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29 **Compliance with Ethical Standards:**

30 **Disclosure of Potential Conflicts of Interest:** None of authors have a conflict of
31 interest in this manuscript. All products used are commercially available and the authors
32 have no interest in any of the manufacturers, products, or distributors.

33 **Research involving human participants and/or animals:** The institutional review
34 board (the Human Research Review Committee) has approved the above study and has
35 permitted us to perform data analysis and manuscript submission. No animal studies were
36 performed.

37 **Informed Consent:** The subjects gave informed consent to participate prior to all
38 interventions and study was approved by the institutional review board. All studies were
39 carried out in accordance with the World Medical Association Declaration of Helsinki
40 (JBJS 79A:1089-98,1997). Patient confidentiality was protected according to the U.S.
41 Health Insurance Portability and Accountability Act (HIPAA) and all data has been de-
42 identified.

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44 **Clinical Trial:** This was not a clinical trial. This was a report of continuous quality
45 improvement using bioengineering advances.

46

47 **ABSTRACT**

48 **Objective:** The present study reports the introduction of mechanical compression of the
49 knee for arthrocentesis as quality improvement intervention in a procedure clinic.

50 **Methods:** 430 consecutive symptomatic osteoarthritic knees underwent arthrocentesis
51 followed by corticosteroid injection (1mg/kg of triamcinolone acetonide). The first 215
52 consecutive knees underwent conventional arthrocentesis and injection; the quality
53 intervention of a mechanical compression brace was introduced, and the next 215
54 consecutive knees underwent mechanical compression-assisted arthrocentesis follow by
55 injection. Pain scores, arthrocentesis success, fluid yield, time-to-next-intervention,
56 injections/year, and medical costs were measured.

57 **Results:** No serious adverse events occurred in 430 subjects. Diagnostic synovial fluid
58 (≥ 2 ml) was obtained in 9.3% (20/215) without compression and 40.9% (88/215) with
59 compression ($p=0.00001$, z for 95% CI= 1.96, Pierson). Mechanical compression was
60 associated with a 231% increase in mean arthrocentesis volume: compression 5.3 ± 11.2
61 ml, conventional 1.6 ± 6.4 ml (CI of difference $2.0 < 3.7 < 5.4$; $p=0.00001$). Time-to-next-
62 intervention after compression-assisted arthrocentesis was longer: 6.9 ± 3.5 months
63 compared to conventional: 5.1 ± 2.7 months ($p<0.00001$, 95% CI of difference $1.2 < 1.8 <$
64 2.3). Mechanical compression was associated with a reduction in the number of
65 corticosteroid injections administered per year: mechanical compression: 1.7 ± 0.9
66 injections/year; conventional: 2.4 ± 0.5 injections/year ($p<0.00001$, 95% CI of difference -
67 $0.83 < -0.70 < -0.56$). Mechanical compression did not increase overall yearly costs
68 associated with management of the symptomatic knee (mechanical compression:

69 \$293.30/year/knee, conventional: \$373.29/year/knee) ($p < 0.0001$, 95% CI of difference 47
70 $< 80 < 112$).

71 **Conclusions:** Routine mechanical compression of the knee for arthrocentesis and
72 injection is an effective bioengineering quality improvement intervention in a procedure
73 clinic.

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76 **Key words: arthrocentesis, intraarticular, injections, quality, knee**

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80 **INTRODUCTION**

81 After non-pharmacologic interventions and topical and oral medications,
82 complete arthrocentesis followed intraarticular injection of corticosteroids is often
83 recommended for symptomatic flares and short-term relief of pain of arthritis of the knee
84 [1-5]. Klocke and colleagues have recently reported that corticosteroid injection of the
85 osteoarthritic knee may actually decrease cartilage degradation in the short-term as
86 measured by biomarkers, providing indirect support for the above recommendations [1-
87 6]. Recently, Meehan et al, Bhavsar et al, and Yaqub et al have demonstrated that
88 mechanical compression of the knee provides more complete arthrocentesis before
89 injection in both the effusive and non-effusive knee and suggest that mechanical
90 compression might be a reasonable quality improvement intervention for arthrocentesis
91 [6-9]. In the present study we determined knee arthrocentesis and injection quality
92 measures before and after the introduction of mechanical compression as a quality
93 improvement intervention.

94 **MATERIALS AND METHODS**

95 This Quality Improvement program was formalized in our medical center in a
96 formal effort to improve rheumatology outcomes and services with a commitment to
97 continuous quality improvement in outpatient rheumatology as recently described
98 recently by Chow et al [10]. The study was approved by the institutional review board
99 (IRB) and in compliance with the Helsinki Declaration and subsequent revisions. The
100 sequential study design was typical of quality improvement prospective cohort study with
101 1) measurement of baseline quality factors in consecutive traditionally treated patients, 2)
102 introduction of the quality intervention, and 3) re-measurement of quality factors in

103 patients after the intervention. A total of 430 knees with grade II-III osteoarthritis were
104 included in this study. In the primary corticosteroid arm, the first consecutive 215 knees
105 underwent conventional arthrocentesis and injection, then the quality intervention was
106 introduced, and the second 215 consecutive knees underwent mechanical compression-
107 assisted arthrocentesis and injection. Inclusion criteria for the study consisted of: 1)
108 painful symptomatic grade II-III osteoarthritis knee with the patient requesting a knee
109 injection, 2) indications for therapeutic-diagnostic arthrocentesis and/or injection, 3)
110 indication for corticosteroid injection, and 4) formal signed consent of the patient to
111 undergo the procedure [11]. Prior to the procedure, the presence or absence of clinical
112 effusion was confirmed by physical examination by palpation of the extended knee for
113 suprapatellar bursa distention, ballottement of a floating patella while applying pressure
114 superiorly and inferiorly, and visible-palpable fluid shift with asymmetric compression.
115 The knee was then classified as “effusive” (swollen) or “non-effusive” (dry).
116 Arthrocentesis prior to injection was attempted in all subjects prior to injection regardless
117 of the presence or absence of a clinical effusion.

118 **Arthrocentesis and Joint Injection Technique**

119 Chlorhexidine 2% was used for antisepsis. Knee procedures were performed
120 using the conventional lateral approaches with the one-needle multiple syringe technique
121 [12-20]. A 22 gauge 2 inch needle (4710007050 – 22 GX2” (0.7X50 mm), FINE-JECT,
122 Henke Sass Wolf, Kettenstrasse 1 D-78532 Tuttlingen, Germany) on a 3 ml syringe (3 ml
123 Luer Lok syringe, BD, 1 Becton Drive, Franklin Lakes, NJ 07417, website:
124 <http://www.bd.com>) filled with 3 ml of 1% lidocaine (Xylocaine® 1%, AstraZeneca
125 Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437)

126 was introduced into the lateral parapatellar recess of the suprapatellar bursa and if no
127 fluid returned, into the patellofemoral joint. The knee was then compressed or “milked”
128 by the operator’s free hand to optimize fluid return [8,9,12-17]. If fluid return was
129 obtained and the syringe filled with synovial fluid, the intraarticular needle was left in
130 place, the 3 ml syringe was removed, and a syringe exchange was performed with
131 additional 20 ml syringes until fluid return ceased. Pain scores, arthrocentesis success,
132 and fluid yield were recorded. After the fluid return ceased, a final syringe exchange was
133 performed, and the joint was then injected through the already-placed intraarticular
134 needle using a 3 ml syringe with 1 mg/kg triamcinolone acetonide suspension (maximum
135 80 mg) (Kenalog® 40, Westwood-Squibb Pharmaceuticals, Inc (Bristol-Myers Squibb),
136 345 Park Ave, New York, NY 10154-0004, USA). In the quality intervention group, an
137 elastomeric knee brace (YooSoo Adjustable Knee brace, Shenzhen Shi Hai Xun Yun Wei
138 Co., Ltd. No.203, 69 Dong, Liyuan Xin Cun, Bantian Street, Longgang, 518000,
139 Shenzhen, China, Amazon, <https://www.amazon.com>) was placed and modified so the
140 lateral suprapatellar bursa and patellofemoral joint could expand with fluid (Figures 1 and
141 2]. The brace applies constant mechanical compression to the medial suprapatellar bursa
142 and the synovial compartments of the inferior knee, collapsing these compartments, and
143 forcing fluid to the lateral suprapatellar bursa and the patellofemoral joint where the fluid
144 could be accessed (Figures 1 and 2). Before the brace was applied, the skin surfaces of
145 the knee were cleaned with 2% chlorhexidine. As the brace itself was clean but non-
146 sterile, after the compressive brace was placed, the antisepsis with 2% chlorhexidine was
147 again applied to the skin of the operative portal overlying the lateral recess of the

148 suprapatellar bursa, and arthrocentesis and injection were performed identically as
149 described above.

150 **Outcome Measures:**

151 Patients were observed for serious adverse events. Diagnostic fluid was defined as
152 \geq to 2.0 milliliters (ml) (1 ml for culture, and 1 ml for cell counts and crystal examination
153 [8]. Patient pain was measured with the 0-10 cm Visual Analogue Pain Scale (VAS Pain
154 Scale), where 0 cm = no pain and 10 cm = unbearable pain [18-20]. The total number of
155 corticosteroid injections per year were recorded in each individual including those
156 administered in different clinics leveraging the electronic medical record to tract
157 comprehensive quality of care as described by Schmajuk and colleagues [21]. Weitoft et
158 al has demonstrated that complete arthrocentesis extends the time-to-next-symptomatic-
159 flare and thus the time-to-next-intervention [5]. Time-to-next-intervention also
160 corresponds to the time to the next corticosteroid or hyaluronan injection, surgical
161 intervention, physical therapy or splint referral, joint imaging, or referral to another
162 specialist, all of which increase costs. Thus the time-to-next-intervention permits
163 preliminary baseline cost determinations [5,18,22-24].

164 **Costs associated with the Quality Intervention**

165 Costs of the procedure in US dollars (\$) were defined as those costs reimbursed
166 by 2017 Medicare (United States) national rates for HCPC/CPT 20610 code for a large
167 joint arthrocentesis for a physician office (\$68.97/procedure), 15 minute outpatient
168 encounter (\$76.69), 60 mg triamcinolone acetonide (\$13.00/procedure), and compressive
169 brace (\$10.00/brace) [25]. Yearly costs were calculated by multiplying the
170 costs/procedure x 12 months divided by the months to-the-next-intervention (time to

171 reinjection, surgical intervention, physical therapy or splint referral, joint imaging, or
172 referral to another specialist) – this calculation is an actual underestimate of true medical
173 costs but provides a standardization of the lowest level of costs from an injection
174 intervention as previously described [5,20,24,25].

175 **Statistical analysis:** Data were entered into Excel (Version 5, Microsoft, Seattle, WA),
176 and analyzed in SISA (Simple Interactive Statistical Analysis,
177 <http://www.quantitativeskills.com/sisa/>). A power calculation was made using
178 preliminary data at this level where $\alpha=0.0001$, power = 0.9, and allocation ratio = 1.0
179 indicated that n=100 in each group would provide statistical power at the $p<0.001$ level
180 and n = 200 in each group at the $p<0.0001$ level. Pierson Chi square two by two table
181 analysis was performed on categorical data calculating both p values and confidence
182 intervals with significance reported at the $P < 0.05$ level. Measurement data was analyzed
183 using the t-test calculating both p values and confidence intervals.

184 **RESULTS**

185 The two study cohorts (215 conventional and 215 compression-assisted) were
186 similar in demographics and baseline pain measures. The mean age of the conventional
187 cohort was 63.2 ± 11.6 years and the compression-assisted cohort was 60.1 ± 12.1 years
188 ($p=0.007$, 95% CI of difference $-5.3 < -3.1 < -0.9$). Male:female ratio was 17:198 (92%
189 female) in the conventional cohort, and 19:196 (88% female) in the compression cohort
190 ($p=0.73$, z for 95% CI= 1.96, Pierson), typical of studies of osteoarthritis of the knee
191 demonstrating a female gender bias. Pre-procedural pain according to the 10 cm VAS
192 was 7.2 ± 1.9 cm in the conventional cohort and 7.2 ± 1.8 cm in the compression cohort (p
193 $=0.87$, 95% CI of difference: $-0.4 < 0.0 < 0.3$ (Wald)). Procedural pain was 2.6 ± 1.6 cm in

194 the conventional cohort and 2.4 ± 1.8 cm in the compression cohort ($p = 0.22$, 95% CI of
195 difference $-0.5 < -0.2 < 0.1$ (Wald)). Post-Procedural pain was 1.1 ± 1.5 cm in the
196 conventional cohort and 1.0 ± 1.6 cm, in the compression cohort ($p = 0.5$, 95% CI of
197 difference $-0.4 < -0.1 < 0.2$ (Wald)).

198 There were no serious adverse events encountered by the 430 patients in the
199 cohort including but not limited to reaction to local anesthesia, needle-stick, infection,
200 septic joint, hemarthrosis, deep venous thrombosis, pseudoseptic arthritis, dermal
201 atrophy, significant bruising, hemorrhage or post-injection visits to emergency facilities.

202 Diagnostic synovial fluid (≥ 2 ml) was obtained in 9.3% (20/215) without
203 compression and 40.9% (88/215) with compression ($p=0.00001$, z for 95% CI= 1.96,
204 Pierson). Absolute volume of arthrocentesis fluid yield without compression was 1.6 ± 6.4
205 ml versus 5.3 ± 11.2 ml with compression (231% increase, CI of difference $2.0 < 3.7 < 5.4$,
206 $p=0.00001$). These data are shown in Figure 3 in graphic form.

207 In the palpably non-effusive (dry) knees ($n = 177$) the absolute volume of
208 arthrocentesis fluid obtained without compression was 0.0 ± 0.00 ml versus 1.5 ± 2.4 ml
209 with compression ($n = 178$) ($>100\%$ increase, 95% CI of difference $0.995 < 1.5 < 2.005$,
210 $p=0.0001$).

211 In the palpably effusive knee absolute volume of arthrocentesis without
212 compression ($n=38$) was 14.7 ± 13.8 ml versus 25.3 ± 15.5 ml with compression ($n = 37$)
213 (72.1% increase, 95% CI of mean difference: $-3.0 < -1.7 < -0.3$, $p=0.02$).

214 Mechanical compression was associated with fewer subsequent corticosteroid
215 injections per year: mechanical compression: 1.7 ± 0.9 injections/year as opposed to

216 conventional: 2.4 ± 0.5 injections/year ($p < 0.00001$, 95% CI of difference $-0.83 < -0.70 <$
217 0.56).

218 Time-to-next-intervention after intraarticular corticosteroid injection was longer
219 with constant compression 6.9 ± 3.5 months as opposed to conventional treatment 5.1 ± 2.7
220 months ($p < 0.00001$, 95% CI of difference $1.2 < 1.8 < 2.3$). These data are shown in Figure
221 4 in graphic form.

222 Time-to-next-intervention was also longer in the effusive knees treated with
223 mechanical compression, 7.3 ± 3.0 months as opposed to conventional 5.6 ± 3.0 months
224 ($p < 0.016$, 95% CI of difference $-3.1 < -1.7 < -0.3$).

225 Time-to-next-intervention was also longer in the 178 non-effusive knees treated
226 with constant compression, 6.9 ± 3.5 months as opposed to 177 non-effusive knees who
227 receive conventional treatment 5.0 ± 2.6 months ($p < 0.01$, 95% CI of difference $-3.3 < -1.9 <$
228 -0.5).

229 Lowest level costs per year for conventional knee aspiration/injection was
230 $\$373 \pm 189$ /year/knee; and for mechanical compression was $\$293 \pm 152$ /year/knee
231 ($p < 0.0001$, 95% CI of difference $47 < 80 < 112$), thus, mechanical compression did not
232 increase yearly costs.

233 **DISCUSSION:**

234 In an effort to improve the arthrocentesis process, Meehan et al have recently
235 demonstrated that an external compressive brace shifts fluid in the knee where it can be
236 more easily accessed [7]. Similarly, Bhavsar et al demonstrated that external mechanical
237 compression of the knee collapsed non-target synovial spaces and dilated and expanded
238 target spaces and thus improved arthrocentesis success and yield in both the effusive and

239 non-effusive knee [8]. Yaqub et al have also demonstrated that mechanical compression
240 permits improved arthrocentesis success with the knee in different positioning [9].
241 Because of low cost and improved arthrocentesis success it has been proposed that
242 mechanical compression could be used as a low cost quality improvement intervention in
243 procedure clinics [7-9].

244 As part of an institutional quality improvement program to reduce occupational
245 needle-sticks and optimize needle procedures of the knee, we introduced mechanical
246 compression of the osteoarthritic knee before arthrocentesis and corticosteroid injection.
247 Meehan et al, Bhavsar et al, and Yaqub et al used a repeated measure paired study design
248 in the same subject that was sensitive to aspiration success, but not to other outcomes,
249 costs, or changes in adverse events [7-9]. The present pragmatic study used a different
250 design to study the quality effects of mechanical compression, specifically a two-cohort
251 design typical of quality improvement interventions [7-10,21-26].

252 In the present two-cohort study mechanical compression was associated with an
253 increased diagnostic joint aspiration success from 9% to 44%, and the volume of fluid
254 collected by 231% (Figure 3), similar to the findings of Bhavsar et al who used a repeated
255 measure in the same individual study design [8]. The use of the mechanical compression
256 brace did not appear to have a negative effect on subsequent injection outcomes. Time-
257 to-next-intervention after compression-assisted arthrocentesis was 6.9 ± 3.5 months
258 compared to conventional arthrocentesis: 5.1 ± 2.7 months ($p < 0.00001$). Mechanical
259 compression was associated with in a reduction in the total number of corticosteroid
260 injections administered per year: mechanical compression: 1.7 ± 0.9 injections/year;
261 conventional: 2.4 ± 0.5 injections/year ($p < 0.00001$). Mechanical compression did not

262 increase overall costs associated with management of the knee (mechanical compression:
263 \$293.30/year/knee, conventional: \$373.29/year/knee, $p < 0.0001$). Thus, mechanical
264 compression of the knee for arthrocentesis before injection appears to be a reasonable
265 quality improvement intervention for knee procedures that improves quality measures
266 and does not increase overall costs.

267 A number of prior studies have focused on the need to accurately place the needle
268 intraarticularly and completely aspirate as much effusion as possible prior to injection,
269 and all have generally demonstrated improved joint injection outcomes [5,18,27-29].
270 In 2003 Weitoft et al demonstrated that complete aspiration of the knee prior to
271 corticosteroid injection prolonged the time-to-flare, and thus, reduced the need for
272 repetitive corticosteroid injection [5]. If the data in Figure 4 of the present study are
273 directly compared to the published data in Figure 1 of Weitoft et al, the present
274 independent data show a similar relationship in regards to improvement in outcome after
275 complete aspiration [5].

276 Extraction of joint fluid for biomarker analysis even in the dry (non-effusive)
277 knee is presently an important area in arthritis research and may also be integral to future
278 joint preservation strategies and therapies [6,22,29,30]. Similar to Bhavsar et al, Yaqub
279 et al, and Meehan et al, but using a different study design, we found that mechanical
280 compression permitted fluid extraction in a much greater proportion of osteoarthritic
281 knees that presented clinically as dry, non-effusive knees (Figure 3) [7-9]. The failure of
282 full synovial fluid extraction during conventional aspiration of both the effusive and non-
283 effusive knee may be due to a combination of mistargeting of the needle, the complex
284 intraarticular synovial compartments that trap viscous fluid, ineffective manual

285 compression, resistance to movement of fluid due to the semi-solid gel-like properties of
286 synovial fluid, and its non-Newtonian elasticity and viscosity [8,29-31]. A constant
287 circumferential pressure as provided by a mechanical compressive brace dilates the joint
288 space to be targeted (Figures 1 and 2) and takes advantage of the classic rheological
289 properties of synovial fluid to permit linear non-turbulent fluid flow to the needle access
290 point, enhancing fluid aspiration (Figure 3).

291 One limitation of this study is that medial approaches to aspiration and injection
292 were not used; it is possible that medial approaches might be just as successful by placing
293 the compressive brace in a reverse orientation. Another potential limitation was the
294 sequential rather than randomized study design that potentially could be a cause of
295 consistent bias; however, sequential methodology is a standard quality improvement
296 vehicle in all hospitals [10,22,23,26]. In the present study, an elastomeric brace was
297 used, it is anticipated that commercially available pneumatic braces would have similar
298 mechanical and clinical effects [32].

299 **Conclusion.**

300 Mechanical compression of the knee prior to corticosteroid injection permits more
301 complete synovial fluid extraction, and does not appear to increase costs or adversely
302 affect outcomes. Routine mechanical compression of the knee for arthrocentesis and
303 injection is a reasonable quality improvement intervention in a procedure clinic.

304

305 **Conflict of Interest:** None of authors have a conflict of interest in this manuscript. All
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307 manufacturers, products, or distributors.

308

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411

412 **FIGURES.**

413

414 **FIGURE 1.** The arthrocentesis is performed through the superiolateral approach with an
415 elastomeric brace applying circumferential (radial) constant mechanical compression to
416 the knee and forcing residual fluid where it can be accessed at the superiolateral portal.
417 An absorbent impermeable drape can be placed in the access portal to protect the brace.

418

419 **FIGURE 2.** This ultrasound image demonstrates the lateral recess of the suprapatellar
420 bursa with manual compression versus mechanical constant compression with the
421 elastomeric brace showing substantial shift of intraarticular synovial fluid toward the
422 access point at the lateral recess of the suprapatellar bursa. The aspiration/injection
423 needle can be seen in the effusion on the right hand side after the constant compression
424 brace has been applied.

425

426 **FIGURE 3.** This graph shows the markedly increased synovial fluid yield with
427 mechanical constant compression (upper line) (n=215) and conventional (lower line)
428 (n=215), demonstrating a mean 230% increase in synovial fluid yield ($p<0.0001$).

429

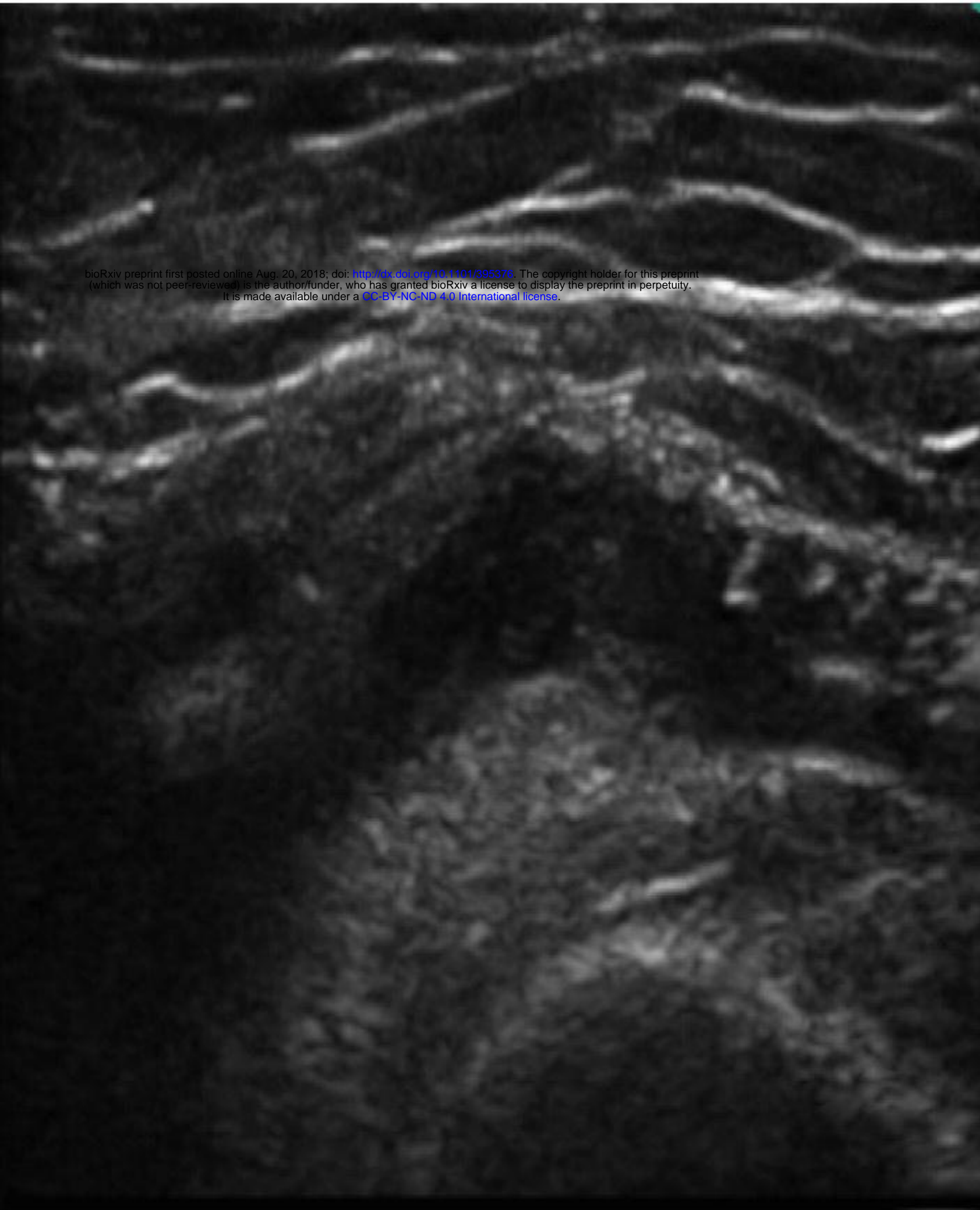
430 **FIGURE 4.** This graph shows the increased time-to-next intervention with mechanical
431 constant compression (upper line) (n=215) and conventional (lower line) (n=215) in 430
432 knees demonstrating a mean 35% increase in time-to-next-intervention ($p<0.00001$).

433

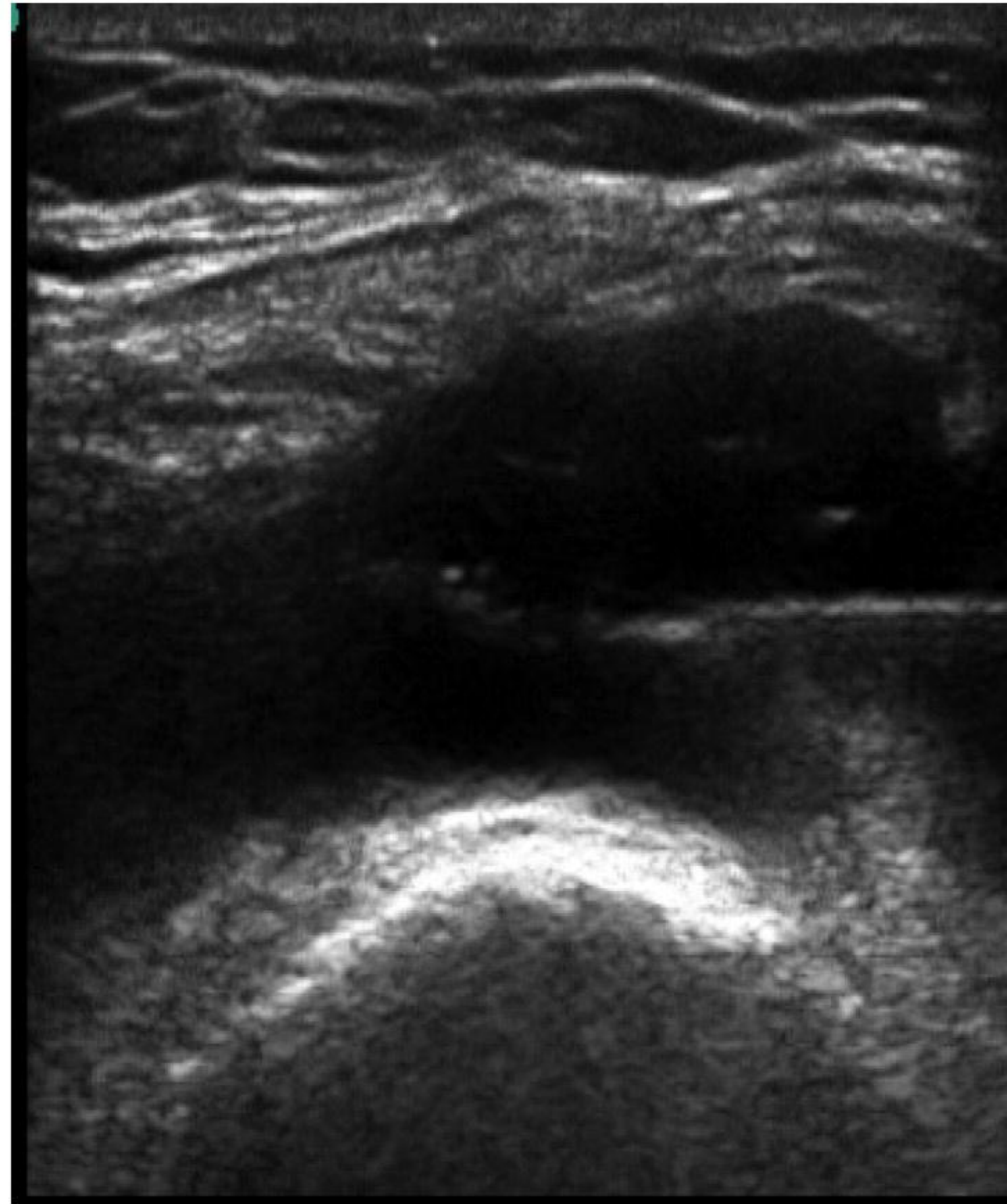
434

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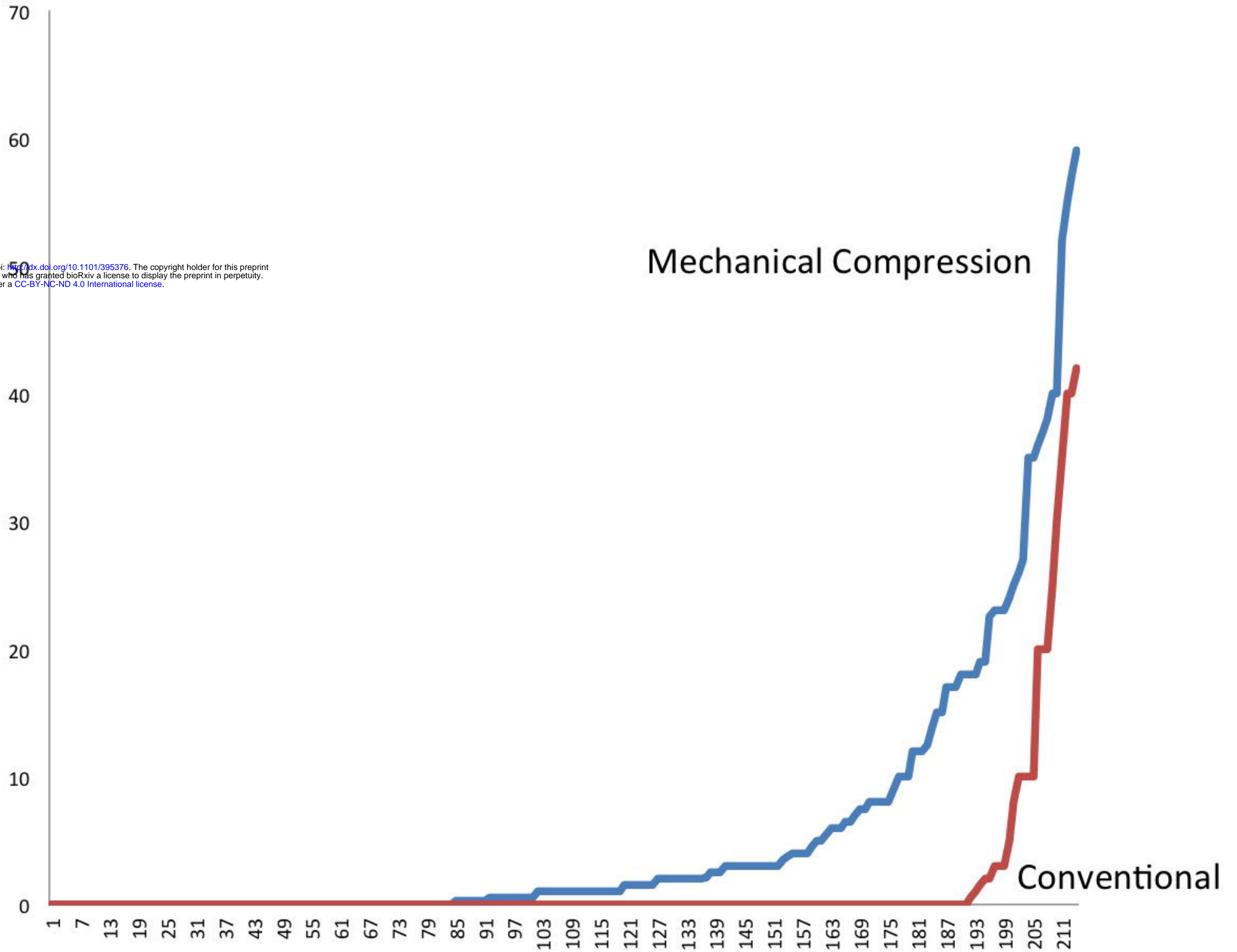
Manual Compression



Mechanical Compression

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Arthrocentesis
Fluid Yield
Milliliters (ml)



ALL KNEES UNDERGOING ARTHROCENTESIS BEFORE INJECTION

TIME TO INTERVENTION (months)

