EXTRAMEDULLARY FIXATION

DePuy Synthes
HAMMERTOE CCI
CONTINUOUS COMPRESSION IMPLANT

Evidence Summary

DEPUY SYNTHES IS WITH YOU—AND YOUR PATIENTS EVERY STEP OF THE WAY
HAMMERTOE EPIDEMIOLOGY, CLINICAL AND ECONOMIC BURDEN

EPIDEMIOLOGY OF HAMMERTOE
- A foot study with 3,429 participants identified hammertoe as one of the most prevalent foot disorders, with 16.2% of patients.
- Instability of the metatarsophalangeal (MTP) joints from age-related changes or gait, as well as inflammatory conditions such as rheumatoid arthritis, can lead to contracture of the digits.
- Pes planus foot posture was associated with increased odds of hammertoes.
- Hammertoes have particular importance in diabetic patients as they increase the risk for developing foot ulcers.

CLINICAL AND ECONOMIC BURDEN OF HAMMERTOE
- Direct healthcare costs were responsible for 12% of total estimated costs, while indirect productivity costs related to work loss and disability resulted in 88% of estimated costs.
- Surgical correction of hammertoe was the most common and most costly foot and ankle surgical procedure, with high infection and reoperation rates.

114,993 Medicare hammertoe procedures resulted in an estimated total of $1.04 direct and indirect (work loss and disability) healthcare costs in 2011.

Treatment alternatives are needed to lower complications and cost to the healthcare system.
TREATMENT METHODS AND COMPLICATIONS OF HAMMERTOES

- **Arthrodesis** of proximal inter-phalangeal (PIP) joint represents the **standard treatment** for deformities not suited for manual correction.\(^2\)

- **Complications of hammertoe surgery** may include infection, prolonged swelling, recurrence or postsurgical deformity, or devascularization with possible loss of the toe.\(^2\)

- Many intramedullary (IM) implants such as cannulated screws or absorbable pins have been designed for the fixation of the arthrodesis, however, the **K-wire is the traditional and most utilized method**.\(^5\)

- **Implant-caused complications** include infection, bending, breakage, malalignment, pain, and premature extrusion.\(^6\)

- The **nonunion rate** of PIP fusion may be as high as **50%**.\(^7\)

---

**2015–2018 US CLAIMS DATABASE STUDY: HAMMERTOE INCIDENCE AND COMPLICATIONS**

<table>
<thead>
<tr>
<th></th>
<th>US Medicare Supplemental Database(^8)</th>
<th>US Commercial Claims Database(^8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>≥65 years; mean age 73.0 years</td>
<td>18–64 years; mean age 52.0 years</td>
</tr>
<tr>
<td># of patients</td>
<td>5,786 patients</td>
<td>21,811 patients</td>
</tr>
<tr>
<td>Gender</td>
<td>76.7% female</td>
<td>78.6% female</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Hypertension (69.1%), hypothyroidism (24.7%), diabetes (23.0%)</td>
<td>Hypertension (38.4%), depression (17.4%), hypothyroidism (16.5%)</td>
</tr>
<tr>
<td>Complication rates (2 years)</td>
<td>Infection 13.6%</td>
<td>Infection 8.8%</td>
</tr>
<tr>
<td></td>
<td>Delayed healing 0.1%</td>
<td>Delayed healing 0.6%</td>
</tr>
<tr>
<td></td>
<td>Mechanical failure 1.5%</td>
<td>Mechanical failure 2.3%</td>
</tr>
<tr>
<td>Second surgery*</td>
<td>12.9% of patients</td>
<td>14.5% of patients</td>
</tr>
</tbody>
</table>

*Second surgery can be defined as reoperation on the same foot or toe or surgery on another foot or toe.

---

**CONCLUSION**

Surgical correction of hammertoes is a common foot and ankle procedure with high infection and reoperation rates. Treatment alternatives are needed to lower complications and costs to the healthcare system.
The DePuy Synthes Hammertoe CCI is designed to improve rotational stability and distraction resistance, potentially reducing reoperations.

**Rotational Stability**
- Designed to provide **greater rotational stability** compared to IM devices.
- **Minimum of 464% higher rotational stability** compared to IM devices.
- **Better maintenance of stability over time** compared to IM devices.

**Distraction Resistance**
- Designed to provide **higher distraction resistance** compared to IM devices and wires.
- **Considerably higher distraction resistance** compared to IM devices and wires.
- **Active compression** of the construct to maintain reduction.

---

![Graph showing increased peak torque over cycles](image)

- **464% INCREASE**
  - DePuy Synthes Hammertoe CCI Large
  - HAMMERLOCK® 2 IM Device
  - Competitive IM Device

- **~12-fold INCREASE**
  - DePuy Synthes Hammertoe CCI Large
  - Intramedullary Device
  - 1.25 K-Wire

---

*Bench testing may not be indicative of clinical performance.*

*Compared to IM devices, defined as implants used in the intramedullary canal, excluding wires.*
**DEPUY SYNTHES HAMMERTOE CCI**

**EXTRAMEDULLARY POSITION**

**Reduced Invasiveness**

Designed as extramedullary device to reduce invasiveness, preserve the intramedullary pathway of callus formation, and maintain proper stability during healing.

**Simplified Implant Removal**

Designed as extramedullary device to require fewer procedural steps for emergency removal compared to IM devices.

The DePuy Synthes Hammertoe CCI is designed to reduce invasiveness and simplify removal due to its extramedullary position.

**IM = Intramedullary**

**References:**


HAMMERTOE CCI is contraindicated in comminuted bone surface that would militate against implant placement, pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant, and where there is foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.