EXTRAMEDULLARY FIXATION

DePuy Synthes

HAMMERTOE

CONTINUOUS COMPRESSION IMPLANT (CCI)

Evidence Summary

DEPUY SYNTHES IS WITH YOU—AND YOUR PATIENTS
EVERY STEP OF THE WAY

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THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

HAMMERTOE EPIDEMIOLOGY, CLINICAL AND ECONOMIC BURDEN

EPIDEMIOLOGY OF HAMMERTOE

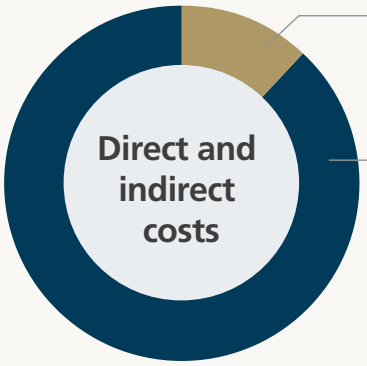
- A foot study with 3,429 participants identified hammertoe as **one of the most prevalent foot disorders, with 16.2% of patients**[1]
- Instability of the metatarsophalangeal (MTP) joints from age-related changes or gait, as well as inflammatory conditions such as rheumatoid arthritis, can lead to contracture of the digits[2]
- Pes planus foot posture was associated with increased odds of hammertoes[1]
- Hammertoes have **particular importance in diabetic patients** as they increase the risk for developing foot ulcers[3]

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[4]
- Surgical correction of hammertoe was the **most common and most costly foot and ankle surgical procedure, with high infection and reoperation rates**[4]

114,993 Medicare hammertoe procedures resulted in an estimated total of $1.04B direct and indirect (work loss and disability) healthcare costs in 2011[4]

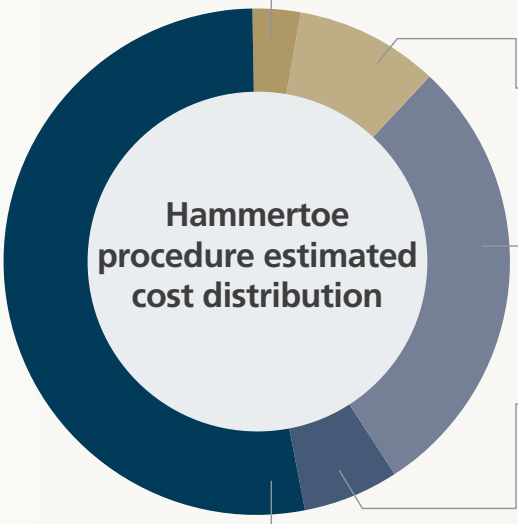
ESTIMATED HAMMERTOE PROCEDURE COSTS[4]



$126M (12%)

$911M (88%)

- Direct healthcare costs
- Indirect productivity costs



$29.5M (3%)
Professional fees

$96.7M (9%)
Hospital charges

$126M (12%)

$301.1M (29%)
Permanent total disability

$65.8M (6%)
Permanent partial disability

$544.2M (53%)
Temporary work loss

$911M (88%)

Treatment alternatives are needed to lower complications and cost to the healthcare system

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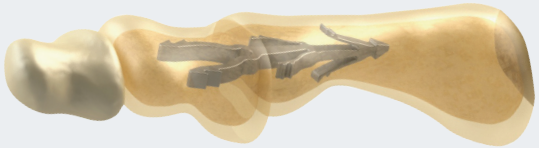
TREATMENT METHODS AND COMPLICATIONS OF HAMMERTOES

- **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]



IM DEVICES & K-WIRES

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

	US Medicare Supplemental Database[8]	US Commercial Claims Database[9]
Age	**≥65 years**; mean age 73.0 years	**18–64 years**; mean age 52.0 years
# of patients	5,786 patients	21,811 patients
Gender	76.7% female	78.6% female
Comorbidities	Hypertension (69.1%), hypothyroidism (24.7%), diabetes (23.0%)	Hypertension (38.4%), depression (17.4%), hypothyroidism (16.5%)
Complication rates (2 years)	**Infection 13.6%** Delayed healing 0.1% Mechanical failure 1.5%	**Infection 8.8%** Delayed healing 0.6% Mechanical failure 2.3%
Second surgery*	**12.9% of patients**	**14.5% of patients**

*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.

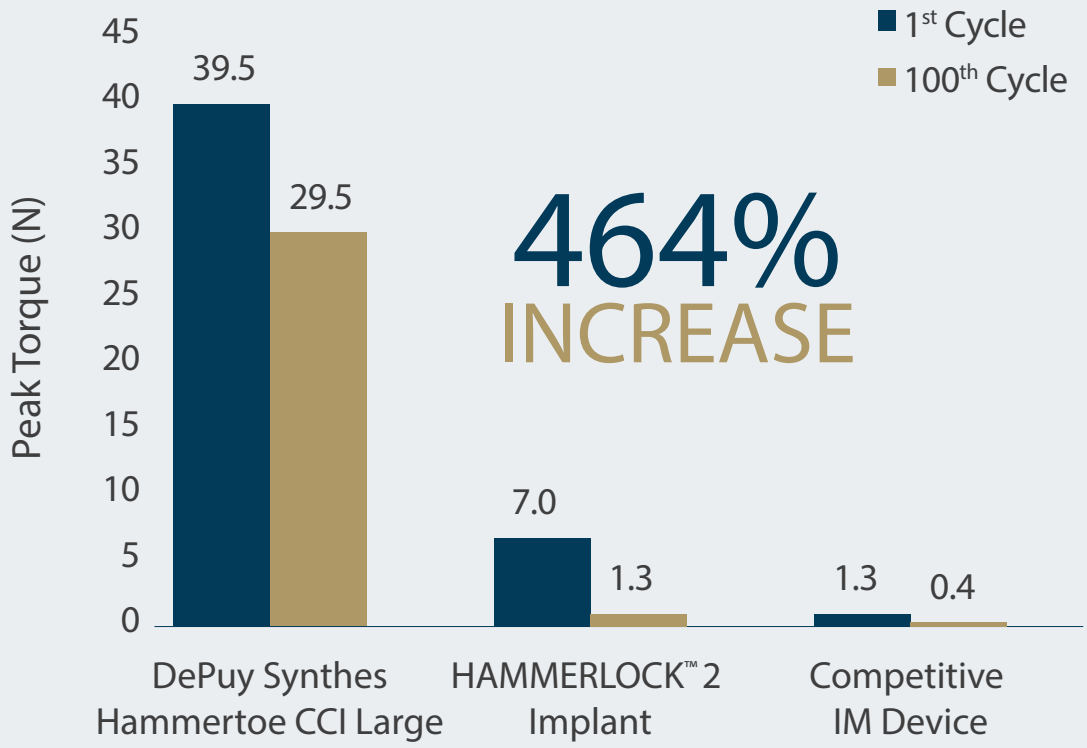
INTRODUCING DEPUY SYNTHES HAMMERTOE CONTINUOUS COMPRESSION IMPLANT (CCI)

EXTRA STABILITY VS IM IMPLANTS

Rotational Stability[10†]

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

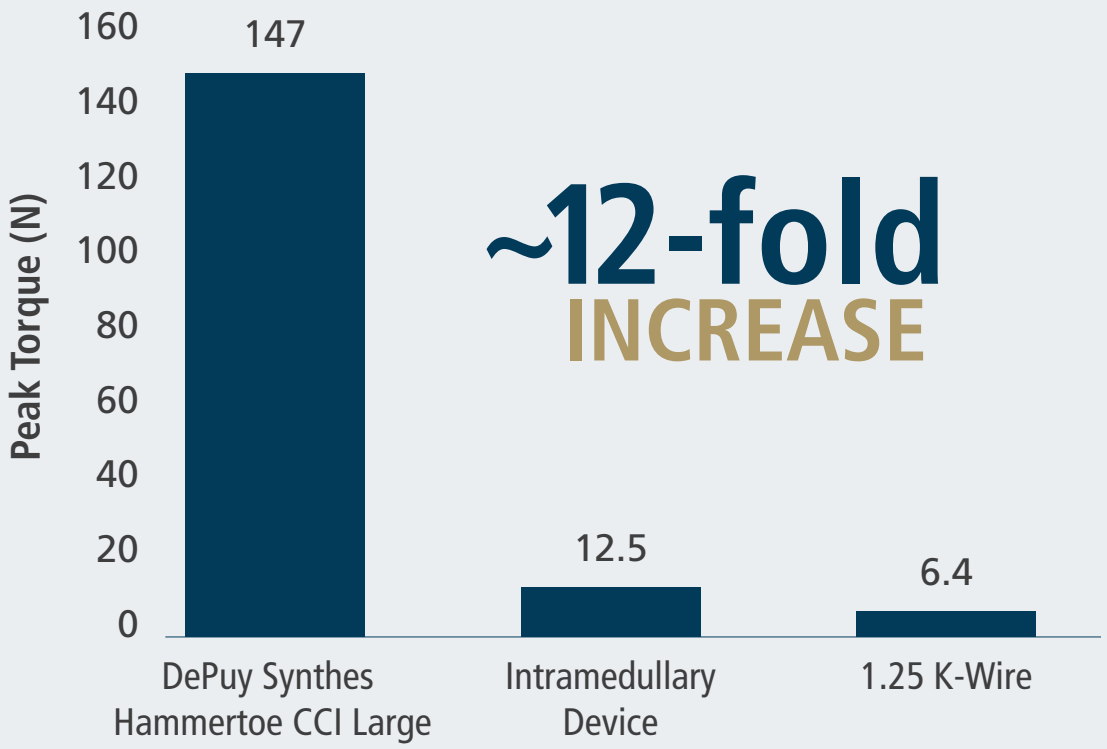


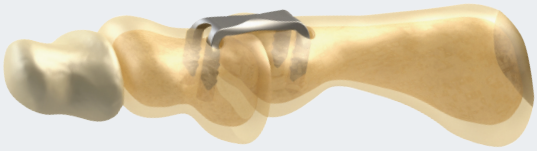
The DePuy Synthes Hammertoe CCI is designed to improve rotational stability and distraction resistance, potentially reducing reoperations

Distraction Resistance[11†]

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





— DEPUY SYNTHES HAMMERTOE CCI

[†]Pre-clinical test data are not necessarily be indicative of clinical performance. n=10 total, 5 each size.
[‡]Compared to IM devices, defined as implants used in the intramedullary canal, excluding wires.

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DEPUY SYNTHES HAMMERTOE CCI

EXTRAMEDULLARY POSITION

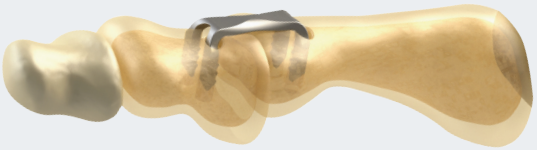
Reduced Invasiveness[12]

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

Simplified Implant Removal[13,14*]

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



DEPUY SYNTHES HAMMERTOE CCI

IM = Intramedullary

*Pre-clinical test data are not necessarily indicative of clinical performance.

References: 1. Hagedorn TJ, Dufour AB, Riskowski JL, et al. Foot disorders, foot posture, and foot function: the Framingham foot study. *PLoS One.* 2013;8(9):e74364. **2.** Zelen CM, Young NJ. Digital arthrodesis. *Clin Podiatr Med Surg.* 2013;30(3):271-282. **3.** Mavrogenis AF, Megaloikonomos PD, Antoniadou T, et al. Current concepts for the evaluation and management of diabetic foot ulcers. *EFORT Open Rev.* 2018;3(9):513-525. **4.** Belatti DA, Phisitkul P. Economic burden of foot and ankle surgery in the US Medicare population. *Foot Ankle Int.* 2014;35(4):334-340. **5.** Coughlin MJ, Dorris J, Polk E. Operative repair of the fixed hammertoe deformity. *Foot Ankle Int.* 2000;21(2):94-104. **6.** Konkel KF, Sover ER, Menger AG, Halberg JM. Hammer toe correction using an absorbable pin. *Foot Ankle Int.* 2011;32(10):973-978. **7.** Solan MC, Davies MS. Revision surgery of the lesser toes. *Foot Ankle Clin.* 2011;16(4):621-645. **8.** Chitnis A, Behrle J, Gudiboina S, et al. Complications and reimbursement among patients with hammertoe surgery: a Medicare Supplemental database study with two years follow-up. Accepted as poster at ISPOR Europe 2019. **9.** Behrle J, Chitnis A, Gudiboina S, et al. Complications and reimbursement among patients with hammertoe surgery: a commercial claims database study with two-year follow-up. Accepted as poster at ISPOR Europe 2019. **10.** BME, Hammercuff construct torsion, 05/2019, QCBD, TR- 239-12-19039. **11.** BME HammerCuff-Rev. X7-Construct Distraction, 31 May 2019, QCBD (BME quality system), TR-239-19-19040. **12.** DePuy Synthes BME Test Report, 2019. Ref: TNR-239-17 Signed (002). **13.** DePuy Synthes, Technique guide, 02/2020, Adaptiv, A239-002. **14.** BME, Surgical Technique for BME HAMMERLOCK2, 03/2017, EOS, DSEM/TRM/0317/0810.

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.

Please refer to the instructions for use for a complete list of indications, contraindictations, warning and precautions.

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