COMPLICATIONS LEADING TO SURGICAL INTERVENTION FOLLOWING ORIF OF CLAVICLE FRACTURES:
PLATE FIXATION COMPARED TO FIRST AND SECOND GENERATION INTRAMEDULLAY FIXATION

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Abstract:

Background:
In 2007, the Canadian Orthopaedic Trauma Society published a study demonstrating superior results for treating clavicle fractures with plates vs. non-operative treatment1. However, several studies have established plating mid-shaft clavicle fractures causes discomfort in the majority of patients, often leading to removal surgeries2. The absence of hardware prominence makes the Sonoma CRx® intramedullary nail an attractive option for clavicle repair due to improved patient tolerance.

Materials and Methods:
Eleven clavicle plate clinical studies were summarized to determine complications that occurred following plate repair for clavicle fractures. Patient follow-up averaged 12.3 months. In comparison, post market surveillance was conducted for the CRx over two time periods that tracked first generation instrumentation and VELOX™ second-generation instrumentation; following 342 and 408 patients respectively with an average tracking time of 11.5 months. Incidence of CRx® removal and complications was calculated.

Results:
Surgical intervention was required to resolve complications for 18.64% of the 558 plated fractures. The 342 fractures treated with the CRx using first-generation instrumentation resulted in 8.77% of implants being removed for complications. Removal rates were further reduced by implanting CRx with VELOX instrumentation, which resulted in a 2.96% removal rate. These results were highly statistically significant (p<0.001 to P<0.00001). The incidence of hardware failure in CRx implanted with first-generation instruments was slightly less than plates at 2.34% and 2.51% respectively. However, the incidence of failure dropped to .74% with the use of VELOX instrumentation.

Conclusion:
Implanting the Sonoma CRx with first generation instrumentation led to 53% fewer secondary surgical interventions for complications compared to plating. Furthermore, when the CRx was implanted with second-generation VELOX instrumentation, there was an 84% lower removal rate for complications compared to plating.
It appears the ability of VELOX instrumentation to ease preparation of the medial clavicle to the necessary 50mm depth has significantly reduced the removal rate and improved the survivorship of CRx.

References
**Background:** In 2007, the Canadian Orthopaedic Trauma Society published a landmark article demonstrating plate fixation for completely displaced midshaft clavicle fractures resulted in improved functional outcomes and a lower rate of malunion and nonunion when compared to non-operative treatment at one year follow-up.

Despite the improvements over slinging, plate fixation is not without complications. Wijdicks, *et al.* summarized 11 different plate clinical studies and reported on the types of complications that occurred following plate repair for clavicle fractures. Surgical intervention was required to resolve complications for 18.64% of the 558 plated fractures. Wijdicks concluded that although plate fixation is a safe treatment for midshaft clavicle fractures, complications related to the implant frequently require a second surgical intervention to remove, debride or revise the clavicle plate. The patients referenced in the Wijdicks publication averaged 12.3 months follow-up with the shortest study reporting on complications at 3 months follow-up.

The first flexible-to-rigid intramedullary clavicle implant (IM) was branded CRx® by Sonoma Orthopedic Products (Sonoma) and was released in 2009, with the intention of reducing complications compared to plate fixation. Sonoma has continued to improve the design of the CRx and its instrumentation along with simplifying the surgical procedure. Introduced in April of 2011, the newest generation of CRx implant eliminated welds in the rigid shaft, leading to a stronger construct. Furthermore, studies conducted by Steadman Philippon and Sonoma in 2011 and 2012 confirmed that by achieving a medial implant depth greater than 50mm, the static and cyclic fatigue performance of the implant is optimized and reaches a biomechanical performance level well beyond that of clavicle plates. Late in 2012, Sonoma launched second generation surgical instrumentation (VELOX) and an improved surgical procedure intended to improve clinical outcomes by ensuring implants were placed at a minimum of 50mm of medial depth beyond the fracture.

Sonoma conducts post market surveillance on patients who experience complications necessitating surgical intervention (implant removal). Over the initial tracking period, 342 consecutive patients were implanted with CRx using first generation instrumentation. The average tracking time following implantation was 13.2 months, with a minimum surveillance time of six months post implantation. Over the second tracking period, 408 consecutive patients were implanted with CRx using VELOX instrumentation. The average tracking time was 11.5 months, with a minimum surveillance time of six months post implantation.

**Data Collection Methodology For Sonoma CRx Surgical Interventions:** The CRx is implanted into the clavicle via a fluoroscopically-guided minimally invasive surgical procedure. While the vast majority of patients experience successful outcomes, sometimes implants are removed for patient complications. To remove the implant, the surgeon must contact Sonoma to obtain proprietary instrumentation. This allows Sonoma to be aware of surgical interventions, solicit information to identify the cause, and maintain records of the actions that took place to address the complication.
**Results:** As stated previously, clavicle fractures treated with plates demonstrated an **18.64%** removal rate for complications. Fractures treated with the CRx using first generation instrumentation resulted in **8.77%** implant removal. The CRx implanted with the VELOX procedure had only a **2.96%** removal rate for complications. The difference in surgical interventions needed to resolve complications was highly statistically significant between both the CRx first generation instrument group and plating *(p<0.001)* as well as between VELOX and plating *(p<0.0001)*. Additionally, the difference between VELOX and CRx first generation instruments was also highly statistically significant *(p<0.001)*.

<table>
<thead>
<tr>
<th>Complications Requiring Hardware Removal</th>
<th>Plate Studies</th>
<th>Sonoma CRx</th>
<th>Sonoma VELOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections</td>
<td>16</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Hardware Failures</td>
<td>14</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Nonunion/malunion</td>
<td>24</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Refractures</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Irritation/prominence/other</td>
<td>47</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Total Implant Removal</td>
<td>104</td>
<td>30</td>
<td>12</td>
</tr>
</tbody>
</table>


Sonoma CRx and VELOX data has been captured from Sonoma CRx and VELOX removal records

**References:**

1. Each removal is only counted once. As a result, only the primary cause, based on the surgeon’s assessment, is listed for each removal. In some cases a non-union or refracture may lead to broken hardware.
2. The Cho study did not report on surgical intervention and was excluded from the analysis.
3. Hardware failures include breakage, angulation and loosening
4. In the Sonoma CRx category, four of the ten non-union/malunions led to hardware failure and one of three refractures led to hardware failure.
5. In the Sonoma VELOX category, one of the three non-union/malunions led to eventual hardware failure.

**Conclusions:** The CRx implanted with first generation instrumentation led to 53% fewer removals for complications when compared to plating. When VELOX was utilized to implant CRx there was an 84% lower incidence of removal surgeries to resolve complications compared to plating. Furthermore, VELOX reduced the removal rate to one-third the rate of CRx first generation instrumentation.

Based on these improved outcomes, serious consideration should be given to implanting the CRx using VELOX instrumentation rather than increasing the risk of a second surgery by repairing the fracture with a plate.
Bibliography:


