desired form and consistency. It should permit permanent tissue integration.

Three-dimensional contouring increases stability and rigidity and thus implant endurance to compression, distraction, and bending forces in multiple vectors (Figure 6). It lessens the chance that there will be subsequent deformation from external and internal forces (eg, scar contraction and muscle pull). Masseter muscle reattachment and return of function have been seen; in the patient described herein who underwent a bilateral maxillectomy, the function of both masseter muscles returned. The degree of functional return, however, has not been quantified.

My colleagues and I have also used the mesh in children (the youngest was 7 years old), but, to date, the follow-up has been only 2 years. It is anticipated that when mesh implants are used in a growing child some growth asymmetry will develop in time, which may require another appositional implant (eg, porous polyethylene for the malar and periorbital region).

The porous high-density pure polyethylene implant Medpor, as stated by Sauer, harvests the wound healing and regenerative properties characterized by tissue ingrowth into the implant. This fibrovascular tissue ingrowth not only provides long-term stability for the implant but also limits the chances for subsequent infection...
as the “ingrown” blood supply minimizes it. The connecting pores of polyethylene range in size from 150 to 250 µm. This implant also has sufficient stiffness to withstand the subsequent process of tissue contracture during the healing period.

Romano et al10 also favorably reviewed their experience with the use of Medpor. In 140 patients with maxillofacial injuries, they found that technically this implant was easy to work with; could be carved, contoured, adapted, and fixated; and did not resorb or degenerate over time. It demonstrated long-term stability, high tensile strength, resistance to stress and fatigue, and a virtual lack of surrounding soft tissue reaction. Rapid tissue ingrowth into the pores was observed. One infection with implant removal was encountered, but no migration or implant exposure was seen.

Dougherty and Wellsiz,9 in an animal model (New Zealand white rabbit), studied Medpor placed over a defect in an orbital floor that communicated with the maxillary sinus. At the completion of the study, the Medpor implant demonstrated bone and soft-tissue fixation, as well as reconstitution of mature overlying mucosa over the defect. This has been my clinical experience as well, not only with the polyethylene but also with the titanium mesh. Both implants developed full mucosal coverage over any exposed area facing the nasal or sinus cavi-
ties. (We have not used any soaking of the implants in an antibiotic solution prior to insertion.)

As outlined by Rubin and Yaremchuk,7 in their review of literature dealing with complications and toxic effects, the titanium mesh and porous polyethylene implants are useful and well tolerated in cases of facial reconstruction. The risk of cancer with metal and polymer implants was found to be extremely low. Corrosion of metal implants does lead to the release of metal ions, but, to my knowledge, there have been no reports of a direct association between implant corrosion products and systemic disease. In their study, Rubin and Yaremchuk extracted information from the reviewed literature, which included 2639 cases in which complications were reported. The infection rate was 7.4% and the plate exposure was 3.3%. When the mandibular reconstruction was followed by chemotheraphy and radiotherapy, the incidence of infection rose to 14.3% and the plate exposure to 14.9%. The experience with the use of “surgical mesh” reported in the literature was also reviewed. Only 2 studies qualified for inclusion (total, 69 patients). No complications were reported with the use of the mesh in the orbit, but the follow-up period was only 1 to 3 months. On the contrary, 3 studies on the use of mesh for nasal implants (266 patients; follow-up, 11 months to 5 years) demonstrated a combined infection rate of 5.3% and an implant removal rate of 4.5%. The reported use of porous polyethylene (for nasal implants) was also reviewed (1 study; 27 patients), with a combined incidence of 7.4% for infection, exposure, extrusion, and removal. In the series reported herein, most of the patients received chemotherapy and/or radiotherapy either before or after surgery, for an overall complication rate of 7% (6% exposure rate and 1% infection/exposure rate).

Both implants that were used in the reconstructive procedures described herein, ie, titanium mesh and porous polyethylene, seem to be well tolerated by the patients. The surface characteristics and the porosity play an important role in tissue integration. The porous polyethylene contains pores that are 150 to 250 μm in diameter. Reevaluation of several cases 2 years after the initial reconstruction (for tumor recurrence) revealed well-integrated implants with full (through-and-through) ingrowth of soft tissue. I have not seen a hypersensitivity reaction to either implant.

Definite reconstruction should be considered an integral part of primary oncologic surgery, as careful oncologic follow-up does not require deferral of reconstruction. The extent and type of reconstructions should, however, be the surgeon's choice. The protocol at our Skull Base Program calls for primary reconstruction to be carried out simultaneously with tumor resection in all patients. An exception would be an intraoperative change in patient's health status demanding shortening of the surgical procedure or evidence of limited perfusion of the available soft tissue coverage. The current quality of imaging modalities, such as computed tomography and magnetic resonance imaging, permits satisfactory assessment of any previous tumor site. To lessen the possible ambiguities of tissue appearance on imaging scans (surgical changes vs tumor recurrence), a baseline scan is recommended at 3 months after surgery. Subsequent scans obtained at frequent intervals are then compared with the baseline scans for any changes, especially nodularity and alterations in the contour of transferred flaps, to rule out recurrence.

Certain anatomical sites (eg, orbit and nasoethmoidal region) require a high degree of reconstructive precision to match the needed functional and esthetic demands. The 3-dimensional mesh is a very satisfactory material for this purpose. A recent study has demonstrated that the orbital content can be saved in a greater number of patients with periorbital neoplasm.16 Oncologic outcomes with and without orbital exenteration appear to be the same. Resecting the periorbita for margins when the tumor has transgressed the bony orbit, but not the periorbita, permits achieving clear margins at this perimeter, while saving the functional globe. After resection, the globe support lacks not only the bony orbit, but often the tight soft tissue envelope of the periorbita as well. This loss of bone and periorbita increases the globe's dystopia, interfering with optimal position and function. Near-perfect orbital reconstruction is then needed not only to save the eye, but also to make sure that it functions in synchrony and that it esthetically matches its counterpart.

Accepted for publication September 15, 1999.
Presented at the annual meeting of the American Head and Neck Society, Palm Desert, Calif, April 27, 1999.
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REFERENCES