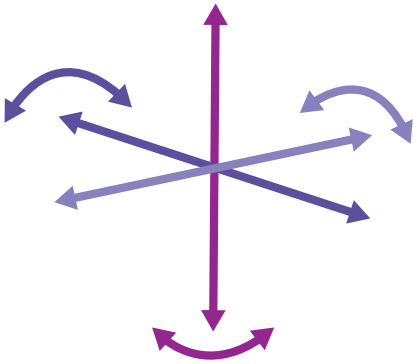
EVIDENCE FOR THE LONG-TERM ROBUSTNESS AND SAFETY OF POLYCARBONATE URETHANE IMPLANT COMPONENTS : A NARRATIVE REVIEW

INTRODUCTION

Spine Innovations is a French company that manufactures and distributes two types of total disc replacements (TDR), one for the cervical spine (the CP-ESP) and one for the lumbar spine (the LP-ESP). In these acronyms, CP and LP refer to 'cervical prosthesis' and'lumbar prosthesis', respectively, while ESP represents 'elastic spine pad'. Both are viscoelastic disc arthroplasty devices with 6 degrees of freedom (DOF) [1]. This characteristic is intended to reproduce the 6 DOF exhibited by natural human intervertebral discs.



6 DOF

Surprisingly, in the field of spinal disc arthroplasty manufacturing, many players still propose devices with only 5, or even fewer DOF. Among the 5 physiologic movements imitated by TDRs with 5 DOF, 3 are rotational (flexion-extension, lateral bending, and axial rotation) and 2 are translational (antero-posterior and left-right translation). The 6th DOF that is lacking in the latter TDRs, but present in viscoelastic TDRs is up-down translation, which is intended to imitate the shock absorption provided by healthy discs.

Long-term clinical follow-up of CP-ESP (Kaplan-Meier survivorship out to 8 years in a series of 142 patients) [submitted for publication] and LP-ESP (73 patients with average follow-up of 12.2±2.0 years) [submitted for publication] suggests that these two devices provide relative protection against vertebral endplate impaction fractures and device subsidence that can sometimes lead to failure in disc arthroplasty [2].

Because the viscoelastic cores of LP-ESP and CP-ESP are securely attached above and below to titanium endplates, these devices also promote elastic return during bending and axial rotation similar to the elastic return observed in healthy discs. This feature is designed to limit facet joint pressure that could contribute to painful degeneration, especially in the lumbar spine [3]. Indeed, in a U.S. database study that included 1,203 lumbar TDR patients, the 5-year rate of lumbar facet injections was 11.5% [4]. Among the 73 LP-ESP patients cited above, none required facet joint injections throughout the average follow-up of 12 years [series submitted for publication].

Of course, the most important property of either viscoelastic or mechanical TDRs is to maintain intervertebral mobility instead of eliminating it as would a successful intervertebral fusion procedure. TDRs were developed as an alternative to surgical fusion (in patients with no contraindication to TDR) to reduce the rate of symptomatic degenerative disc disease at the levels adjacent to the treated level. Controlled trials with sufficient follow-up have, in fact, demonstrated that rates of such adjacent segment disease is lower in patients randomized to TDR than in those randomized to intervertebral fusion both in the lumbar [5] and cervical [6] spine. Among 56 one-level LP-ESP patients, the average ROM at the LP-ESP level was 5.9±4.0° at 1 year, 7.0±3.8° at 2 years, and 7.3±3.5° at 5 years [7]. Similar mobility was found in the above-cited series of 73 LP-ESP patients, in whom average mobility at the treated level was 6.2±1.5° at one year, 7.0±1.7° at two years, 7.2±1.4° at five years, and 6.9°±1.4° at final follow-up (average, 12.2 years) [series submitted for publication]. The overall 12-year rate of adjacent-level reoperations in the latter cohort was only 5.5%, strongly supporting a protective effect of this sustained mobility against adjacent segment disease.

In both of Spine Innovations arthroplasty devices, the primary viscoelastic component, which can be credited for long-term protection against subsidence, painful facet joint degeneration, and adjacent segment disease, is made of a polycarbonate urethane (hereafter, PCU) [1]. PCU is one of many polyurethane elastomers, all of which include three components: a diisocyanate, an oligomeric macromonomer (a carbonate in PCUs) and a chain extender that can be combined in different ratios to produce polyurethane elastomers with vastly differing physicochemical and mechanical properties [8]. The carbonate group of PCUs provides polymers with high pressure resistance and tensile strength; these properties are non-linear and strain-rate dependent, closely matching intervertebral disc mechanics [9, 10]. PCU is also superior to other polyurethanes in terms of resistance to hydrolysis, oxidation and stress cracking [11-13]. To be perfectly precise, the Bionate (also referred to as Corethane in the literature) family of PCU elastomers is formed by polymerizing the "soft-segment" component poly(1,6-hexyl-1,2-ethyl carbonate) diol with 4,4'-methylene bisphenyl diisocyanate and the chain extender butanediol [14]. Bionate with a Shore stiffness of 80A (DSM Corporate, Heerlen, Netherlands) is the specific PCU used in the CP-ESP and LP-ESP TDRs that accounts for their shock absorption, elastic return, and mobility [9, 15].
Unfortunately, in today's world disinformation has become a widely used means of influence. Fact checking has currently become a necessary routine. There have been untrue claims by competitors of Spine Innovations that 1) PCU is a novel substance with no previous history of use in patients, and 2) consequently, there is no evidence supporting the long-term safety and robustness of PCU in implants.

The present review was undertaken to demonstrate that PCU has long been extensively used in implants in patients, and that, as such, PCU has exhibited safety and robustness.

METHODS

The PubMed internet site of the United States National Library of Medecine was searched to document both analyses of PCU material and the actual clinical use of PCU implants. As the present review is intended for professionals involved in spinal surgery, particular attention is given to reports on spinal implants that include PCU.The present review of the literature was systematic, but not exhaustive in that Embase was not consulted and only one search string, i.e. «polycarbonate urethane», was used in PubMed. Nevertheless, it would be difficult to qualify the search itself as illogical or biased. The viscoelastic core of the CP-ESP and LP-ESP includes pure Bionate 80A PCU, which has been the object of disinformation in the field. For those who might question the good faith of Spine Innovations in the choice of articles generated by the PubMed search to exclude from discussion in the present white paper, the company retains a complete table that explains why each article was included or excluded from consideration. This voluminous table may be shared with current and potential clients upon request.

In addition to reports found by the aforementioned PubMed search, certain references from those reports were cited, as well, including references from articles that otherwise would have been excluded from consideration herein. For example, animal studies and biomechanical studies were excluded unless they contained relevant information about PCU. Finally, additional ad hoc searches were used to further investigate some of the TDRs cited in the articles found by the primary literature search. One justification of such ad hoc searches involves the CAdisc cervical and lumbar TDRs. In a case report published in 2018 generated by the primary literature search, the authors stated that the CAdisc-L had been removed from the market, but they failed to state the year it was withdrawn [16]. Additional searches in PubMed did not answer this question, which was finally resolved by a Google search (see below). Although these devices were withdrawn from the market in 2014 and 2015, respectively, they were described in at least four separate reports generated by our prior literature searches and published years later (in 2019, 2020, 2023 and 2024), leaving readers to believe that the CAdisc TDRs were still being implanted [17-20].

RESULTS & DISCUSSION

Applying the search string "polycarbonate urethane" to PubMed in late December 2024 generated 186 articles from as early as 1995 to the present. To limit the number of referenced articles, we excluded reports on composite materials only partially made of PCU or on modified PCU. Also excluded from consideration were many animal studies, biomechanical studies, veterinary studies, and a study of a biomaterial comparable to PCU.

Clinical use of PCU outside the field of spinal surgery

Outside the realm of spinal operations, implants containing PCU are used in patients for hip replacements [21-27], hemodialysis [28-34], vascular surgery [35-38], knee meniscus replacements [39-41], total knee replacement [42], implantable extra-articular knee load absorbers [43], and breast implants [44].

Use of PCU in spinal implants other than TDRs

Since 1994 [45], PCU has been used in spinal surgery for posterior dynamic stabilization devices such as Dynesys [46-49]. Other posterior dynamic stabilization systems with PCU components include Flex+2® (Spine Vision, S.A., Belgium), TDX® (Orthofix, Inc.), Transition® (Globus Medical, Inc.) [10, 50], PercuDyn (Interventional Spine Inc.; Irvine, CA) [51, 52] and the BDyn device (S14 Implants, Pessac, France) [53, 54]. The PCU used in BDyn is the same Bionate 80A used in the ESP TDRs [9].
Bionate 80A is also the material that has been selected for the development of a nucleus pulposus replacement because of its biocompatibility, high resistance to pressure, good tensile strength and Poisson creep contraction ratio similar to that of the nucleus pulposus [55, 56]. That device is designed to minimize the risks of subsidence and extrusion through the annular gap used for removal of the nucleus pulposus [56]. Dedicated instruments have been developed to squeeze this Bionate nucleus inside the annulus [57]. PCU was the primary component of another nucleus pulposus replacement, the Newcleus (Sulzer Centerpulse, Switzerland) [58]. Development of this device began in 1990 and led to trials in five patients in 1998 [59]. Although the average 2-year clinical results of this PCU device were good in all five patients with no complications [59, 60], Sulzer Centerpulse never commercialized it in Europe or the United States [58]. Soon after the development of Newcleus, Zimmer Holdings, Inc. acquired Centerpulse [61]. It appears that Zimmer chose to focus on Dynardi, the lumbar TDR that had also been developed by Sulzer Centerpulse [62], rather than sustaining both devices.

Use of PCU in TDRs

The Bryan cervical TDR (Medtronic) had a proprietary PCU core surrounded by a polyether urethane sheath, both of which were sandwiched between two pure titanium plates [63-65]. Clinical use of PCU in TDRs began 25 years ago, as the first human studies of the Bryan cervical TDR started in January 2000 [65].

The Freedom Lumbar Disc (Axiomed Spine Corporation) consists of a proprietary silicone PCU (Bionate-S) bonded to and sandwiched between two titanium alloy end plates [66, 67]. The silicone PCU core is surrounded by a polyether urethane sheath made of Biospan-S [66]. In a comparative registry study, 48 Freedom Lumbar Disc patients from the SWISSspine registry were compared to 141 unmatched anterior lumbar interbody fusion (ALIF) patients from the Spine Tango registry. At one-year follow-up the probability of achieving a minimum clinically important improvement of 2/10 in back pain was 93.8% after the Freedom lumbar device and 74.8% after ALIF. Complications and revision surgeries were not included in this report [68].

The eDisc lumbar TDR (Integra) contains a proprietary formulation of PCU between two titanium endplates [66]. The Physio-L (K2M Group Holdings, Leesburg, Virginia) lumbar TDR consists of a PCU core that is securely attached to 2 titanium endplates by a purely mechanical attachment that employs no adhesives [69, 70]. A small retrospective single-arm study of 10 one-level and 5 two-level patients was reported with 7-year follow-up. Index or adjacent level additional surgery was performed in 1 of the one-level patients and 3 of the two-level patients [70]. The Shore stiffness of the Physio-L PCU core was not reported.

The M6-L is a lumbar TDR with a PCU core between titanium alloy endplate and surrounded by an ultra-high molecular weight polyethylene (hereafter, polyethylene) «annulus» and a polymer sheath intended to prevent dissemination of polyethylene wear debris [71-73], which is associated with osteolysis-related issues in disc, hip and knee arthroplasty [74]. The M6-L was approved for clinical use in 2006, and over 18,000 were implanted between 2009 and 2021 with no reports of polyethylene debris-related osteolysis, which has led to failures of the M6-C cervical TDR [75-80]. Such osteolytic failures in the cervical device are typically associated with rupture of the wear debris sheath, and primarily at C5-6, where cervical mobility is highest [77].

The primary factor explaining why no osteolytic failure of the M6-L has appeared in the literature to date might be the low mobility of the lumbar spinal segments that would theoretically have a protective effect on the polymer sheath that retains polyethyene debris. It is important to note that the osteolysis issues of M6-C are related to debris from its polyethylene annulus, not debris from its PCU nucleus. In any event, Orthofix has recently announced its plan to discontinue both the M6-C and the M6-L product lines for economic reasons [81].

Here, it should be recalled that polyethylene wear debris-related osteolysis is impossible with LP-ESP or CP-ESP, because neither includes polyethylene components. Nonetheless, even viscoelastic disc replacements without polyethylene cannot provide 100% protection against rare bone-loss related device failures. For example, after more than four years follow-up among 28 Bryan cTDR patients, one underwent additional surgery for severe bone-loss related subsidence with evidence that suggested bacterial infection [82]. In TDRs with or without polyethylene, an allergy to PCU can potentially lead to osteolysis. This possibility has been reported in a patient treated with M6-C devices at C5-6 and C6-7 [83].

Although we do know that the PCU used in the LP-ESP and CP-ESP (Bionate 80A) is the same used in TriboFit hip arthroplasty [84] and the BDyn dynamic stabilization devices [9], we ignore whether Bionate 80A is used in the PCU cores of M6-C, M6-L [66] or Physio-L [69, 70]. However, we can be certain that the PCU used for the TDRs of Ranier Technology Ltd (CAdisc-L and CAdisc-C) in the UK was definitely not Bionate 80A. [85-87]. Bionate 80A has a Young's modulus of elasticity that varies somewhat from 22 to 24 N/mm2 depending on surrounding conditions [88]. While the the Young's moduli of elasticity of the PCU in CAdisc devices was not reported, we know that the modulus of elasticity of the inner, «nucleus» portion was roughly 55% of the modulus value of the surrounding, «annulus and cartilaginous endplates» portions of the implants [85]. Consequently, the PCU they used was definitely not Bionate 80A. Moreover, the high and low modulus portions were separated by a transitional region with a progressive, graduated modulus of elasticity. This innovation was based upon the assumption that a smooth interface between the annulus and nucleus, mimicking that of a natural disc, would likely be beneficial to the lifetime and performance of the device [85, 89]. A prospective non-randomized multicenter clinical trial of the device led to good clinical outcomes at 12-month follow-up with no device-related adverse event [86]. Unfortunately, using a zone of transitional PCU elasticity in the CAdisc-L in order to simulate natural discs might have contributed to an unpardonable flaw in the device. Within two years of implantation, cases were observed of the soft inner PCU penetrating the transitional zone and ultimately forcing a path through the stiff outer layer, perfectly simulating a natural disc… herniation. Ranier Technology withdrew the Cadisc-L from the market in 2014 [16, 90].

In two LP-ESP studies with follow-up of 7 years and 12 years, respectively, no herniation of the device's silicone core through the stiffer PCU core component around it has been observed [15][series submitted for publication]. There is no complex transitional modulus of elasticity between these two portions of the core [3].

Taken together, the long-term success of the LP-ESP and the multiple failures of the CAdisc-L strongly suggest that a sharp interface between two different core materials is preferable to a transitional interface.As it turns out, homogeneous Bionate 80A around a silicone core has proven to be a simpler, more elegant solution for viscoelastic disc arthroplasty than the complex PCU conceived in Cambridge.

Reports on the robustness and durability of PCU implants

Perhaps the best example of the durability of Bionate 80A PCU is the ESP product line itself. The LP-ESP in the lumbar spine undergoes much higher loading than the CP-ESP in the cervical spine. Consequently, the robustness and durability of the LP-ESP are more relevant than those of the CP-ESP. After the LP-ESP was approved in Europe, Asia, and Australia in 2006, more than 20,000 had been implanted as of 2020 [91] with no reported failure of its PCU component to date to the best of our knowledge.

Another testament to the durability of PCU is the Dynesys pedicle screw-based dynamic stabilization device that has been used in the lumbar spine since 1994. Dynesys consists of extension-limiting cylindrical PCU spacers through which pass flexion-limiting polyester cords attached to ipsilateral pedicle screw heads of adjacent lumbar or lumbosacral motion segments [47]. Retrieval analyses of both Dynesys and BDyn dynamic stabilization devices have shown surface oxidation and micro-cracking of their PCU components, but these alterations involve no more than the first 10 microns of the surface, suggesting no influence on the mechanical properties of the entire devices [92, 93].

Multidirectional compressive load fatigue testing at 1200 N under physiologic conditions of the pure PCU Newcleus nucleus pulposus replacement was run up to 50 million cycles and resulted in no significant wear [59].

When researchers were looking for materials to replace the polyethylene liners in total hip arthroplasty devices, they investigated various polyurethane elastomers, which were known for their toughness, durability, flexibility, biocompatibility and biostability [94-96]. Biomedical polyurethanes have been the object of investigation for at least 60 years [97]. Compared to three other polyurethane elastomers, a commercially available PCU, Corethane 80A (later branded as Bionate 80A and produced under licence by Polymer Technology Group, Berkeley, CA) displayed the best overall resistance to hydrolysis, environmental stress cracking, metal ion oxidation and calcification [94]. The Bionate 80A liner functioned well, with the bearing surfaces of the retrieved hip cups showing no significant evidence of biodegradation or wear damage after 3 years in vivo [95]. In trial applications of the TriboFit Bionate 80A buffer directly on the acetabulum, backside abrasion occurred [84], but backside abrasion is obviated when the buffer is used conventionally, as the shock absorbing liner of a metal shell [26]. Given the obstacles to long-term clinical studies of arthroplasty devices, wear characteristics of both sides of the TriboFit Bionate 80A were determined for 20 million simulated gait cycles. All five test samples survived the 20 million cycles with no adverse event. The concentrations of particles generated by the implants' back side were 1–2 orders of magnitude lower than those measured for the articulating surface, but more importantly, the number of Bionate 80A particles generated each million cycles was 5, 6, and 6–8 orders of magnitude lower than those of conventional polyethylene, highly cross-linked polyethylene, and metal bearings, respectively [98].

In 1996 and 1997, four patients received a prototype total knee replacement with an articulating surface of PCU on the tibial side. All four of these knee replacements remained functional after more than 20 years with no signs of wear or osteolysis [42].

Reports relevant to the safety of PCU implants

In a thorough evaluation of neurotoxicity, there was no evidence of an acute neural or systemic histopathological response at either 3 months or 6 months to titanium alloy, cobalt-chromium alloy, polyethylene, silicone, or PCU wear debris applied to the epidura of rabbits [99].The macrophage foreign body response to pure PCU is known to induce a potent inflammatory pathway [100-102]. Because inflammatory reactions may adversely affect PCU vascular implants by contributing to thrombosis [29], much research has been invested in coatings of the implant inner linings that are in contact with blood flow [28, 103].

In disc arthroplasty, device failure can be caused by wear alone, but also by wear particle-induced osteolysis [104]. Wear debris-related osteolysis in total hip, knee, and disc replacements is an inflammatory process [105]. Whereas such inflammatory osteolysis is a relatively frequent cause of aseptic implant loosening in hip and knee arthroplasties, its frequency was considered to be rather rare in spinal TDRs [106] until 2020 when an Implant Hazzard Alert was issued concerning the M6-C [77, 79]. Previously, the incidence of inflammatory osteolysis in TDRs was considered impossible to determine, because debris-related osteolysis adjacent to TDRs had only been described in case reports [107]. Here, it is essential to note the difference between debris-related inflammatory osteolysis, which typically leads to revision surgery, and non-progressive device-adjacent bone loss that occurs in roughly half of cervical TDR patients, as well as in many ACDF patients, with no effect on clinical outcome measurements in either case [107, 108]. Whereas bone loss is frequently observed on scheduled follow-up X-rays within the first six postoperative months, it usually takes years for wear debris and/or metal corrosion to induce osteolysis [107, 109].

Two cases of aseptic osteolysis involving the Bryan cTDR have been reported. In one of these cases, osteolysis of the vertebral bodies adjacent to the artificial disc was found at a routine follow-up examination 3 years after implantation. The other case occurred 5 years postoperatively revealed by radiculopathy attributed to osteolysis and subsequent reactive hypertrophic bone formation compressing the nerve root [63]. However, potential involvement of PCU debris would only be possible with prior degradation of the Bryan cTDR polyether urethane sheath around the PCU core. Moreover, histology techniques cannot distinguish polyether urethane debris from PCU debris [63]. It should be noted that, such cases of soft debris-related osteolysis have only been reported in PCU TDRs that also have components made of polyether urethane [63] or polyethylene [75-80].

In comparison to polyethylene, retrieval analyses of a Bionate 80A hip prosthesis (TriboFit) confirmed both the low wear rate of PCU [110, 111] and the extra-clinically determined superior biocompatibility of PCU debris [112, 113]. In terms of wear debris generation and a resulting osteolytic response to wear debris, the difference between polyethylene and PCU is largely in favor of PCU in general [112, 113], and Bionate 80A PCU in particular [14, 114]. These differences are so marked that development is underway of metal-on-polymer ball-and-socket TDRs in which the polyethylene components are being upgraded to Bionate 80A PCU, in both cervical [115, 116] and lumbar [18-20] applications. In addition to these wear debris considerations, there may even be biomechanical advantages other than shock absorption for using PCU instead of polyethylene in ball-and-socket lumbar TDRs [117].

CONCLUSIONS

PCU is an implant material that has been used for up to thirty years in many fields of medicine, but most notably in large joint replacements, vascular surgery, hemodialysis and spine surgery. Bionate 80A, the PCU used in the core of the CP-ESP and LP-ESP, as well as in hip arthroplasty, has nineteen years of clinical follow-up. In implants under similar conditions, PCUs such as Bionate 80A generate fewer wear particles than polyethylene. Moreover, an osteolytic response to PCU debris has yet to be documented, in sharp contrast to the many reports of polyethylene wear particle-induced osteolytic failures in hip, knee, and spine arthroplasty. The future of Bionate 80A and other PCUs in TDRs appears to be quite bright.

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