Lead Stuck (Frozen) in Header: Salvage by Bone Cutter Versus Other Techniques

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FISHER J.D., ET AL.: Lead Stuck (Frozen) in Header: Salvage by Bone Cutter Versus Other Techniques. It is occasionally difficult to disconnect leads from headers at the time of pulse generator replacement without injuring the fragile leads. Over a 2.5-year period we encountered this problem in six cases (1.7% of pulse generator replacements). The posterior portion of the header was clipped off using an orthopedic bone cutter in four cases. The cut was aligned with the deep end of the lead socket in the header. A metal rod was then used to push the lead out of the socket. Bench testing of alternative methods was done on previously explanted pulse generators that were firmly held in a vice. Motorized microtools were used to drill holes from the end of the header to the deep end of the socket; or with a rotary saw attachment to slice off the back of the header, allowing a retained lead to be pushed out. The latter was also done with a hand held razor saw, and attempts were made with a scalpel. Lead removal in the clinical cases was accomplished quickly in the four cases using the bone-cutter, without trauma to the lead. Bench testing results varied. The bone cutter was the most efficient method for most brands, but was ineffective on one. The motorized tool was difficult to position, produced sprays of plastic particles, and would have been risky in a clinical setting. The razor saw was difficult to use safely, or efficiently, except in some headers that resisted the bone cutter. The scalpel failed except in one “soft header” pacemaker. An orthopedic bone cutter is a useful tool for removing a retained lead from a pulse generator header. Different header designs and materials necessitate knowledge of several lead detachment methods. (PACE; 27:1136–1143)

Introduction

At the time of pulse generator replacement, the leads must be detached from the header (connector block) of the old device. Most often this is accomplished by loosening the appropriate set screws, grasping the lead near the header and tugging gently, taking care not to stress the relatively fragile junction between the lead insulation and the connector pins. Occasionally the disconnection process is challenging. The literature is sparse on this topic. There is no mention in textbooks.1,2 There are two reports3,4 of successful removal by drilling the back of the header with an orthopedic drill until the distal socket was reached, and then pushing the lead out. Another report describes slicing the back off the header with a scalpel.5 The overall incidence of frozen leads is reported as 1.2% to 12.5%.3–5 We report a simple and effective method for achieving disconnection while preserving the integrity of the lead that is effective with most headers. We also report bench testing of alternative methods in a variety of previously explanted devices.

Methods

Over the last 2.5 years we encountered six devices from four different manufacturers in which the IS-1 connector pins could not withdrawn from the header at the time of routine pulse generator replacement, an incidence of 1.7%. The devices involved were a Teletronics 5282D Optima MPT (Teletronics Pacing Systems Inc., Engelwood, Co USA) with a “soft header”; a Teletronics 1254 Meta DDR (hard header), a Guidant 1130 Vigor SR (Guidant Inc., St Paul, MN, USA); a Guidant 1273 Discovery DR, a Biotronik 330-444 Belos ICD (Biotronik, Berlin, Germany), and an ELA Chorus 1034 “soft header” (ELA Medical, Segrate, Italy).

Initial Steps

When it was found that the lead could not easily be withdrawn from the header, attempts were made to break any seal that may have been formed near the opening of the socket in the header, e.g., by body fluids or silicone bonding. This was done...
with gentle manipulation using a clamp and a very small blunt instrument such as an iris forceps. If this was not successful, the steps were repeated after silicone lubricant was applied to the region of the socket opening. Thereafter, the set screws were removed, and silicone lubricant was injected into the empty screw holes, and the connector was gently tapped and manipulated through the opening. At each step, attempts were made to detach the lead from the header, and were unsuccessful in each of the cases presented here.

**Clip and Push**

At this point it was decided to cut off the back of the header, exposing the tips of the IS-1 connector pins, allowing them to be pushed out. All but one of the headers, including the “soft header” of the Telectronics 5282D pacemaker resisted attempts to slice the header cleanly using a scalpel: the exception was the ELA Chorus 1034 “soft header.” An orthopedic bone cutter was then used (Stille-Lipton 27.3 cm articulated, Fig. 1). This is a substantial instrument capable of producing great force directed at sharp hardened metal edges. The original purpose of the instrument ensures that it can be positioned suitably on most headers, and that a cut can be delivered with considerable precision (Fig. 2). Once the back of the header was cut, it was removed or displaced using a large Kelly clamp. Then a suitable instrument, e.g., a pacemaker ratchet set-screwdriver or a sizer rod from an extraction kit, was used to push the IS-1 pin out of the header. In the case of the Telectronics 1254, it was the atrial lead that was frozen, and as the patient was in permanent atrial fibrillation it was decided not to wait for the bone cutter but to cut, cap, and abandon the lead. The relevance of the 1254 lies in its place in a consecutive series, and in the implications from bench testing results (below).

**Bench Testing of Alternative Methods**

These tests included ten previously explanted pulse generators with a variety of header plastic materials. The units were: Telectronics 1254 Meta DDDR pacer; Guidant 1226 Prelude DR DDDR pacer; Guidant 1176 Meridian SR SSIR pacer; Guidant A135 Vitality AVT ICD; Medtronic 7085 Elite II DDDR pacer (Medtronic Inc., Minneapolis, MN, USA); Medtronic 7940 Thera DR 7940 DDD pacer; St. Jude (Pacesetter) 2022L Synchrony II DDDR pacer, (St. Jude Medical, St. Paul, MN, USA); St. Jude 5376 Identity XL DR DDDR pacer; Ventritex V-185C Contour II ICD, Sunnyvale, CA, USA; Intermedics 294-05 Stride DDDR pacer (Intermedics Inc., Angleton, TX, USA), and an ELA Chorus 1034 “soft header.” The 1254 and 1034 units were not the same ones from the clinical series. Each of the methods described was used on each device unless indicated below. (Figs. 3 and 4).

**Motorized Microtool**

A surgical field towel was placed over a small work bench vice, and previously explanted pulse generators were positioned in the vice and gently clamped at the level of the case, leaving the header exposed. A microtool (Dremel Moto-Tool model 595, Dremel, Racine, WI, USA) electrically powered with a variable speed motor, was fitted with small drill bits and then a rotary saw.

**Drill Bit Method**

Holes were drilled from the back of the header intended to be in line with and reaching to the deep

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**Figure 1.** Stille-Liston 27.3 cm bone cutting forceps (articulated). More effective on more models tested than the nonarticulated Liston forceps.
end of the connector socket. Holes were drilled in the header sides in designs where the metal case forms a “cap” to the rear of the header (Fig. 5). Such a design is used in many devices, including the present series’ St. Jude 5376 and Ventritex V-185C.

Rotary Saw Method

The microtool was fitted with a circular saw (3/4 inch c. 19 mm) in diameter and a cut was made at right angles to the long axis of the connector socket, aligned and aimed at the deep end of the socket within the header.
LEAD STUCK IN HEADER

Figure 4. Razor saw. This proved effective when the bone cutter failed (Table I), and shares the advantage of being nonmotorized.

Razor Saw

A razor saw (#35 blade, X-ACTO, Statesville, NC, USA) is a knifelike tool with a serrated thin razor edge (Fig. 4). This was positioned to make a cut similar to that described for the microtool rotary saw, but at a different area on the header from that used with the circular saw.

Scalpel

A new Number 11 blade (Moore Medical, New Britain, CT, USA) was tested on each device using both pressure and slicing motions.

Bone Cutters

Instruments were a Liston 21.6 cm nonarticulated, and if this proved ineffective then a Stille-Liston 27.3 cm articulated was used. Additional tests were done on two units (Teletronics 1254 and Intermedics 294-05); these were tested with the Liston initially and then with both bone cutter models after a 24-hour rehydration bath (some of the plastic header materials are designed to absorb water).

Four manufacturers (Biotronik, Guidant, Medtronic, and St. Jude) were contacted for information regarding the characteristics of the plastic compounds used in their pulse generator headers. Technical manuals for these and other manufacturers were reviewed. United States Food and Drug Administration (FDA) website postings on premarket approvals were consulted.

Results

Clinical Cases (Fig. 2)

The bone cutter proved effective in all four devices in which it was used. Each of the leads was successfully and atraumatically separated from the header using the method described. Except for the Biotronik unit, the first attempt to align and cut was successful (Table I).

Teletronics 5282D

The bone cutter cleanly and easily made an appropriate cut, and the IS-1 connector of the Teletronics 033-444 lead was easily pushed out.

Figure 5. (Left) Guidant 1273 pacer from the clinical series. The vertical arrow points to the neat cut made by the Stille-Liston bone cutter. (Right) St. Jude 5376 pacer from the bench testing series prior to completion of testing; only a rotary saw has been applied to the top of the header. This design features the upturn of the can that forms a rear cap to the header. The horizontal arrow indicates the problem with drilling in from the rear.
### Table I.
Clinical and Bench Testing Findings

<table>
<thead>
<tr>
<th>Device</th>
<th>Motor Drill</th>
<th>Motor Saw</th>
<th>Drill &amp; Rotary Saw</th>
<th>Razor Saw</th>
<th>Scalpel Saw Dust</th>
<th>Scalpel Saw No. 11</th>
<th>Bone Cutter</th>
<th>Comment</th>
</tr>
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<tr>
<td><strong>Clinical Series</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telectronics 5282D</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Failed</td>
<td>Very easy</td>
<td>“soft header”</td>
<td></td>
</tr>
<tr>
<td>Telectronics 1254</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Failed</td>
<td>N/A</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Guidant 1130</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Failed</td>
<td>Easy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guidant 1273</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Failed</td>
<td>Easy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biotronik 330-444 (ICD)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Failed</td>
<td>Mildly difficult</td>
<td>Chips.</td>
<td></td>
</tr>
<tr>
<td>ELA 1034</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Very Easy</td>
<td>N/A</td>
<td>See text</td>
<td>“soft header”</td>
</tr>
<tr>
<td><strong>Bench Testing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telectronics 1254*</td>
<td>Difficult</td>
<td>OK †</td>
<td>Fine “dust”</td>
<td>Difficult</td>
<td>Failed</td>
<td>Difficult</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Guidant 1176</td>
<td>Difficult</td>
<td>OK</td>
<td>Medium &amp; melted globs</td>
<td>Difficult</td>
<td>Failed</td>
<td>Easy</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Guidant 1226</td>
<td>Difficult</td>
<td>OK</td>
<td>Medium &amp; melted globs</td>
<td>Difficult</td>
<td>Failed</td>
<td>Easy</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Guidant A135 (ICD)</td>
<td>Difficult</td>
<td>OK</td>
<td>Medium &amp; melted globs</td>
<td>Difficult</td>
<td>Failed</td>
<td>Easy</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Medtronic 7085</td>
<td>Difficult</td>
<td>Easy</td>
<td>Medium &amp; melted globs</td>
<td>OK</td>
<td>Failed</td>
<td>OK</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Medtronic 7940</td>
<td>Difficult</td>
<td>Easy</td>
<td>Medium &amp; melted globs</td>
<td>OK</td>
<td>Failed</td>
<td>OK</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>St. Jude 2022L</td>
<td>Difficult</td>
<td>Easy</td>
<td>Medium-fine</td>
<td>Easy</td>
<td>Failed</td>
<td>Impossible</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>St. Jude 5376</td>
<td>Difficult</td>
<td>Easy</td>
<td>Fine debris</td>
<td>Easy</td>
<td>Failed</td>
<td>Impossible</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Ventritex V185C (ICD)</td>
<td>Difficult</td>
<td>Difficult</td>
<td>Fine debris</td>
<td>Difficult</td>
<td>Failed</td>
<td>Easy</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>Intermedics 294-05</td>
<td>Difficult</td>
<td>OK</td>
<td>Fine debris</td>
<td>Easy</td>
<td>Failed</td>
<td>Difficult</td>
<td>See text</td>
<td></td>
</tr>
<tr>
<td>ELA 1034*</td>
<td>Medium</td>
<td>Easy</td>
<td>Fine debris</td>
<td>Easy</td>
<td>Easy</td>
<td>Very Easy</td>
<td>See Text</td>
<td></td>
</tr>
</tbody>
</table>

*Not the same 1254 or 1034 as in the clinical series; †OK means “can be done” but see text for problems or comments; N/A = Not applicable. Not used in the clinical series.

Testing confirmed that the lead was intact, functional, and suitable for continued use.

**Telectronics 1254**

Included here as part of the “frozen lead” series. The bone cutter was not used and the lead was destroyed and capped. In vitro testing of a similar 1254 (below) suggests that the bone cutter may have failed.

**Guidant 1130 and 1273**

Although somewhat more force was required, a clean cut was made in each of the headers and the leads were successfully removed: an Intermedics 431-07 lead from the 1130, and from the 1273 a Guidant 4269 atrial lead and Guidant 4185 ventricular lead, respectively.

**Biotronik Belos 330-444**

The header for this ICD seemed to be distinctly harder than the others when initially tested with a scalpel. The bone cutter successfully removed the appropriate part of the header allowing the IS-1 connector of the Biotronik Kainox SL 65/16 lead to be pushed out. However, rather than producing a clean cut, the bone cutter produced a shattering as well as a cutting effect on the plastic compound. Several cuts were needed to expose the distal socket. Small bits of plastic covered the field, which had been previously covered with an additional sterile towel, so that no particles entered the incision or pocket.

**ELA 1034**

This “soft header” DDD pacemaker yielded easily to a #11 scalpel blade. The rear portion of the header was sliced off, and the retained ELA BT46 lead was pushed outatraumatically.

**Bench Studies (Table I)**

All methods revealed a potential for depositing dust, particles, melted plastic globs, or chips on the field, and thus the need for careful protective draping and subsequent lavaging in a clinical setting.
**Microdrill Tool**

**Drill Bit Method.** It proved difficult to initiate the hole in the intended spot on the header; the drill bit tended to slip off target, and alignment was difficult even with the header held solidly in the vice. The drilling process resulted in expulsion of small heated particles of plastic. In the Guidant and Medtronic units, the particles tended to fuse together in globs that solidified quickly, tending to block the drilled channel. Considerable pressure was required at various drill speeds so that it was easy to overshoot, with potential damage to the retained lead. The method cannot be used in devices where the metal case forms a “cap” to the rear of the header (Fig. 5).

**Microdrill Tool**

**Rotary Saw Method (with the saw at right angles to the header).** This was easier to align, but small plastic particles were sprayed onto the field, sometimes covering a large area with dust. The saw tended to “roll” suddenly off the header to the potential jeopardy of the operator (and possibly the patient). The maximum cut depth attainable with the 19 mm diameter saw was 6.5 mm; a larger diameter saw would be needed for most clinical situations.

**Razor Saw**

This tool provided remarkably variable results. It was difficult to achieve a straight deep cut even with multiple stokes at considerable pressure on most headers, including those that seemed softer and yielded easily to the bone cutter. There was a tendency to “bind” which inhibited the sawing motion. Paradoxically, the razor saw worked well and quickly on the devices that were most resistant to the bone cutters (Table I).

**Scalpel**

It was not possible to cut any of the headers tested, except for the ELA Chorus 1034 “soft header,” and this was very easy.

**Bone Cutters**

The smaller Liston cutter was effective on a minority of devices, those listed as “easy” in Table I. Those listed as “OK” yielded only to the larger Stille-Liston articulated cutter. The “difficult” headers required the added strength of a large muscular younger author (A.D.), and even he was unable to cut those listed as “impossible.” Rehydration did not appear to have any effect.

**Discussion**

There are infrequent occasions when it is difficult to separate a lead from the header of a pacemaker or an ICD. If simple and gentle mechanical maneuvers prove unavailing, additional measures must be considered that may preserve the integrity of the relatively fragile lead. One option is a drill type device fitted either with a properly sized drill bit or circular saw. Both methods pose hazards to the operator because the pulse generator must be held by hand or hand held clamp making it a relatively unsteady platform. The same applies to the orthopedic drill used in previous reports. This drill method cannot be used in devices where the metal case forms a “cap” to the rear of the header (Fig. 5). For rear-capped designs, holes drilled from the side or a sawed line as described, may permit detachment of part of the header, allowing a right-angled rod to push out the retained lead. Based on the present study, we believe the drill, rotary saw or razor saw may be a reasonable option for some headers (Table I), although all are relatively slow, produce particles, and pose some risk to operator and patient. An editorial addition to a previous report also cautioned about potential dangers of current leakage with motorized tools. As indicated, our clinical and bench results with the scalpel method failed to duplicate the success reported in two cases, except in one “soft header.”

In contrast to the drills and saws, the bone cutter technique described in this paper was easy to position, and produced quick clean, quick particle-free cuts in the intended position in most of the clinical series. Bench testing revealed however, that certain plastic compounds resist bone cutters better than saws. In general, we believe the bone cutter should be tried first: It is easiest to position, quickest, and is safest for the operator and patient.

It is possible that difficulties with disconnecting the leads at the time of pulse generator replacement could be reduced by lubricating the seal rings on the lead connector pins at the time of initial implant. There is clearly no industry standard on this matter. Several manuals for each of nine manufacturers were reviewed. Several manuals vary, some not commenting on lubrication, but others recommending that the lead tip be dipped in medical grade light mineral oil prior to insertion into the header. This recommendation appears in the manual for the Optima series which includes the 5282D of the present clinical series. Guidant has recommend the use of sterile mineral oil or sterile water for lubrication. The technical manuals from Biotronik recommend using silicone oil on certain unipolar models. Medtronic notes that “lubricating the lead with sterile water may ease lead insertion.” St. Jude, Ventritex, and CCS manuals do not comment on lubrication. Intermedics manuals either prescribe or recommend silicone oil. Vitatron indicates that saline may be used if necessary, but “silicone grease is strictly prohibited.” At our institution we do not
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Table II.
Header Materials: General Description

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Header Material Description</th>
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<tr>
<td>Telectronics soft headers</td>
<td>Silicone elastomer</td>
</tr>
<tr>
<td>Telectronics hard headers</td>
<td>Epoxy, Hardened epoxy</td>
</tr>
<tr>
<td>Guidant</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>St. Jude-Pacesetters</td>
<td>Epoxy</td>
</tr>
<tr>
<td>Intermedics</td>
<td>Epoxy</td>
</tr>
<tr>
<td>Biotronik</td>
<td>Epoxy</td>
</tr>
<tr>
<td>CCS</td>
<td>Epoxy</td>
</tr>
<tr>
<td>Vitatron</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>ELA soft headers</td>
<td>Silicone elastomer</td>
</tr>
</tbody>
</table>

routinely lubricate the connector at the time of initial implant.

Header Materials

“Soft headers” such as used in the Telectronics and ELA devices described in this paper, are no longer being produced. These headers have a somewhat rubbery but nevertheless very firm consistency. Differences in the silicone elastomer were apparent: the Telectronics unit was resistant to a scalpel, whereas the ELA unit was easily cut. The headers in common use by Guidant, Medtronic, St. Jude, Biotronik and others look and feel like hard plastic, but materials vary greatly (Tables II, III). The present study demonstrates very different responses to the techniques used to cut the headers, even when the material is nominally the same, e.g., with Guidant and Medtronic (Table III), perhaps related to differences in the curing process. Of interest, the Guidant 1226 was actually a “reflagged” Medtronic device, but the header responded like a Guidant product (Table I). Although “frozen” leads are not very common. Manufacturers should consider the problem in selection of header materials and design (e.g., the rear-capped header noted above).

Header Connector-Lead Pin Considerations

The leads in the present study were made by five different manufacturers, and the hardness of the header did not appear to be a factor in the problem. Thus there was no common manufacturer, lead, or header characteristic identified as tending to cause the “lead stuck in header” problem. However, three of six clinical cases had headers with internal sealing rings together with leads with sealing rings (the two Guidant devices, and the Telectronics 5282). These had unipolar-bipolar 3.2 mm IS-1 compatible headers with sealing rings (which are not present in regular IS-1 headers). The Guidant technician commented that he had observed difficulties separating “ring-on-ring” connections more frequently than with IS-1 to IS-1. It is possible that the interdigitating sealing rings may exhibit the known tendency of silicone to bond to other silicone structures. This may be an area to watch, particularly as design progresses with IS-4 and DF-4 connections.

Limitations

In all of the devices in the clinical series, the joint between the header and the pulse generator case was composed of straight flat surfaces. Once the “rear” of the header was cut using the method described, it was easy to insert a rod parallel to the header/case joint to push out the retained lead. This may have proved more difficult in a ‘rear-capped’ header design. Sawing or cutting the header can be accomplished, but it might prove difficult to insert a push rod into the confined space between the upturned “rear cap” of the case and the now-exposed end of the socket in the header. If careful manipulation with a curved or flexible rod is ineffective, it may be necessary to detach the header entirely from the case using a strong clamp. This would then allow the lead to be pushed out as described for other headers in this paper. Devices from eight manufacturers were

Table III.
Some Specific Header Material Characteristics

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Material</th>
<th>Ultimate Tensile Strength (psi)</th>
<th>Hardness (Durometer Shore)</th>
<th>Elongation Index (%)</th>
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<tr>
<td>Guidant15, 16</td>
<td>Tecothane® TT 1075D-M</td>
<td>8300</td>
<td>75D</td>
<td>150</td>
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<tr>
<td>Medtronic15, 17</td>
<td>Tecothane® TT 1075D-M</td>
<td>8300</td>
<td>75D</td>
<td>150</td>
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<tr>
<td>Biotronik18, 19</td>
<td>Hyso® Epoxy EE0079/HD0070</td>
<td>8000</td>
<td>85D</td>
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involved in this report. The results were variable, though generally consistent for each manufacturer. Further variation would be expected from testing of additional models or manufacturers.

**Conclusions**

When it proves difficult to detach a lead from the header of an implanted pulse generator, a bone cutter may quickly and accurately slice off the rear of header. This exposes the deep ends of the connector sockets, and allows the retained lead to be pushed out atraumatically using a properly sized rod. Drill and saw methods are needed for some headers, but are more hazardous to the operator. A scalpel, bone cutter, and razor saw should cover most clinical cases. Header materials and manufacturer recommendations vary widely.

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**References**